Patient Safety and Quality: An Evidence-Based Handbook for Nurses

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Foreword

The Agency for Healthcare Research and Quality (AHRQ) and the Robert Wood Johnson Foundation (RWJF) are pleased to have jointly sponsored the development of this handbook for nurses on patient safety and quality. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* examines the broad range of issues involved in providing high quality and safe care across health care settings.

We know that nurses are at the center of patient care and therefore are essential drivers of quality improvement. From the Institute of Medicine's reports, including *To Err is Human* and *Keeping Patient's Safe: Transforming the Work Environment of Nurses*, we know that patient safety remains one of the most critical issues facing health care today and that nurses are the health care professionals most likely to intercept errors and prevent harm to patients. For us, both at AHRQ and RWJF, improving patient safety and health care quality is embedded in our mission and at the core of what we do.

We strongly believe that the safety and quality of health care in this nation is dependent upon the availability of the best research possible and on our ability to deliver the results of that research into the hands of providers, policymakers, and consumers so that all can make better decisions. We believe the result will be improved health care and safety practices, which will be manifested in measurably better outcomes for patients.

Given the diverse scope of work within the nursing profession in this country, AHRQ and the RWJF expect that the research and concepts presented in the book will be used to improve health care quality by nurses in practice, nurse-educators, nurse-researchers, nursing students, and nursing leaders. The 89 contributors to this book represent a broad range of nurse-researchers and senior researchers throughout this nation.

The product of this joint effort underscores the commitment of AHRQ and the RWJF to achieving a health care system that delivers higher quality care to everyone. We believe that high-quality health care can be achieved through the use of evidence and an enabled and empowered nursing workforce.

We welcome written comments on this book. They may be sent to Ronda Hughes, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

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Preface

Errors pervade our lives in our homes, on the roads, and in our places of work. Each hour of each day, patients and clinicians are affected by near errors and the consequences of adverse events. The effects of health care errors and poor quality health care have impacted all our lives—sometimes directly, at other times indirectly. Even during the writing of this book, many of the authors had firsthand experiences with near errors, adverse events, and a level of poor-quality care that should never have been presented to any patient. Given the importance of health and health care in our lives, the purpose of this book is to bring safety and quality to the forefront in nursing.

Throughout these pages, you will find peer-reviewed discussions and reviews of a wide range of issues and literature regarding patient safety and quality health care. Owing to the complex nature of health care, this book provides some insight into the multiple factors that determine the quality and safety of health care as well as patient, nurse, and systems outcomes. Each of these 51 chapters and 3 leadership vignettes presents an examination of the state of the science behind quality and safety concepts and challenges the reader to not only use evidence to change practices but also to actively engage in developing the evidence base to address critical knowledge gaps. Patient safety and quality care are at the core of health care systems and processes and are inherently dependent upon nurses. To achieve goals in patient safety and quality, and thereby improve health care throughout this nation, nurses must assume the leadership role.

Despite being a relatively new field of inquiry, particularly in terms of how patient safety and quality are now defined, the need to improve the quality and safety of care is the responsibility of all clinicians, all health care providers, and all health care leaders and managers. As clinicians, we are obligated to do our best, regardless of whether we are acting as a clinician or a patient. Just as we say there are “good patients” and “bad patients,” clinicians as patients can unfortunately be considered “bad patients” because they may know too much, ask too many questions, or are not up-to-date on the research or current practice standards. Yet that is a mindset that must end and become a part of history, not to be repeated. Instead, nurses need to ensure that they and other team members center health care on patients and their families. All patients—whether they include ourselves, our loved ones, or the millions of our neighbors throughout this country—need to be engaged with clinicians in their care.

Each of the chapters in this book is organized with a background section and analysis of the literature. At the end of each chapter, you will find two critical components. First, there is a “Practice Implications” section that outlines how the evidence can be used to inform practice changes. Practice leaders and clinicians can use this information, based on the state of the science, to guide efforts to improve the quality and safety of delivering services to patients. Second, there is a “Research Implications” section that outlines research gaps that can be targeted by researchers and used by clinicians to inform and guide decisions for practice. Faculty and graduate students will find innumerable questions and issues that can be used to develop dissertation topics and grant applications to uncover the needed evidence.

In all but a few chapters, you will find evidence tables. These tables were developed by critically assessing the literature, when possible, and present invaluable insight as to the type and quality of research that can inform practice, clarify knowledge gaps, and drive future research. As the reader will observe, the majority of patient safety and quality research presented in the evidence tables represent cross-sectional studies. In fact, 81 percent of the studies exploring the

various aspects of safety and quality employed cross-sectional study designs, predominately representing assessments at single sites of care and using qualitative surveys. This may be the byproduct of the challenges of the research process (including sources of funding) or the challenges of engaging in collaborative research. From this review of the literature, we can learn the importance of the need for longitudinal, multisite analyses to bring us forward into the next generation of evidence-based knowledge.

Great is the importance of nurses being involved throughout the research process and collaborating with interdisciplinary teams throughout care settings. Then, too, it is critical that nursing leaders and managers, clinical leaders, and nurses across care settings engage in a lifelong pursuit of using data and information as well as research evidence to inform practice. Combined with experiential knowledge, analyses, and evidence, nurses will be challenged to continuously improve care processes and encourage our peers and interdisciplinary colleagues to make sure patients receive the best possible care, regardless of where they live, their race or gender, or their socioeconomic circumstances.

The chapters in this book are organized into six sections. Each chapter can be read independently of the others; however, some do make reference to other chapters, and a greater understanding of the breadth and depth of patient safety and quality can be better obtained by reading the book in its entirety. Highlights from the chapters are summarized by section as follows:

In *Section I – Patient Safety and Quality*, patient safety is discussed as being foundational to quality, where nurses can be invaluable in preventing harm to patients and improving patients' outcomes (chapter 1). Even though the quality and safety of health care is heavily influenced by the complex nature of health care and multiple other factors, nurses have been held accountable for harm to patients, even when other clinicians and health care providers and characteristics of the care system in which they work often have—almost without exception—greater roles and, in some respects, have ensured that an error would happen (chapters 2 and 3). With the many challenges facing health care today, the Institute of Medicine's 11-volume Quality Chasm series brings to light the multitude of issues and factors that individuals and organizations, both within and outside of nursing and health care, need to understand and to work together to overcome (chapter 4). Moving toward and securing a culture of safety throughout health care will, by definition, acknowledge the influence of human factors in all clinicians, the results of human-system interfaces and system factors, and will institutionalize processes and technology that will make near errors and errors very rare (chapter 5). This paradigm shift will enable nurses to think more critically and clinically (chapter 6), and to achieve greater insights as to how education, training, and experience are needed and can be leveraged to ultimately achieve high-quality care in every care setting and for all patients.

To improve patient safety and quality, one needs to understand the state of the science at hand, as well as strategies that can be behind effective utilization of evidence and implementation of change, as discussed in *Section II – Evidence-Based Practice*. It is here that one can learn that implementing evidence into practice can be accomplished though several approaches—often more than one simple intervention is possible—and by early on engaging key stakeholders to move toward adoption of change by translating research-based evidence into everyday care (chapter 7). Yet in assessing the state of the science, it becomes apparent that the majority of care afforded patients is not evidence based, emphasizing the need for health services research to examine progress toward safer and higher-quality care and to assess new and innovative practices (chapter 8). While the future of health care is uncertain, clinicians must

continually assess, understand, and meet the needs of patients and prepare themselves to meet emerging health needs we might not expect (chapter 9).

Due to innumerable pressures to improve patient safety and quality, it may be important to focus on those areas of care delivery, as discussed in *Section III – Patient-Centered Care*, that are significantly influenced by nursing care. Providing health care is all about patients and their needs and meeting those care needs in settings where the majority of care is provided by clinicians—or, in certain circumstances, where loved ones and family members supplement nursing care or solely provide for the care needs of patients in community settings. Almost all the adverse events and less-than-optimal care afforded patients can be prevented, beginning by implementing research in practice. Situations in which failure to use evidence can be detected can include when preventable patients falls with injury occur (chapter 10), when illness-related complications are missed and lead to functional decline in the elderly (chapter 11), and when pressure ulcers develop in patients of any age (chapter 12). For nurses, ensuring and/or providing evidence-based, safe, and high-quality care become even more challenging when patients need care in their homes and subsequently rely on care rendered by family members and loved ones—care that can be dependent upon the guidance of nurses (chapter 13). Not only can the resources and functionality of the community or home setting pose potential threats to the safety of patients and may relegate them to care of a lower quality, but those who care for patients may also succumb to the physical and emotional demands of providing informal care; amelioration can require broadening nursing care to caregivers (chapter 14).

Nursing can also have a significant effect on the outcomes of specific groups of patients, particularly in preventing not only adverse events but the lasting effects of comorbidities and symptoms. The reason behind focusing on these specific populations is that their unique needs must not be considered less important than those of the majority. In the case of children, who are some of the most vulnerable patients due to developmental and dependency factors, it is difficult to provide safe, high-quality care that meets their unique needs. Instead, nurses need to use current best practices (chapter 15) to avert potentially lifelong comorbidities and address symptoms—and develop new practices when the evidence is not available. It is also important to focus on simple strategies to prevent morbidity—not just preventing adverse events—and ensure that patients receive preventive care services whenever possible, especially when the use of these services is supported by evidence (chapter 16). Especially for patients with moderate to severe pain, it is also important to prevent the adverse effects of their diseases and conditions by working with patients to manage their pain, promoting healing and improving function (chapter 17). And finally, in the case of potential adverse effects of polypharmacy in the elderly, nurses can also focus on simple strategies to improve adherence to intended therapies and detect unnecessary side effects, thereby improving medication safety (chapter 18).

Beyond the influence of evidence on quality processes and outcomes, there are health care system and organization factors and characteristics to consider. As discussed in *Section IV – Working Conditions and the Work Environment for Nurses*, evidence concerning the impact of health care system factors illustrates that working conditions and the work environment, which are heavily influenced by leaders, can have a greater impact on the safety and quality of health care than what an individual clinician can do. Instead of aggregating the various aspects of working conditions, the chapters in this section define and focus on specific aspects of key factors associated with patient and systems outcomes, centering on the importance of leadership.

The leadership and management of health care organizations and health systems are pivotal to safer and higher quality of care because they direct and influence: which model of care is used

to organize inpatient care services for patients (chapter 19); whether or not the organization embraces and is committed to fostering and sustaining a climate of safety and high-quality care (chapter 21); the impact of external factors, and the functionality and organization of microsystems within the context of the organization and relationships with others (chapter 22); how the specific care needs of patients are met with sufficient numbers of the right types of nurses (chapter 23 and chapter 25); how resource allocations and cost-saving strategies that involve restructuring, mergers, and organizational turbulence impact care delivery and patient outcomes (chapter 24 and chapter 29); the type of work environment that influences work stress and patient outcomes (chapter 26 and chapter 27); and how the actual physical environment and care processes influence the workload and workflow of nursing care (chapter 28, chapter 30, chapter 31).

Taken together, leadership throughout organizations, led by nurse executives and influenced by physicians, is critical in determining whether or not safety and high-quality care can be achieved through daily teamwork, collaboration, and communication (chapter 20). It is because of the importance of senior nursing leadership that emphasis is put on the moral imperative that senior nursing leadership has to lead health care in the quest for safer and higher-quality care (vignette *a*), to demonstrate the right type of leadership (vignette *b*), and to excel in the right competencies (e.g., business skills and principles, communication and relationship management, and professionalism) (vignette *c*).

Nursing leaders must actively work with and enable staff to transform the current work climate and care delivery. *Section V – Critical Opportunities for Patient Safety and Quality Improvement* puts forth several critical opportunities that leaders and staff can work together to achieve success. In almost every care setting and situation, effective communication is essential. Not only do clinicians need to constantly communicate in a professional and technical way (chapter 32) and with team members in a way that is respectful and attuned to individual differences (chapter 33), clinicians must also ensure that the right information is communicated to next caregiver or health care provider so that the safety and quality of care is not compromised (chapter 34).

Other opportunities for improvement center on the necessity to continually assess near errors and errors, not only those events that harm patients, and put in place strategies to avert the recurrence of both the near error and errors. Assessing and evaluating near errors and errors—and the ability to avert the recurrence of errors—is dependent upon having information that is reported by clinicians (chapter 35), so that some errors (e.g., wrong-site surgery) never happen (chapter 36). Many initiatives to improve patient safety and health care quality have focused on medication safety. While many medication errors are prevented from harming patients because a nurse detected the error, monitoring and evaluating both near misses and adverse drug events can lead to the adoption of strategies to decrease the opportunities for errors, including unit dosing, using health information technology (chapter 37), and reconciling a patient's medications (chapter 38).

The nature of the work and the stress of caregiving can place nurses and patients at risk for harm. Moving patients, being in close proximity to therapeutic interventions, the implications of shift work and long work hours (chapter 39 and chapter 40), and ignoring the potential risk of injury and the impact of fatigue can increase the risk of occupational injury. It follows then that, because of the nature of the work, the proximity of nurses to patients, and the chronic and acute needs of patients, particular attention must be given to preventing health care–associated infections through known effective strategies, such as environmental cleanliness, hand hygiene,

protective barriers (chapter 41), and strategies to address ventilator-acquired pneumonia (chapter 42).

The influence of nurse practitioners and of the new generation of doctorate-level nurse clinicians has the potential of enabling significant improvements in critical opportunities for patient safety and quality improvement (chapter 43). The opportunities to demonstrate the influence of these clinical leaders is endless. The last section of this book, *Section VI – Tools for Quality Improvement and Patient Safety*, focuses on the strategies and technologies that can be used to push health care to the next level of quality. One of the tools that can be used is quality methods, including continuous quality improvement, root cause analysis, and plan-do-study-act (chapter 44). Quality and patient safety indicators can also be used to assess performance and monitor improvement (chapter 45). These, as well as other tools, are integral in efforts to develop and demonstrate nursing excellence (chapter 46). With recent developments in information technologies, there are many potential benefits that can be afforded by these technologies that can facilitate decisionmaking, communication of patient information (chapter 47, chapter 48, chapter 49), therapeutic interventions (so long as the information technologies are used and function properly) (chapter 49), and education and training (chapter 51).

All of these various issues and factors come together to define the complexity and scope of patient safety and quality care but also the necessity for multifaceted strategies to create change within health care systems and processes of care. In using evidence in practice, engaging in initiatives to continually improve quality, and striving for excellence, nurses can capitalize on the information from this book and lead health care in the direction that it should and needs to be heading to better care for the needs of patients. What it all comes down to is for us, as nurses, to decide what kind of care we would want as patients then to do all that is possible to make that happen. Today we may be doing what we can, but tomorrow we can improve. With this evidence and the call to action to nurses, in 5 years from now, headlines and research findings should carry forth the message that there are significant improvements in the quality and safety of health care throughout this nation, and it was because nurses led the way.

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Ronda G. Hughes

This book is dedicated to nurses everywhere.

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45. AHRQ Quality Indicators (*Draft—Do Not Reproduce*)
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Chapter 1. Defining Patient Safety and Quality Care

Pamela H. Mitchell

Introduction

The goal of this chapter is to provide some fundamental definitions that link patient safety with health care quality. Evidence is summarized that indicates how nurses are in a key position to improve the quality of health care through patient safety interventions and strategies.

Quality Care

Many view quality health care as the overarching umbrella under which patient safety resides. For example, the Institute of Medicine (IOM) considers patient safety "indistinguishable from the delivery of quality health care."[1] Ancient philosophers such as Aristotle and Plato contemplated quality and its attributes. In fact, quality was one of the great ideas of the Western world.[2] Harteloh[3] reviewed multiple conceptualizations of quality and concluded with a very abstract definition: "Quality [is] an optimal balance between possibilities realised and a framework of norms and values." This conceptual definition reflects the fact that quality is an abstraction and does not exist as a discrete entity. Rather it is constructed based on an interaction among relevant actors who agree about standards (the norms and values) and components (the possibilities).

Work groups such as those in the IOM have attempted to define quality of health care in terms of standards. Initially, the IOM defined quality as the "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[4] This led to a definition of quality that appeared to be listings of quality indicators, which are expressions of the standards. Theses standards are not necessarily in terms of the possibilities or conceptual clusters for these indicators. Further, most clusters of quality indicators were and often continue to be comprised of the 5Ds—death, disease, disability, discomfort, and dissatisfaction[5]—rather than more positive components of quality.

The work of the American Academy of Nursing Expert Panel on Quality Health focused on the following positive indicators of high-quality care that are sensitive to nursing input: achievement of appropriate self-care, demonstration of health-promoting behaviors, health-related quality of life, perception of being well cared for, and symptom management to criterion. Mortality, morbidity, and adverse events were considered negative outcomes of interest that represented the integration of multiple provider inputs.[6, 7] The latter indicators were outlined more fully by the National Quality Forum.[8] Safety is inferred, but not explicit in the American Academy of Nursing and National Quality Forum quality indicators.

The most recent IOM work to identify the components of quality care for the 21st century is centered on the conceptual components of quality rather than the measured indicators: quality care is safe, effective, patient centered, timely, efficient, and equitable. Thus safety is the foundation upon which all other aspects of quality care are built.[9]

Patient Safety

A definition for patient safety has emerged from the health care quality movement that is equally abstract, with various approaches to the more concrete essential components. Patient safety was defined by the IOM as "the prevention of harm to patients."[1] Emphasis is placed on the system of care delivery that (1) prevents errors; (2) learns from the errors that do occur; and (3) is built on a culture of safety that involves health care professionals, organizations, and patients.[1, 10] The glossary at the AHRQ Patient Safety Network Web site expands upon the definition of prevention of harm: "freedom from accidental or preventable injuries produced by medical care."[11]

Patient safety practices have been defined as "those that reduce the risk of adverse events related to exposure to medical care across a range of diagnoses or conditions."[12] This definition is concrete but quite incomplete, because so many practices have not been well studied with respect to their effectiveness in preventing or ameliorating harm. Practices considered to have sufficient evidence to include in the category of patient safety practices are as follows:[12]

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections
- Asking that patients recall and restate what they have been told during the informed-consent process to verify their understanding
- Continuous aspiration of subglottic secretions to prevent ventilator-associated pneumonia
- Use of pressure-relieving bedding materials to prevent pressure ulcers
- Use of real-time ultrasound guidance during central line insertion to prevent complications
- Patient self-management for warfarin (Coumadin®) to achieve appropriate outpatient anticoagulation and prevent complications
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients, to prevent complications
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections

Many patient safety practices, such as use of simulators, bar coding, computerized physician order entry, and crew resource management, have been considered as possible strategies to avoid patient safety errors and improve health care processes; research has been exploring these areas, but their remains innumerable opportunities for further research.[12] Review of evidence to date critical for the practice of nursing can be found in later chapters of this Handbook.

The National Quality Forum attempted to bring clarity and concreteness to the multiple definitions with its report, *Standardizing a Patient Safety Taxonomy*.[13] This framework and taxonomy defines harm as the impact and severity of a process of care failure: "temporary or permanent impairment of physical or psychological body functions or structure." Note that this classification refers to the negative outcomes of lack of patient safety; it is not a positive classification of what promotes safety and prevents harm. The origins of the patient safety

problem are classified in terms of type (error), communication (failures between patient or patient proxy and practitioners, practitioner and nonmedical staff, or among practitioners), patient management (improper delegation, failure in tracking, wrong referral, or wrong use of resources), and clinical performance (before, during, and after intervention).

The types of errors and harm are further classified regarding domain, or where they occurred across the spectrum of health care providers and settings. The root causes of harm are identified in the following terms:[8]

- Latent failure—removed from the practitioner and involving decisions that affect the organizational policies, procedures, allocation of resources
- Active failure—direct contact with the patient
- Organizational system failure—indirect failures involving management, organizational culture, protocols/processes, transfer of knowledge, and external factors
- Technical failure—indirect failure of facilities or external resources

Finally, a small component of the taxonomy is devoted to prevention or mitigation activities. These mitigation activities can be universal (implemented throughout the organization or health care settings), selective (within certain high-risk areas), or indicated (specific to a clinical or organizational process that has failed or has high potential to fail).

Nursing As the Key to Improving Quality Through Patient Safety

Nursing has clearly been concerned with defining and measuring quality long before the current national and State-level emphasis on quality improvement. Florence Nightingale analyzed mortality data among British troops in 1855 and accomplished significant reduction in mortality through organizational and hygienic practices.[14] She is also credited with creating the world's first performance measures of hospitals in 1859. In the 1970s, Wandelt[15] reminded us of the fundamental definitions of quality as characteristics and degrees of excellence, with standards referring to a general agreement of how things should be (to be considered of high quality). About the same time, Lang[16] proposed a quality assurance model that has endured with its foundation of societal and professional values as well as the most current scientific knowledge (two decades before the IOM definition was put forth).

In the past, we have often viewed nursing's responsibility in patient safety in narrow aspects of patient care, for example, avoiding medication errors and preventing patient falls. While these dimensions of safety remain important within the nursing purview, the breadth and depth of patient safety and quality improvement are far greater. The most critical contribution of nursing to patient safety, in any setting, is the ability to coordinate and integrate the multiple aspects of quality within the care directly provided by nursing, and across the care delivered by others in the setting. This integrative function is probably a component of the oft-repeated finding that richer staffing (greater percentage of registered nurses to other nursing staff) is associated with fewer complications and lower mortality.[17] While the mechanism of this association is not evident in these correlational studies, many speculate it is related to the roles of professional nurses in integrating care (which includes interception of errors by others—near misses), as well as the monitoring and surveillance that identifies hazards and patient deterioration before they become errors and adverse events.[18] Relatively few studies have had the wealth of process data evident in the RAND study of Medicare mortality before and after implementation of diagnosis-related groups. The RAND study demonstrated lower severity-adjusted mortality related to better

nurse and physician cognitive diagnostic and treatment decisions, more effective diagnostic and therapeutic processes, and better nursing surveillance.[19, 20]

Further, when we consider the key role of communication or communication lapses in the commission of error, the role of nursing as a prime communication link in all health care settings becomes evident. The definition of "error chain" at PSNet clearly indicates the role of leadership and communication in the series of events that leads to patient harm. Root-cause analyses of errors provide categories of linked causes, including "(1) failure to follow standard operating procedures, (2) poor leadership, (3) breakdowns in communication or teamwork, (4) overlooking or ignoring individual fallibility, and (5) losing track of objectives."[21] This evidence was used in developing the cause portion of the National Quality Forum's patient safety taxonomy and is further discussed in other chapters of this book.

Conclusion

Patient safety is the cornerstone of high-quality health care. Much of the work defining patient safety and practices that prevent harm have focused on negative outcomes of care, such as mortality and morbidity. Nurses are critical to the surveillance and coordination that reduce such adverse outcomes. Much work remains to be done in evaluating the impact of nursing care on positive quality indicators, such as appropriate self-care and other measures of improved health status.

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Chapter 2. Nurses at the "Sharp End" of Patient Care

Ronda G. Hughes

Background

The work environment in which nurses provide care to patients can determine the quality and safety of patient care.[1] As the largest health care workforce, nurses apply their knowledge, skills, and experience to care for the various and changing needs of patients. A large part of the demands of patient care is centered on the work of nurses. When care falls short of standards, whether because of resource allocation (e.g., workforce shortages and lack of needed medical equipment) or lack of appropriate policies and standards, nurses shoulder much of the responsibility. This reflects the continued misunderstanding of the greater effects of the numerous, complex health care systems and the work environment factors. Understanding the complexity of the work environment and engaging in strategies to improve its effects is paramount to higher-quality, safer care. High-reliability organizations that have cultures of safety and capitalize on evidence-based practice offer favorable working conditions to nurses and are dedicated to improving the safety and quality of care. Emphasis on the need to improve health care systems to enable nurses to not be at the "sharp end" so that they can provide the right care and ensure that patients will benefit from safe, quality care will be discussed in this chapter.

The Everydayness of Errors

Health care services are provided to patients in an environment with complex interactions among many factors, such as the disease process itself, clinicians, technology, policies, procedures, and resources.[2] When these complex factors interact, harmful and unanticipated outcomes (e.g., errors) can occur. Human error has been defined as a failure of a planned action or a sequence of mental or physical actions to be completed as intended, or the use of a wrong plan to achieve an outcome.[2] By definition, errors are a cognitive phenomenon because errors reflect human action that is a cognitive activity. Near misses, or "good catches,"[3] are defined as events, situations, or incidents that could have caused adverse consequences and harmed a patient, but did not.[4] Factors involved in near misses have the potential to be factors (e.g., root causes) involved in errors if changes are not made to disrupt or even remove their potential for producing errors.

Reason[2] described errors as the product of either active (i.e., those that result primarily from systems factors, producing immediate events and involve operators (e.g., clinicians) of complex systems) or latent factors (i.e., factors that are inherent in the system). Latent factors (e.g., heavy workload, structure of organizations, the work environment) are embedded in and imposed by systems and can fester over time, waiting for the right circumstances to summate individual latent factors and affect clinicians and care processes, triggering what is then considered an active error (e.g., an adverse drug event). Leadership and staff within organizations essentially inherit and can create new latent factors through scheduling, inadequate training, and outdated equipment.[5] Latent factors or conditions are present throughout health care and are inevitable in organizations. These factors and conditions can have more of an effect in some areas of an

organization than others because resources can be "randomly" distributed, creating inequities in quality and safety.[5] The number of hazards and risks can be reduced by targeting their root causes. In doing so, the path between active failures when the error occurred would be traced to the latent defects in the organization, indicating leadership, processes, and culture. Then, if organizational factors (e.g., latent factors) become what they should be, few active causes of accidents will come about.

The Institute of Medicine (IOM) stated that safety was dependent upon health care systems and organizations, and patients should be safe from injury caused by interactions within systems and organizations of care.[6] Organizational factors have been considered the "blunt end" and represent the majority of errors; clinicians are considered the "sharp end." Therefore, to prevent errors, the organizations in which humans work need to be adapted to their cognitive strengths and weaknesses and must be designed to ameliorate the effects of whatever human error occurs. The most effective strategies to improve safety target latent factors within organizations and systems of care. This point is emphasized by the IOM, which further stated that the safety and quality of care would be improved by holding systems accountable, redesigning systems and processes to mitigate the effects of human factors, and using strategic improvements.[7]

According to Reason,[2] a large part of mental functioning is automatic, rapid, and effortless. This automatic thinking is possible because we have an array of mental models (e.g., schemata) that are expert on some minuscule recurrent aspect of our lives (e.g., going to work). Many errors result from flaws in thinking that affect decisionmaking.[8, 9] Ebright and colleagues[10] assert that nurses' ability to make logical and accurate decisions and influence patient safety is associated with complex factors, including their knowledge base and systems factors (e.g., distractions and interruptions), availability of essential information, workload, and barriers to innovation. The effects of these factors are complicated by the increasingly complex nature of nursing's roles and responsibilities, the complex nature of preventing errors from harming patients, and the availability of resources.[10]

When errors occur, the "deficiencies" of health care providers (e.g., insufficient training and inadequate experience) and opportunities to circumvent "rules" are manifested as mistakes, violations, and incompetence.[11, 12] Violations are deviations from safe operating procedures, standards, and rules, which can be routine and necessary or involve risk of harm. Human susceptibility to stress and fatigue; emotions; and human cognitive abilities, attention span, and perceptions can influence problem-solving abilities.[2] Human performance and problem-solving abilities are categorized as skill based (i.e., patterns of thoughts and actions that are governed by previously stored patterns of preprogrammed instructions and those performed unconsciously), rule based (i.e., solutions to familiar problems that are governed by rules and preconditions), and knowledge based (i.e., used when new situations are encountered and require conscious analytic processing based on stored knowledge). Skill-based errors are considered "slips," which are defined as unconscious aberrations influenced by stored patterns of preprogrammed instructions in a normally routine activity. Distractions and interruptions can precede skill-based errors, specifically diverting attention and causing forgetfulness.[2] Rule-based and knowledge-based errors are caused by errors in conscious thought and are considered "mistakes."[13] Breaking the rules to work around obstacles is considered a rule-based error because it can lead to dangerous situations and may increase one's predilection toward engaging in other unsafe actions. Work-arounds are defined as "work patterns an individual or a group of individuals create to accomplish a crucial work goal within a system of dysfunctional work processes that prohibits the accomplishment of that goal or makes it difficult"[14] (p. 52). Halbesleben and colleagues[15]

assert that work-arounds could introduce errors when the underlying work processes and workflows are not understood and accounted for, but they could also represent a "superior process" toward reaching the desired goal.

Clinicians' decisionmaking and actions are also influenced by the "human condition." Reason[5, 16] asserted that because of the fallibility of the human condition, we can change the working conditions so that the potential for errors is reduced and the effect of errors that do occur is contained. Humans are limited by difficulty in attending to several things at one time, recalling detailed information quickly, and performing computations accurately.[6] As discussed by Henriksen and colleagues,[17] the scientific field of human factors focuses on human capabilities and limitations and the interaction between people, machines, and their work environment. The focus is on system failures, not human failures, and on meeting the needs of the humans interacting within it. Systems would be redesigned and dedicated to continuous improvement to protect against human error by employing simplification, automation, standardization of equipment and functions, and decreasing reliance on memory.[18] The "work system" would account for the interrelatedness of the individual, tasks, tools and technologies, the physical environment, and working conditions.[19] Conditions that make errors possible would be redesigned to reduce reliance on memory, improve information access, error-proof processes, standardize tasks, and reduce the number of handoffs.[20, 21] Errors would be identified and corrected and over time there would be fewer latent failure modes and fewer errors. However, because patient outcomes are dependent upon human-controlled processes, health care settings will never be 100 percent safe.

The IOM defined patient safety as freedom from accidental injury.[6] Adverse events are defined as injuries that result from medical management rather than the underlying disease.[22, 23] While the proximal error preceding an adverse event is mostly considered attributable to human error, the underlying causes of errors are found at the system level and are due to system flaws;[24] system flaws are factors designed into health care organizations and are often beyond the control of an individual.[25, 26] In other words, errors have been used as markers of performance at the individual, team, or system level. Adverse events have been classified as either preventable or not,[21, 27] and some preventable adverse events (fewer than one in three) are considered to be caused by negligence.[28] The concept of an error being preventable has not been widely understood in its context, and definitions have been conflicting and unreliable,[21, 29] partially because the source of the majority of errors have been ascribed to vague systems factors,[30] and the relationship between errors and adverse events is not fully understood.[30, 31]

Although the true number of errors and adverse events may not be known because of underreporting, failure to recognize an error, and lack of patient harm, it is difficult to understand the pervasiveness of errors because there are differences in definitions of reportable errors and adverse events.[32] Research and quality improvement initiatives have focused predominately on medication safety because of existing information systems and the potential frequency for which errors can occur. In the case of medications, the types and causes of errors describe how nurses are at the "sharp end." Medications pose the largest source of errors, yet many do not result in patient harm.[33, 34] Since errors actually occur during the process of medication therapies, the usual 'practice' has been to blame individuals.[35, 36] A medication intervention goes from prescribing, transcribing, and dispensing to administration. Physicians are primarily responsible for prescribing medications and nurses are primarily responsible for administering medications to patients. Errors made by physicians can be intercepted by pharmacists and nurses, errors made

by pharmacists can be intercepted by nurses, and errors made by nurses could potentially be intercepted by peers or patients.

Several classifications of health care errors have been posed.[37–39] Classifications or categorizations of errors have been based on types of adverse events,[40–42] incident reports,[38, 39] individual blame,[37] and system causes. Given what is known about error causation,[1, 5, 6, 16] particularly what has been learned from root-cause analysis and failure modes and effects analysis, when errors/adverse events involve clinicians, classifications/taxonomies of errors would be centered on all the related systems factors and would consider them the major contributors of the error/adverse event.[5, 16] For example, one classification of errors differentiates endogenous errors (i.e., arise within the individual or team) from exogenous errors (i.e., arise within the environment).[43] Endogenous errors are generally either active or latent[2] and result from departure from normative knowledge-based, skill-based, or rule-based behaviors.[44]

The complexity of factors involved in errors and adverse events is exemplified in medication safety. Researchers have found that between 3 percent and 5 percent,[45] 34 percent,[46] 40 percent,[47] or 62 percent[48] of medication errors are attributable to medication administration. For an administration error to not occur, the nurse would be at the "sharp end," having the responsibility to intercept it. Administration errors have been found to be the result of human factors, including performance and knowledge deficiencies;[49] fatigue, stress, and understaffing were found to be two major factors for errors among nurses.[50] Administering medications can take up to 40 percent of the nurse's work time,[51] and medication administration errors have been found to be due to a lack of concentration and the presence of distractions, increased workloads, and inexperienced staff.[48, 52, 53] If we consider what has been learned in other industries, medication administration errors would also be caused by systems factors, such as leadership not ensuring sufficient training, maldistribution of resources, poor organizational climate, and lack of standardized operating procedures.[54]

Since the publication of the IOM's *To Err Is Human*,[6] millions of dollars of research funds—e.g., from the Agency for Healthcare Research and Quality (AHRQ) and the Robert Wood Johnson Foundation—have been devoted to building the evidence base in patient safety research. Findings reported from the IOM and other related research is being disseminated on key aspects of patient safety. It is interesting to note that before the publication of *To Err Is Human*, the major focus of patient safety was on individual blame and malpractice.[55] Since the publication of *To Err Is Human,* that has no longer been the case and there is more focus on the need to improve health care organizations,[56] but the concerns associated with malpractice have not dissipated. In fact, concerns about malpractice have thwarted many patient safety improvement efforts primarily because of the need for data collection and analysis as well as performance measures to inform patient safety changes.[57]

The focus on the responsibilities and influences of systems does not negate the challenge of understanding error and accepting the inevitability of many errors while concurrently increasing the quality of health care. It is not possible for every aspect of health care and every setting of care to be 100 percent error free, and leaders and clinicians are challenged to define what is an acceptable level of error. Because safety is foundational to quality,[58] one way to define quality is providing "the right care, at the right time, for the right person, in the right way."[59] In doing so, efforts to improve safety and quality need to address concerns with potential overuse, misuse, and underuse of health care services that can threaten the quality and safety of care delivered to patients. Since patient safety, and quality in many respects, "is a new field, identifying which safe practices are effective has presented a significant challenge"[60] (p. 289), in part because of

the resource requirements, the complex nature of changing practice, and the influences of units within the whole.[60]

The Importance of High-Performing Organizations

The quality and safety of care is associated with various factors within systems, organizations, and their work environments—the combination of which influences the type of quality and safety of care provided by nurses.[1] Donabedian's[61] definition of quality of care represents the entire continuum from structure to process and to outcome. Structures, processes and outcomes are interdependent, where specific attributes of one influence another according to the strength of the relationship.[61–63] When organizational structure factors support the care processes and enable teamwork, nurses are more satisfied with their jobs[64, 65] and patients receive higher-quality care.[65] Leaders who engage in transactional (e.g., establish trust in relationships with staff, provide structure and expectations)[66, 67] and transformational leadership (e.g., develop a stronger collective identity and commitment to change)[68, 69] and who view change as opportunities to learn, adapt, and improve[70] organizations to improve health care quality. When teams function well and organization structure factors support their work, outcomes are better, even at institutions that have a high intensity of specialized care for those particular needs.[71, 72] The effectiveness of individuals and teamwork is dependent upon leadership, shared understanding of goals and individual roles, effective and frequent communication,[72-74] having shared governance,[75] and being empowered by the organization.[76]

In his seminal work, Shortell asserted that the characteristics of high-performing health care organizations included "a willingness and ability to: stretch themselves; maximize learning; take risks; exhibit transforming leadership; exercise a bias for action; create a chemistry among top managers; manage ambiguity and uncertainty; exhibit a 'loose coherence;' exhibit a well-defined culture; and reflect a basic spirituality"[77] (page 8). These organizations are engaged in continuous improvement to improve outcomes. Since then, Shortell and colleagues[78] furthered his seminal work, finding that what distinguished high-performing organizations was certain key factors, such as having a quality-centered culture, reporting performance, and the ability to overcome quality improvement redesign barriers by "(1) directly involving top and middle-level leaders, (2) strategically aligning and integrating improvement efforts with organizational priorities, (3) systematically establishing infrastructure, process, and performance appraisal systems for continuous improvement, and (4) actively developing champions, teams, and staff"[79] (p. 599).

The significance of these characteristics of high-performing organizations was furthered by findings from an evaluation of 12 health care systems, where factors critical to redesigning current systems to achieve quality and safety goals and improve patient outcomes were found to be successful when there was an "(1) impetus to transform; (2) leadership commitment to quality; (3) improvement initiatives that actively engage staff in meaningful problem solving; (4) alignment to achieve consistency of organization goals with resource allocation and actions at all levels of the organization; and (5) integration to bridge traditional intra-organizational boundaries among individual components"[80] (p. 309). Yet to address these factors in redesigning care systems and processes, Lucas and colleagues found that organizations needed to have "(1) mission, vision, and strategies that set its direction and priorities; (2) culture that reflects its informal values and norms; (3) operational functions and processes that embody the work done in patient care; and (4) infrastructure such as information technology and human resources that support the delivery of patient care"[80] (p. 309).

Yet, many organizations do not meet the standards of high-reliability organizations (HROs). Reason and colleagues[81] described the "vulnerable system syndrome" as a cluster of organizational pathologies that interact, making some systems more liable to unsafe practices that threaten patient safety. These pathologies (e.g., blame, denial, and the pursuit of financial excellence) are perpetuated in work environments by leaders and peers targeting individuals at the "sharp end," simultaneously failing to question core beliefs, recognize systemic causes, or to implement systemwide reforms. Reason and colleagues further asserted that indicators of vulnerabilities of the work environment, such as a culture of individual blame, were associated with workplace cultures that influenced safety and could be categorized as (1) high reliability (where recognizing how safety can be improved is rewarded), (2) pathological (where punishment and covering up of errors/failures are pervasive and new ideas are discouraged), or (3) bureaucratic (where failures are considered isolated, systematic reforms are avoided, and new ideas are problematic). An indicator of the presence of work environment vulnerabilities and patient safety improvements could be whether or not an organization has Joint Commission accreditation.[82]

Nurses perceive multiple and complex work environment factors that influence nurse and patient outcomes, including the quality of leadership and management, staffing resources, workload,[83] job stress and anxiety, teamwork, and effective communication.[84] Heath and colleagues asserted that in healthy work environments, nurses "feel valued by their organization, have standardized processes in place, have staff empowerment, have strong leadership, feel a sense of community, and recognize that strategic decision-making authority [influences] how their units were run and how scarce resources were disseminated"[85] (p. 526–7). Healthy work environments are also places where safe and high-quality nursing care is expected and rewarded. Healthy work environments also need to foster effective communication, collaborative relationships, and promote decisionmaking among all nurses.[85] Unhealthy work environments can have adverse consequences on the quality of care delivered as well as nurses' intention to leave the profession.[1, 86–88]

As proposed by Stone and colleagues,[89] there are microclimates (e.g., a unit or department) that function within the larger context of the organization. These microclimates or "microsystems" have a core team of health care professionals; a defined population of patients they are responsible for; and information, staff, and health technologies that provide support to the work of the clinicians.[90]

Yet, the majority of this research has examined outcomes at the hospital-wide level, and not at the unit level. Since the work environment within microclimates/microsystems can be different than that found organization-wide, it would be important to focus on these subunits to support efforts to standardize common care processes, to better examine process and outcome measures and what subunit factors and organization-wide factors contribute to less-than-optimal care, to emphasize the impact of multidisciplinary teams throughout the organization, and to ascertain how lessons learned in these subunits could be applied organization-wide.[90]

High-Reliability Organizations

Inherently related to high-performing organizations, HROs are defined as organizations that function daily under high levels of complexity and hazards. Reliable organizations have "procedures and attributes that make errors visible to those working in the system so that they can be corrected before causing harm"[6] (p. 152) and produce consistent results. Accordingly, the

IOM has advocated for hospitals to transition into HROs to improve the quality and safety of care.[6] In HROs, reliability and consistency are built into organizational routines where errors can have catastrophic consequences. In health care, reliability is defined as the "measurable ability of a health-related process, procedure, or service to perform its intended functions in the required time under commonly occurring conditions"[91] (p. 82). Applying the theory behind high reliability organizations and normal accident theory (e.g., understanding how health system factors affect safety), patient safety improvements have been linked to high-reliability safety interventions, including double checking, and improving the validity of root-cause analyses.[92]

Because improving safety is complex and should be continuous,[2, 4, 11] HROs continually measure their performance, learn from experience, and take action to resolve problems when they are discovered. HROs have a (1) preoccupation with avoiding failure, (2) reluctance to simplify interpretations, (3) sensitivity to operations, (4) commitment to resilience, and (5) deference to expertise.[93, 94] A preoccupation with avoiding failures is based on comprehensive error reporting, where human failure is accepted as being inevitable, and being overconfident because of successes is considered highly risky. A reluctance to simplify interpretations is supported by thoroughly examining situations. Being sensitive to operations involves being constantly concerned about the unexpected and recognizing that active errors result from latent errors in the system. Committing to resilience involves being able to identify, control, and recover from errors, as well as developing strategies to anticipate and responds to the unexpected. Having deference to expertise means that everyone is involved and decisions are made on the front line.[94]

Health care leaders and researchers have been looking to HROs in industry, such as the National Aeronautics and Space Administration, aviation, and the U.S. Postal Service,[21, 94, 95] to apply their lessons learned to health care. HROs are known to approach safety from a systems perspective, involving both formal structures and informal practices, such as open inquiry and deep self-understanding that complement those structures.[96] Through careful planning and design, HROs have been found to share common features: (1) auditing of risk—to identify both expected and unexpected risks; (2) appropriate reward systems—for safety-related behaviors; (3) system quality standards—evidence-based practice standards; (4) acknowledgment of risk—detecting and mitigating errors; and (5) flexible management models—promoting teamwork and decentralized decisionmaking.[97] Shapiro and Jay asserted that health care organization can become HROs though "(1) attitude change, (2) metacognitive skills, (3) system-based practice, (4) leadership and teamwork, and (5) emotional intelligence and advocacy"[98] (p. 238).

Implementing quality and safety improvement strategies in organizational microclimates/microsystems, and for that matter organization-wide, should be predicated on increasing the subunits' awareness of how they function and mindfulness of the reliability of their outcomes. Mindfulness is a "combination of ongoing scrutiny of existing expectations, continuous refinement and differentiation of expectations based on newer experiences, willingness and capability to invent new expectations that make sense of unprecedented events, and a more nuanced appreciation of context and ways to deal with it, and identification of new dimensions of context that improve foresight and current functioning"[94] (p. 42). Mindfulness speaks to the interrelationships among processes of perception and cognition that stimulate a rich awareness of and hypervigilance for emerging factors and issues that could threaten the quality of care and enable the identification of actions that might be taken to deal with the threats to quality.[94] Weick and Sutcliff[94] argue that organizations can become HROs when they become

mindful, as manifested by being preoccupied with failure, reluctant to simplify interpretations, sensitive to operations, committed to resilience, and deferent to expertise.

What Is It Going To Take To Improve the Safety and Quality of Health Care?

Changes in health care work environments are needed to realize quality and safety improvements. Because errors, particularly adverse events, are caused by the cumulative effects of smaller errors within organizational structures and processes of care, focusing on the systemic approach of change focuses on those factors in the chain of events leading to errors and adverse events.[5, 99] From a systems approach, avoidable errors are targeted through key strategies such as effective teamwork and communication, institutionalizing a culture of safety, providing patient-centered care, and using evidence-based practice with the objective of managing uncertainty and the goal of improvement.

The Right Work Environment

The major focus of the IOM's report, *Keeping Patients Safe: Transforming the Work Environment of Nurses*,[1] was to emphasize the dominant role of the work environment within health care organizations and the importance of the work environment in which nurses provide care to patients. Research reviewed by the IOM committee reported that nurses were dissatisfied with their work and wanted better working conditions and greater autonomy in meeting the needs of patients. The significance of these and many other findings led to the committee recommending significant changes in the way all health care organizations were structured, including "(1) management and leadership, (2) workforce deployment, (3) work processes, and (4) organizational cultures"[1] (p. 48). After the release of that report, the American Association of Critical-Care Nurses (AACN) expanded upon these concepts and put forth the following standards for establishing and sustaining healthy work environments: (1) effective, skilled communication; (2) true collaboration that is fostered continuously; (3) effective decisionmaking that values the contributions of nurses; (4) appropriate staffing that matches skill mix to patient needs; (5) meaningful recognition of the value of all staff; and (6) authentic leadership where nurse leaders are committed to a healthy work environment and engage everyone.[100] To achieve these standards, many organizations will need to significantly change the work environment for nurses.

The nursing "practice environment" is defined by organizational characteristics that can either facilitate or constrain professional nursing practice.[101] Changes to the nurses' work environment need to focus on enabling and supporting nurses to provide high-quality and safe care.[102] To do so, there needs to be significant changes in the way health care is organized that also address nursing workforce resources, training, and competencies. Researchers have found that nurses may experience greater professional fulfillment when strategies are implemented that promote autonomous practice environments, provide financial incentives, and recognize professional status.[103] Whether because of unequal distribution of nurses or expected nursing workforce shortages with the aging of practicing nurses and faculty,[104, 105] staffing shortages increase a nurse's stress, increases their workload, and can adversely impact patient outcomes. More important, clinicians in practice will need new skills and empowerment to work effectively with colleagues within their work environments. Nurses also need to possess certain

competencies that reflect the nature of nursing in improving patient and systems outcomes, including evidence-based practice, patient-centered care, teamwork and collaboration, safety, quality improvement, and informatics.[106]

Opportunity, power, and the composition of the workforce within organizations influence what nurses are able to do and how they are able to use resources to meet patients' needs. Lashinger and colleagues[76, 107–109] have found that the empowerment of staff nurses increased with greater responsibilities associated with job advancements and was related to the nurses' commitment to the organization, burnout, job autonomy, their ability to participate in organizational decisionmaking, as well as job strain and work satisfaction.[110] Because work environment factors influence the perceptions of nurses as being supported in their work, having a sense of accomplishment,[111] and being satisfied with their work, it is important to empower staff to manage their own work, collaborate in effective teams,[112] and practice nursing in "optimal" conditions.[113] Professional empowerment in the workplace is derived from competence and interactions with colleagues and other clinicians within organizations—and with patients—as well as by demonstrating knowledge and gaining credibility.[114] For nurses, structural empowerment can have a direct effect on their experience of providing care in their work environment.[115] Models of care, such as a professional practice model, not only can improve work satisfaction, but they can facilitate patient and nursing outcomes.[116]

Patient-Centered Care

In *Crossing the Quality Chasm*, the IOM recommended that "all health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States"[7] (p. 39). For this recommendation to be realized, the IOM asserted that health care would have to achieve six aims: to be safe, effective, patient-centered, timely, efficient, and equitable. The IOM also asserted that health care for the 21st century would need to be redesigned, ensuring that care would be based on a continuous healing relationship, customized inclusion of patient needs and values, focused on the patient as the source of control, and based on shared knowledge and the free flow of information. Patient-centered care would improve health outcomes and reduce or eliminate any disparities associated with access to needed care and quality.[117–119]

Patient-centered care is considered to be interrelated with both quality and safety.[7] The role of patients as part of the "team" can influence the quality of care they receive[120, 121] and their outcomes.[122, 123] The IOM recommended that clinicians partner with patients (and the patient's family and friends, when appropriate)[124] to realize informed, shared decisionmaking, improve patient knowledge, and inform self-management skills and preventive behaviors. Patients seek care from competent and knowledgeable health professionals to meet their physical and emotional needs. Within this framework, the clinician's recommendations and actions would be customized to the patient and informed by an understanding of the patient's needs, preferences, knowledge and beliefs,[125] and when possible, would enhance the patient's ability to act on the information provided. It follows then that an effective clinician-patient partnership would include informed, shared decisionmaking and development of patient knowledge and skills needed for self-management of chronic conditions.

Patients and families have been and are becoming more involved in their care. Findings from several studies have indicated that patients who are involved with their care decisions and

management have better outcomes than those patients who are not,[126, 127] although some researchers indicate that the evidence concerning the impact of patient-centered care is variable.[128] Patient self-management, particularly for chronic conditions, has been shown to be associated with improvements in quality of life[129] and health status, decreased utilization of services,[130] and improved physical activity.[131, 132] The Chronic Care Model developed by Wagner and colleagues[133–135] similarly emphasized the importance of actively engaging patients in achieving substantial improvements in care. Patient-centeredness is increasingly recognized as an important professional evolution[124] and holds enormous promise for improving the quality and safety of health care. Yet, patient-centered care has not become the standard of care throughout care systems and among all clinicians as recommended by the IOM.[7, 136] For patient-centered care to become the "standard" care process, care processes would need to be redesigned and the roles of clinicians would need to be modified[137, 138] to enable effective teamwork and collaboration throughout care settings.

Teamwork and Collaboration

It is nonsensical to believe that one group or organization or person can improve the quality and safety of health care in this Nation. In that patient safety is inextricably linked with communication and teamwork,[6] there is a significant need to improve teamwork and communication.[139, 140] Teamwork and collaboration has been emphasized by the Joint Commission. The Joint Commission has found communication failures to be the primary root cause of more than 60 percent of sentinel events reported to the Joint Commission.[141] Ineffective communication or problems with communication can lead to misunderstandings, loss of information, and the wrong information.[142] There are many strategies to improve interdisciplinary collaboration (e.g., physician and nurse),[140, 143] including using multidisciplinary teams as a standard for care processes.

Interprofessional and intraprofessional collaboration, through multidisciplinary teams, is important in the right work environments. Skills for teamwork are considered nontechnical and include leadership, mutual performance monitoring, adaptability, and flexibility.[144] Teamwork and interdisciplinary collaboration[139] have the potential to mitigate error and increase system resilience to error.[145] Clinicians working in teams will make fewer errors when they work well together, use well-planned and standardized processes, know team members' and their own responsibilities, and constantly monitor team members' performance to prevent errors before they could cause harm.[6, 146, 147] Teams can be effective when members monitor each other's performance, provide assistance and feedback when needed,[147] and when they distribute workloads and shift responsibilities to others when necessary.[144]

The importance of training members to work effectively in multidisciplinary teams to achieve high reliability in patient (e.g., no adverse events) and staff outcomes (e.g., satisfaction working with team members and improved communication)[145, 148–151] was found to be especially significant when team members were given formal training to improve behaviors.[145] Resources such as AHRQ's TeamSTEPPS™ (visit http://www.ahrq.gov/qual/teamstepps) can provide teams with the opportunities the members need to improve the quality and safety of health care. TeamSTEPPS™ is an evidence-based teamwork system that teams can use to improve communication and other essential teamwork skills.

Conversely, lack of effective teamwork—such as poor communication and collaboration[139] within and between disciplines—was found to have negative effects on patient outcomes (e.g.,

surgical errors)[152] and higher mortality.[153] Poor teamwork as well as disrespectful, rude, and insulting behaviors have no place in health care and can potentially increase unsafe practices.[154–156] In a comparison of medicine to aviation, physicians were found to be significantly more supportive of hierarchical models of practice, where junior physicians would not question their seniors.[152] Hierarchical structures have been found to have an adverse influence on communication among team members and patient outcomes.[157, 158] Nursing's participation in teams is further limited under a hierarchical, mechanistic structure when nurses focus on tasks.[159] Other barriers that have been found to inhibit the effectiveness of nurses in teams were their perceptions of teamwork, having different teamwork skills, and the dominance of physicians in team interactions.[160] When physicians view hospitals as a "platform[s] for their work and do not see themselves as being part of [the] larger organization"[1] (p. 144), physicians may not only thwart the work of nurses, but the organization's efforts to improve the quality and safety of care. When anyone within organizations exhibit intimidating or disruptive behaviors and when there are inappropriate hierarchies, breakdowns in teamwork, and loss of trust, decreased morale and turnover are expected among staff; patients can expect to be harmed and will likely seek care elsewhere.[1, 161–163]

The work environment, communication and collaboration among clinicians, and decisionmaking are also linked to leadership and management within health care organizations.[164–166] Some authors have argued that performance of organizations and the use of evidence in practice were factors dependent upon leadership, particularly among middle/unit-based clinical management.[167–169] The personality and attitudes of leaders has been shown to have an impact on safety[170, 171] and on perceptions about how safety is managed.[172] Visible, supportive, and transformational nursing leadership to address nursing practice and work environment issues is critical as is nursing and medical leadership to ensure that the work environment supports caregivers and fosters collaborative partnerships. However, giving encouragement is not generally stated as a high-priority role of health care supervisors. Traditionally, technical skills and productivity on the job were aspects that received the supervisor's primary focus. However, there is a growing appreciation that encouragement is a transformational leadership technique that is related to productivity on the job and to quality work. Use of encouragement is a leadership technique that fits in today's people-oriented work climate.[1]

Evidence-Based Practice

Evidence should be used in clinical decisionmaking whenever possible. The need for improving quality using evidence was described by Steinberg and Luce as "the recognition that there is much geographic variation in the frequency with which medical and surgical procedures are performed, the way in which patients with a given disease are managed, patient outcomes, and the costs of care, which cannot be explained by differences in patients' demographic or clinical characteristics"[173] (p. 80). Indeed, findings from research continue to provide information that illustrates that only some patients are receiving the recommended quality of care,[117, 174–176] and errors continue to adversely impact patient outcomes. Steinberg and Luce go on to state that there is "strong evidence that much of the care that is being provided is inappropriate (that is, likely to provide no benefit or to cause more harm than good)" and that there are "indications that many patients are not receiving beneficial services"[173] (p. 80). Some examples of these concerns are associated with determining health care interventions and

medication safety. Patients can be harmed if their symptoms and needs are not assessed accurately,[177] if the wrong type of intervention is selected,[178–180] and if patients do not receive information they need to manage their care.[181] Certain types of medication errors, such as the wrong drug, wrong dose,[182] and polypharmacy,[183] threaten the quality of therapeutic interventions and the safety of patient care by aggravating the patient's preintervention health status.

Another reason that health care quality needs to improve and be based on evidence is "continuously rising health care costs"[173] (p. 80). In a country that spends more per capita than anywhere else in the world, patients do not necessarily have better outcomes.[184] Often without knowing it, clinicians have one of the greatest roles in controlling (or increasing) the cost of health care. What type of care is given to patients is sensitive to clinicians (e.g., nurses and physicians) as well as organizational structures, policies, and resources. The skill mix and number of nurses has been found to be associated with adverse events, longer lengths of stay in hospitals, and higher health care costs.[185–187] Findings from research have indicated that understaffing is associated with an increase in errors and adverse events, such as medication errors, pressure ulcers, health care associated infections, and increased mortality rates in hospitalized patients.[86, 185, 188–195] To address workforce shortages, organizations have used financial and shift work incentives, used part-time workers, and improved the image and job satisfaction, among other things.[196, 197] All of these strategies increase the cost of health care.

The combined concern about the growing cost of care and the effects of poor-quality care on patients has resulted in action by the Centers for Medicare and Medicaid Services (CMS) and other insurers to put in place financial penalties for hospitals that have preventable events, such as readmission, never events (e.g., wrong-site surgery), health care associated infections,[198] pressure ulcers, and patient falls with injury. These financial penalties reflect policy based on research that has indicated a significant association between nurse staffing and adverse patient outcomes,[185, 187, 192] and quality measures that have been put forth as being sensitive to nursing care.[199, 200] Adverse patient outcomes are also sensitive to the care directed by physicians, even when physicians and hospitals have a financial incentive to provide specific elements of quality care. This was recently found in a comparison of treatments and outcomes for 5 conditions at 54 hospitals participating in a Medicare pay-for-performance pilot program to the treatments and outcomes at 446 hospitals not participating in the program. The researchers in this investigation found the financial incentive of pay-for-performance was not associated with significant improvement in quality of care or outcomes.[201] Because health care costs are expected to continue to increase, it is important to ensure that costs of health care are not unnecessarily high and that patients receive quality care and are not exposed to preventable adverse events. Nurse leaders and clinical practitioners should be required to be actively engaged with other clinicians and leaders in assessing and monitoring the care of patients and their outcomes, as well as in driving quality improvement efforts to prevent the reoccurrence of these high-risk adverse events.

However, not all evidence is equal. It can be based on research that is not generalizable to other settings and populations[173, 202, 203] and may be difficult to translate into practice without further testing and the development of guidelines.[203] Even when research is available, it is often not used in practice,[204, 205] and adapting the research to practice can be challenging because of numerous barriers and deficits of facilitators to change.[206, 207] A systematic review of interventions aimed at increasing the use of evidence in practice found that greater success was achieved when clinicians were involved in education about and in intervention strategies that

were centered on using evidence in practice with local opinion leaders and multidisciplinary teams. The investigators further asserted that to effectively use research in practice, nurses should use the right evidence to inform and evaluate practice change interventions, longitudinally assess the effects of the intervention using the measures for multiple outcomes, and use a methodologically rigorous approach to design the implementation and evaluation of the intervention.[208]

Evidence-based practice has been defined as using data and information, often from diverse sources, to guide practice. When evidence is available, clinicians must locate and then consider the generalizability of its findings and usability in the practice setting. Randomized controlled trials (RCTs) have been considered the best standard for clinical practice, but they are not available for many common clinical situations and are generalizable only to the population studied during the trial. Clinicians use a broad range of practice knowledge, especially when evidence is not available. Sandars and Heller[209] proposed using the concept of knowledge management, which involves generating research-based evidence, synthesizing the evidence base, communicating that knowledge, and applying it to care processes. Another option would be to employ quality improvement methods, such as Plan-Do-Study-Act, to inform practice.[50] Horn and Gassway[210] proposed using practice-based evidence for clinical practice improvement that is based on the selection of clinically relevant alternative interventions, includes a diverse study population from heterogeneous practice settings, and utilizes data about a broad range of health outcomes.[210] Thus, when evidence is not available, clinicians should use their experience and data and information from other forms of inquiry.

A Culture of Safety

The IOM encouraged the creation of cultures of safety within all health care organizations.[6] A safety culture is defined as "the product of the individual and group values, attitudes, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety [programs]"[211] (p. 2). An organization's culture is based on its history, its mission and goals, and its past and current leadership. Gadd and Collins[211] found that organizations with a positive safety culture were characterized by communication guided by mutual trust, shared perceptions of the importance of safety, and confidence that error-preventing strategies would work.

The terms "culture" and "climate" have been used interchangeably. Organizational climate refers to the atmosphere of aggregate attitudes and perceptions of how individuals feel about their places of work, which are associated with both individual and team motivation and satisfaction. The climate within an organization represents a moveable set of perceptions related to conditions within the workplace,[212] which can be changed by the values, attributes, skills, actions, and priorities of organization leaders and mangers. A safety climate is a type of organizational culture and is the result of effective interplay of structure and processes factors and the attitude, perception, and behavior of staff related to safety. A climate of safety is represented by employee perceptions of: the priority of safety within the work environment on their unit and across the organization, and is influenced by management decisions; safety norms and expectations; and safety policies, procedures, and practices within the organization.[211]

It follows then that the higher the safety culture, the safer and better the quality of care. When researchers compared the safety cultures of hospitals to the aviation industry—which has been associated with high safety cultures—they found that the safety climate in hospitals was

worse; and within hospitals, the safety culture was worse in operating rooms and emergency departments.[213, 214] The perceptions of safety within a hospital have been found to be more positive among leaders and managers than among those directly involved in care;[215] nurses reported the lowest numbers for a safety culture.[216] Hospital staff have been found to understand the importance of safety in their work and their role in patient safety, and to judge patient safety according to their perception of workplace safety and leadership commitment.[217] The perceptions of hospital staff of the patient safety culture have also been found to be associated with empowerment (e.g., being able to practice nursing optimally) and characteristics of Magnet hospitals.[113] Additionally, more errors were found in organizations and units with poor safety cultures. In fact, some researchers found that the safety climate predicted the occurrence of medication errors, that the level of safety was associated with the unit-specific and hospital-wide climates, and that a positive safety climate in a unit could compensate for the detrimental effects of a low hospital-wide climate.[218]

Developing and transitioning to a culture of safety requires strong, committed leadership by executives, hospital boards, and staff.[5] According to the IOM, the essential elements of an effective safety culture include the commitment of leadership to safety and empowering and engaging all employees in ongoing vigilance through communication, nonhierarchical decisionmaking, constrained improvisation, training, and rewards and incentives.[1] The Association of Operating Room Nurses issued guidance about creating such a patient safety culture, emphasizing the necessity of the following components: (1) a reporting culture, (2) a flexible culture, (3) a learning culture, (4) a wary culture, and (5) a just culture.[219]

Yet, it should be understood that changing the culture within an organization is difficult and can happen only over time.[2, 5] Throughout time, nurses have frequently been treated differently if they were involved in an error/adverse event, being at the sharp end of blame because they can stand between errors.[220, 221] Thus, for nurses to not be at the sharp end of blame, it is important for organizational leaders and managers to establish a just culture that values reporting, where errors can be reported without fear of retribution;[222-224] where staff can trust leaders to make a distinction between blameless and blameworthy; and where the organization seeks to ferret out the root causes of that error, focusing on systems and process factors. Just as important, organizational leaders, managers, and staff need to learn from the continuous assessment of safety culture and make efforts to continually improve organizational performance[4, 5] and demonstrate success in safety improvements.[215]

If an organization's culture is based on secrecy, defensive behaviors, professional protectionism, and inappropriate deference to authority, the culture invites threats to patient safety and poor-quality care.[225] Several factors can impede the development of a culture of safety, including (1) a clinician's tendency to view errors as failures that warrant blame, (2) the focus of nurse training on rules rather than knowledge, (3) punishing the individual rather than improving the system,[226, 227] and (4) assuming that if a patient was not injured, that no action is required.[227] Each of these factors stems from organizations and the people in them having unrealistic expectations of clinical perfection, refusing to accept the fallibility of humans, and discounting the benefit of effective multidisciplinary teams.[1, 151]

Changing an organization's culture of safety should begin with an assessment of the current culture, followed by an assessment of the relationship between an organization's culture and the health care quality[228, 229] and safety within the organization. Several tools have been developed to measure the safety culture within organizations to inform specific interventions and opportunities for improvement. They have focused on dimensions of a patient safety climate, including

leadership and management (e.g., personality and attitudes), teamwork, communication, staffing, attitudes/perceptions about safety, responses to error, policies, and procedures. Some of these tools could be used for individual or team assessment, or to compare organization-wide perceptions or unit-specific perceptions.[230] A recent tool that was developed can be used to differentiate patient from staff safety and types of clinicians.[218] Another of these tools (www.ahrq.gov/qual/hospculture/#toolkit) developed for AHRQ has been used to compare safety cultures among hospitals.

The Challenge of Change

The question has been whether efforts to improve the quality and safety of care have been moving quickly enough. Many leaders and researchers[231–234] have raised concern that clinicians, administrators, policymakers, and researchers have *not* been moving quickly enough toward safe care. A few researchers have found improvements in some areas, but little if any change in others.[32, 235–238] Amalberti and colleagues[239]argued that the cultural and historical emphasis on individualism and autonomy in health care, its drive for economic productivity, and structural elements such as chronic staff shortages must be overcome if rapid progress is to be made toward ultrasafe health care. These authors warn that, to achieve progress, we will need to identify closely held values and traditions that enforce the status quo and change them in support of safety and quality.

Organizations such as the IOM, AHRQ, the Joint Commission, and CMS have been emphasizing the need for significant improvements in quality and patient safety. Yet depth and breadth of organizational quality and safety improvement changes are variable. For example, groups such as the Leapfrog Group have been influential in moving safety forward by setting standards for intensivist physician staffing levels in intensive care units,[240, 241] yet many hospitals have been challenged to implement physician staffing standards because of the resource implications (e.g., financial and staffing)[242, 243] and lack of clearly defined leadership.[121] Also, efforts to improve safety by understanding and targeting systems factors through public reporting have been championed in some States, such as Texas (www.texashasp.org) and Pennsylvania (www.psa.state.pa.us), but other States lag behind. The Joint Commission has emphasized national patient safety goals (www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals) to improve safety in areas it has identified as high risk associated with sentinel events reported to the Joint Commission. Furthermore, starting in October 2008, the CMS (as well as other insurers) will begin to deny reimbursement to care providers for care delivered to patients that involved never events, such as health care–associated infections, wrong-site surgery, and hospital-acquired pressure ulcers. Given the role and influence of these various external drivers, health care leaders and managers will need to be actively engaged in quality and safety improvement efforts.

Organizations should be flexible to keep pace with the rapid changes in health care and the growing evidence base. To do so, they need to be willing to adopt new knowledge and innovations, which entails "a social and political process, which nearly always involve[s] debate and reference to others' views"[168] (p. 44), a process that needs to include all leaders, managers, and staff. Those employees within organizations, particularly nurse leaders and staff, will need to redesign care processes and revisit the roles and responsibilities of team members.[244] Pronovost and colleagues[245] emphasized the importance of recognizing that creating change is complex and that improvement strategies need to (1) prevent errors from occurring, (2) raise awareness of

errors and near misses, and (3) be better at diminishing patient harm if an error occurs. For these reasons, changes to the error-producing structural factors of an organization by themselves do not lead to expected improvements in quality.[246, 247] Several organizations have reported difficulties in improving patient safety because of the need for transparency in reporting on performance measures, lack of standardization and functionality of information technology, and no clear pathway identified for improvement.[248] Other difficulties could be associated with the results of the improvement initiative itself. For example, the introduction of computerized provider order entry systems for medication therapy prevented some errors from happening (e.g., related to illegible handwriting), but introduced other errors that might have been avoided with better implementation strategies.[249]

There are many change strategies, from single focus to multifaceted, that have centered on a structural approach and have been used successfully to create quality and patient safety improvements. One approach would be to implement bundles of evidence-based interventions to simultaneously improve multiple outcomes,[207] using health information technology when possible. Other strategies have focused on the components of the change process that need to be addressed. Caramanica and colleges[250] asserted that a successful quality improvement strategy was based on the alignment of the goals of the organization with goals for quality and patient safety improvement, collaboration using interdisciplinary teams, applying evidence-based practice, and monitoring and assessing excellence. Quality improvement strategies that align with the values and beliefs of individuals and build on current processes can determine the pace and diffusion of change.[251] As discussed in chapter 44, "Quality Methods, Benchmarking, and Measuring Performance," many organizations have used the Plan-Do-Study-Act approach to implement change, particularly rapid-cycle improvement. A similar strategy used the Reach-Effectiveness-Adoption-Implementation-Maintenance framework to translate research into practice.[252] The Department of Veterans Affairs has approached patient safety improvement by targeting key strategies, including leaders creating an environment of acceptance, establishing clear goals, creating a fair system that does not focus on blame, creating a transparent system for decisionmaking, facilitating root-cause analysis, requiring leadership and management to be visibly involved, and evaluating performance.[253, 254] While organizations' characteristics differ, as do characteristics of leaders and managers, success can be realized through continuous improvement with careful attention to finding a balance that avoids so much change that change fatigue results.[255]

The IOM asserted that improvements must target organizational factors by using information technologies, developing effective teams, standardizing procedures with evidence, and using data and information to monitor performance.[7] Focusing on the role, the influence, and the complexity of health care systems by thinking about the "big picture" involves understanding how a specific issue or outcome of concern interacts with numerous factors, both within and external to the system. In doing so, it may be more feasible to solve recurring problems with ineffective processes and poor outcomes, even when previous attempts have failed.[256] In the case of medication safety, efforts to significantly reduce medication administration errors must also consider errors associated with prescribing, transcribing, and dispensing errors, as well as errors associated with health information technologies, product labeling,[257] therapeutic consistency across care settings (e.g., medication reconciliation), and miscommunication of drug allergies. For health care systems and organizations to improve safety and quality, they need to learn to improve existing knowledge and processes, understand what is and is not working well, and both adopt and discover better ways to improve patient outcomes.[258]

Organizational changes should be targeted using multifaceted strategies and interventions that focus on redesigning structural factors (e.g., staffing levels, roles and responsibilities of nurses, etc.), revising policies and procedures,[259] and using multidisciplinary teams.[260] Because the factors and issues involved in patient safety and quality improvement are complex, mirroring the complexity of health care systems, no one single intervention will accomplish performance goals and standards. Using a systematic approach to changing practice based on evidence when possible is required to improve patient safety and contribute to the evidential knowledge base and generalizability that can be used eventually for purposes of diffusion.[261] Improving the quality and safety of health care may require the use of mixed or multiple methodologies to continually monitor and evaluate the impact and performance, because no one single method would be expected to be appropriate for the depth and breadth of change interventions.[262–264]

Change can be slow because it is a process that involves many people and issues. Efforts to improve quality and safety need champions throughout the key areas within the organization as well as executive and midlevel managers.[70, 259] Champions can also be found among individuals for whom adverse events have had incredible impact on their lives.[265] It would follow then that when an opportunity is present to adopt new knowledge and evidence into practice, "that individual professionals and professional groups (particularly the doctors) have the power to impede or to facilitate the diffusion process"[168] (p. 50). Adoption of new knowledge and evidence for change is a process that needs leadership involvement and support, fostering effective relationships and enabling action, utilizing ongoing monitoring and evaluation, and demonstrating flexibility according to findings from evaluation and changing needs.[254, 258] Yet the effect of this could be mitigated by the commitment and direction of senior leadership, who co-lead/co-coach with clinical leaders[266] to use evidence in practice, and to continuously evaluate progress and make changes accordingly, to therefore improve organizational performance and patient outcomes.[267]

For changes of care processes that support safe and quality care to be effective, interventions must not be first-order, short-term problem-solving that offers quick fixes but not lasting change. Instead, second-order problem-solving should be used, where the underlying causes and processes are examined.[268] Even when processes and procedures have changed and demonstrated positive effects on patient outcomes, there is a concern about sustainability over time because the tendency of health care providers to deliberately deviate from the new standard of practice may be unavoidable.[95] Ongoing monitoring and management of these new processes and procedures is required.[95] How do you institutionalize change? Change initiatives are successful when they are built on the current way of doing things,[251] are visible and have positive outcomes, are consistent with employees' values and beliefs, are manageable,[269] and are generalizable to the organization.[270]

Practice Implications

To bring the effects of the sharp end away from nurses and put them squarely on the shoulders of health care organizations and systems, there needs to be significant changes in how health care is structured and how it is delivered to patients. While the roles and responsibilities of nurses have changed over the years, including "risk management, quality assurance, case management, clinical trials coordinator, and patient care manager among numerous others,"[271] the diversity of skills, roles, and training[272] places nurses in critical positions to lessen the

incidence of variation by collecting and assessing data, working with interdisciplinary teams, examining performance, and driving evidence-based practice.

From the literature reviewed in this chapter, there are key strategies that can be used to effect change, and subsequently, the quality and safety of care will be improved. The major factor in creating improvement is understanding and accounting for the complexity of health care organizations, health care systems, care processes, and patient needs. To begin, senior nurse leaders need to work with staff to identify and prioritize areas and establish goals to address the issues that are associated with poor-quality and unsafe care. Executive leadership and managers need to be committed to investing both their time and resources to improving the safety and quality of care. As organizations begin plans and reassess the need for changes, nurses will need to be proactive in redesigning care models and redefining the work of nurses,[273] whether the initiatives will initially impact only a single unit or group of clinicians, or are aimed at being systemwide. Furthermore, efforts to improve quality and safety must have involvement and commitment from all stakeholders.

The foundation of quality and safety improvement initiatives needs to be centered on systems factors, not individuals. Nurse leaders, colleagues, and State boards of nursing registration should understand the significant impact of systems factors in any instance when individual culpability is sought, particularly when appraising and disciplinary action is unfortunately taken against an individual clinician (e.g., State boards of licensure and malpractice cases). The responsibility of nurse leaders and State boards of nursing is to determine when errors and adverse events result from deliberate malfeasance as opposed to a mixture of systems factors. Without considering the nature and effect of systems factors, action taken against an individual would not appear to be evidence-based and latent factors will continue, waiting to "ensnare" another nurse.

To improve patient safety and the quality of care, it is important to determine the best strategy and be willing to alter the strategy if necessary to create change. Not all strategies that have been successful in other organizations will be successful in your organization; some interventions have too small a sample size or information about them to be considered as a possible strategy in your organization. As an initiative is implemented, it could be that what was thought to have been generalizable needs to be tailored to the unique characteristics of your organization. Change initiatives should be either evidence based or based on data and information internal to your organization (e.g., incident reports), and should address measures to evaluate improvements in patient safety and quality.[199, 274] Throughout the process of implementing changes, it is important for data and information to be continually monitored and assessed to track performance. It is only through strategic decisions and interventions that the sharp end held against nursing will transition to the organizations in which nurses work.

Research Implications

The nurse's role in and ability to change patient safety and quality improvement within health care systems is a relatively new field of research, but consideration must be given to more than 60 years of nursing research that has implications for both safety and quality processes and nursing, patient, and organizational outcomes. Future research will need to better define the theoretical foundations behind the relationships between organizational systems factors, clinical processes, and patient safety and quality outcomes. It is also important for future research to focus on improving and widening the assessment of the impact of patient safety and quality

improvements on the incidence of the broad array of errors that can and do occur in nurses' work environments. For example, leaders and clinicians need to understand the association between an organization's culture of safety and patient outcomes as well as how nurses can influence executives to lead working environment improvements. In addition, and probably more important, future research needs to address how research and evidence can be translated into and become the new standard of practice, avoiding the lengthy process now involved, which could take as long as 10 to 17 years.[275]

Conclusion

Everything about health care is complex. There are complex care processes, complex health care technologies, complex patient needs and responses to therapeutic interventions, and complex organizations. There are tremendous opportunities and challenges in improving the quality and safety of health care, but the majority require purposeful redesign of health care organizations and processes. Organizations that are committed to high-quality and safe care will not place nurses at the "sharp end" of care, but will focus on system improvements. Recognizing the complexity of care and how several factors combine at a specific time and result in errors and adverse events, organizations, leaders, and clinicians will dedicate themselves to using data and evidence and to continuously improve the quality and safety of care, even when there are complex challenges.

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Chapter 3. An Overview of *To Err is Human*: Re-emphasizing the Message of Patient Safety

Molla Sloane Donaldson

Introduction

On November 29, 1999, the Institute of Medicine (IOM) released a report called *To Err is Human: Building a Safer Health System*.[1] The IOM released the report before the intended date because it had been leaked, and one of the major news networks was planning to run a story on the evening news.[2] Media throughout the country recognized this opportunity for a headline story describing a very large number of hospital deaths from medical errors —possibly as great as 98,000 per year. The problem in other care settings was unknown, but suspected to be great.

The search was on to find out who was to blame and how to fix the problem. Congressional hearings were subsequently held. Governmental agencies, professional groups, accrediting organizations, insurers, and others quickly responded with plans to define events and develop reporting systems. Health care organizations were put on the defensive. Recognizing that individual accountability is necessary for the small proportion of health professionals whose behavior is unacceptable, reckless, or criminal, the public held organizational leadership, boards, and staff accountable for unsafe conditions. Yet imposing reporting requirements and holding people or organizations accountable do not, by themselves, make systems safer.

What was often lost in the media attention to hospital deaths from medical errors cited by *To Err is Human* was the original intent of the IOM Committee on Quality Health Care in America, which developed the report. That committee believed it could not address the overall quality of care without first addressing a key, but almost unrecognized component of quality; which was patient safety. The committee's approach was to emphasize that "error" that resulted in patient harm was not a property of health care professionals' competence, good intentions, or hard work. Rather, the safety of care—defined as "freedom from accidental injury"[3] (p. 16)—is a property of a system of care, whether a hospital, primary care clinic, nursing home, retail pharmacy, or home care, in which specific attention is given to ensuring that well-designed processes of care prevent, recognize, and quickly recover from errors so that patients are not harmed.

This chapter focuses on the principles described in the IOM report, many of which can be mapped to what are now called safe practices[4] and all of which are valuable guides. This chapter is not intended to address the growing body of evidence; rather, the chapter summarizes the starting point—the IOM recommendations based on the literature and the knowledge of the committee members who developed the report.

Moving the Focus From Errors to Safety

Errors occur in health care as well as every other very complex system that involves human beings. The message in *To Err is Human* was that preventing death and injury from medical errors requires dramatic, systemwide changes.[1] Among three important strategies—preventing, recognizing, and mitigating harm from error—the first strategy (recognizing and implementing

actions to *prevent* error) has the greatest potential effect, just as in preventive public health efforts.

The IOM committee recognized that simply calling on individuals to improve safety would be as misguided as blaming individuals for specific errors. Health care professionals have customarily viewed errors as a sign of an individual's incompetence or recklessness. As a result, rather than learning from such events and using information to improve safety and prevent new events, health care professionals have had difficulty admitting or even discussing adverse events or "near misses," often because they fear professional censure, administrative blame, lawsuits, or personal feelings of shame. Acknowledging this, the report put forth a four-part plan that applies to all who are, or will be, at the front lines of patient care; clinical administrators; regulating, accrediting, and licensing groups; boards of directors; industry; and government agencies. It also suggested actions that patients and their families could take to improve safety.

The committee understood that need to develop a new field of health care research, a new taxonomy of error, and new tools for addressing problems. It also understood that responsibility for taking action could not be borne by any single group or individual and had to be addressed by health care organizations and groups that influence regulation, payment, legal liability, education and training, as well as patients and their families. The report called on Congress to create a National Center for Patient Safety within the Agency for Healthcare Research and Quality, to develop new tools and patient care systems that make it easier to do things right and harder to do things wrong. This handbook is a direct result of the implementation of those recommendations.

Improving Safety by Understanding Error

Every day, physicians, advance practice nurses, nurses, pharmacists, and other hospital personnel recognize and correct errors and usually prevent harm. Errors, defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim,"[1] do not all result in injury or harm. Errors that do cause injury or harm are sometimes called *preventable adverse events*—that is, the injury is thought to be due to a medical intervention, not the underlying condition of the patient. Errors that result in serious injury or death, considered "sentinel events" by the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]),[5] signal the need for an immediate response, analysis to identify all factors contributing to the error, and reporting to the appropriate individuals and organizations[7] to guide system improvements.

The key question for the IOM, as for many health professionals now, was what could be done to improve safety. To differentiate between individual factors and system factors, the report distinguished between the "sharp" end of a process in which the event occurs (e.g., administration of the wrong dose of medication that is fatal, a mishap during surgery) and the "blunt" end in which many factors (called latent conditions), which may have seemed minor, have interacted and led to an error.[6] These latent conditions may be attributable to equipment design or maintenance, working conditions, design of processes so that too many handoffs occur, failures of communication, and so forth.[7-9]

Leape[8] greatly enhanced our understanding of errors by distinguishing between two types of cognitive tasks that may result in errors in medicine. The first type of task occurs when people engage in well-known, oft-repeated processes, such as driving to work or making a pot of coffee. Errors may occur while performing these tasks because of interruptions, fatigue, time pressure, anger, distraction, anxiety, fear, or boredom. By contrast, tasks that require problem solving are

done more slowly and sequentially, are perceived as more difficult, and require conscious attention. Examples include making a differential diagnosis and readying several types of surgical equipment made by different manufacturers. Errors here are due to misinterpretation of the problem that must be solved and lack of knowledge. Keeping in mind these two different kinds of tasks is helpful to understanding the multiple reasons for errors and is the first step in preventing them.

People make errors for a variety of reasons that have little to do with lack of good intention or knowledge. Humans have many intellectual strengths (e.g., large memory capacity and an ability to react creatively and effectively to the unexpected) and limitations (e.g., difficulty attending carefully to several things at once and generally poor computational ability, especially when tired).[12] Improving safety requires respecting human abilities by designing processes that recognize human strengths and weaknesses.

There are many opportunities for individuals to prevent error. Some actions are clinically oriented and evidence-based: communicating clearly to other team members, even when hierarchies and authority gradients seem to discourage it; requesting and giving feedback for all verbal orders; and being alert to "accidents waiting to happen." Other opportunities are broader in focus or address the work environment and may require clinical leadership and changing the workplace culture: simplifying processes to reduce handoffs and standardizing protocols; developing and participating in multidisciplinary team training; involving patients in their care; and being receptive to discussions about errors and near misses by paying respectful attention when any member of the staff challenges the safety of a plan or a process of care.

However, large, complex problems require thoughtful, multifaceted responses by individuals, teams, and organizations. That is, preventing errors and improving safety require a systems approach to the design of processes, tasks, training, and conditions of work in order to modify the conditions that contribute to errors. Fortunately, there is no need to start from scratch. The IOM report included some guidance based on what was known at the time, and other specific evidence has accumulated since then that can be put in practice today. Designing for safety requires a commitment to safety, a thorough knowledge of the technical processes of care, an understanding of likely sources of error, and effective ways to reduce errors.

A Report From the Trenches—Systems, not Shame

Nurses sometimes comment:

- "We are really short-staffed. Sometimes I am so busy and distracted that I am sure I must make mistakes when calculating the doses of meds. I haven't killed anyone, but I know when I've made a mistake. How can I make sure I don't make errors?"
- "I was supposed to administer chemotherapy to a patient. Even though I tried hard, I couldn't figure out from the chart what kind of cancer the patient had. What can I do to make sure this sort of thing doesn't happen again?"
- "There is a piece of equipment on our unit that is an accident waiting to happen. The experienced staff knows about it and has learned how to work around it, but what happens when new staff are assigned?"

These types of questions are by no means unusual. Partly because of its sheer complexity and the number of different individuals with different training and approaches, health care is prone to harm from errors—especially in operating rooms, intensive care units (ICUs), and emergency

departments where there is little time to react to unexpected events—and consequences can be very serious. Although most early studies focused on the hospital setting, medical errors present a problem in all settings, including outpatient surgical centers, physician offices and clinics, nursing homes, and the home, especially when patients and families are asked to use increasingly complicated equipment.

Patients should not be harmed by the health care system that is supposed to help them, but the solution does not lie in assigning blame or urging health professionals to be more careful. In what seems to be a simple example, an ICU nurse was wheeling a patient on a gurney to radiology when his knee struck a fire extinguisher hanging on the wall, resulting in the patient needing extra care. In response, the nurse may have been scolded by her supervisor and told to be more careful, or punished in some other way; everyone would feel the problem had been solved. Yet, would that make the hospital safer? Would it prevent other events that are similar but slightly different in circumstances from happening with other staff and patients in other units? The answer is an emphatic no.

Improving safety, arises from attention to the often multiple latent factors that contribute to errors and in some cases, to injury. In the above example, such factors included: 1) the nurse having to move the patient herself because transport had never arrived; 2) a change in hospital policy, so that only one instead of two people guide gurneys; 3) the failure to mount the fire extinguisher in a recessed niche; 4) the decision to transport a seriously ill patient rather than having mobile equipment come to him, requiring extra "handoffs" and opportunities for injury; and 5) poor gurney design, making steering difficult, and possibly still other factors.

The IOM's Four-Part Message

The IOM committee sought what could be learned from other disciplines and applied in health care by clinical and administrative leadership. It described actions that health care professionals can take now in their own institutions, whether they are new trainees, experienced clinical leaders, or instructors. The major thrust of the report was a four-part plan, intended to create financial and regulatory incentives to create a safer health care system and a systematic way to integrate safety into the process of care (the focus of this chapter). The four parts of the IOM recommendations are described below:

- **Part 1: National Center for Patient Safety** – The IOM recommended the creation of a National Center for Patient Safety in the U.S. Department of Health and Human Services's Agency for Healthcare Research and Quality (AHRQ), because health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety, establishing national safety goals, tracking progress in meeting them, and investing in research to learn more about preventing mistakes. This center would also serve as a clearinghouse and source of effective practices that would be shared broadly.
- **Part 2: Mandatory and Voluntary Reporting Systems** – To learn about medical care associated with serious injury or death and to prevent future occurrences, the IOM recommended establishing a nationwide, mandatory public reporting system, where Federal legislation would protect the confidentiality of certain information (e.g., medical mistakes that have no serious consequences). The intent was to encourage the growth of voluntary, confidential reporting systems so that practitioners and health care organizations could learn about and correct problems before serious harm occurs.

- **Part 3: Role of Consumers, Professionals, and Accreditation Groups** – The IOM believed that fundamental change would require pressure and incentives from many directions, including public and private purchasers of health care insurance, regulators (including the Food and Drug Administration), and licensing and certifying groups. A direct result was the announcement of new standards on safety from the Joint Commission and a report, *Safe Practices for Better Health Care. A Consensus Report*, by the National Quality Forum.[10]
- **Part 4: Building a Culture of Safety** – The IOM urged health care organizations to create an environment in which safety becomes a top priority. This report stressed the need for leadership by executives and clinicians and for accountability for patient safety by boards of trustees. In particular, it urged that safety principles known in other industries be adopted, such as designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies and processes; and avoiding reliance on memory. The report stressed medication safety in part because medication errors are so frequent[11] and in part because a number of evidenced-based practices were already known and needed wider adoption. Though at the time of publication, the levels of evidence for each category varied, the members of the committee believed that all were important places to begin to improve safety.

The committee recognized that some actions could be taken at the national level as described in the recommendations contained in Parts 1–3. Yet if patient safety were really to improve, the committee knew it would take far more than reporting requirements and regulations. Creating and sustaining a culture of safety (Part 4) is needed, which would require continuing local action by thousands of health care organizations and the individuals working in these settings at all levels of authority. Hospital leadership must provide resources and time to improve safety and foster an organizational culture that encourages recognition and learning from errors. A culture of safety cannot develop without trust, keen observation, and extensive knowledge of care processes at all levels, from those on the front lines of health care to those in leadership and management positions.

Basic Concepts in Patient Safety

Opportunities to improve safety have been drawn from numerous disciplines such as engineering, psychology, and occupational health. The IOM report brought together what had been learned in these fields and then applied the opportunities to health care, as described in the nine categories that follow.

1. User-Centered Design

Understanding how to reduce errors depends on framing likely sources of error and pairing them with effective ways to reduce them. The term "user-centered design" builds on human strengths and avoids human weaknesses in processes and technologies.[12] The first strategy of user-centered design is to make things visible—including the conceptual model of the process—so that the user can determine what actions are possible at any moment, for example, how to return to an earlier step, how to change settings, and what is likely to happen if a step in a process is skipped. Another principle is to incorporate affordances, natural mappings, and constraints into health care. Although the terms are strange, their meaning can be surprisingly easily applied to common everyday tasks, both in and out of the workplace.

An affordance is a characteristic of equipment or workspace that communicates how it is to be used, such as a push bar on an outward opening door that shows where to push or a telephone handset that is uncomfortable to hold in any but the correct position. Marking the correct limb for before surgery is an affordance that has been widely adopted. Natural mapping refers to the relationship between a control and its movement, for example, in steering a car to the right, one turns the wheel right. Other examples include using louder sound or a brighter light to indicate a greater amount.

Constraints and forcing functions guide the user to the next appropriate action or decision. A constraint makes it hard to do the wrong thing. A forcing function makes it impossible to do the wrong thing. For example, one cannot start a car that is in gear. Forcing functions include the use of special luer locks for syringes and indwelling lines that have to be matched before fluid can be infused, and different connections for oxygen and other gas lines to prevent their being inadvertently switched. Removing concentrated potassium chloride from patient units is a (negative) forcing function because it should never be administered undiluted, and preparation should be done in the pharmacy.

2. Avoid Reliance on Memory

The next strategy is to standardize and simplify the structure of tasks to minimize the demand on working memory, planning, or problem-solving, including the following two elements:

- **Standardize process and equipment.** Standardization reduces reliance on memory and allows newcomers who are unfamiliar with a given process or device to do the process or use a device safely. For example, standardizing device displays (e.g., readout units), operations, and doses is important to reduce the likelihood of error. Other examples of standardizing include standard order forms, administration times, prescribing protocols, and types of equipment. When devices or medications cannot be standardized, they should be clearly distinguishable. For example, one can identify look-alike, but different, strengths of a narcotic by labeling the higher concentration in consistent ways, such as by shape and prominent labeling.

  When developed, updated, and used wisely, protocols and checklists can enhance safety. Protocols for the use of anticoagulants and perioperative antibiotics have gained widespread acceptance. Laminated dosing cards that include standard order times, doses of antibiotics, formulas for calculating pediatric doses, and common chemotherapy protocols can reduce reliance on memory.[13]
- **Simplify key processes.** Simplifying key processes can minimize problem-solving and greatly reduce the likelihood of error. Simplifying includes reducing the number of steps or handoffs that are needed. Examples of processes that can usually be simplified are writing an order, then transcribing and entering it in a computer, or having several people record and enter the same data in different databases. Other examples of simplification include limiting the choice of drugs and dose strengths available in the pharmacy, maintaining an inventory of frequently prepared drugs, reducing the number of times a day a drug is administered, keeping a single medication administration record, automating dispensing, and purchasing equipment that is easy to use and maintain.

3. Attend to Work Safety

Conditions of work are likely to affect patient safety. Factors that contribute to worker safety in all industries studied include work hours, workloads, staffing ratios, sources of distraction, and shift changes (which affect one's circadian rhythm). Systematic evidence about the relative importance of various factors is growing with particular emphasis on nurse staffing.[14-16]

4. Avoid Reliance on Vigilance

Individuals cannot remain vigilant for long periods of time. Approaches for reducing the need for vigilance include providing checklists and requiring their use at regular intervals, limiting long shifts, rotating staff, and employing equipment that automates some functions. The need for vigilance can be reduced by using signals such as visual and auditory alarms. Also, well-designed equipment provides information about the reason for an alarm. There are pitfalls in relying on automation, if a user learns to ignore alarms that are often wrong, becomes inattentive or inexpert in a given process, or if the effects of errors remain invisible until it is too late to correct them.

5. Train Concepts for Teams

People work together throughout health care in multidisciplinary teams, whether in a practice; for a clinical condition; or in operating rooms, emergency departments, or ICUs. In an effective interdisciplinary team, members come to trust one another's judgments and expertise and attend to one another's safety concerns. Team training in labor and delivery and hospital rapid response teams are examples. The IOM committee believed that whenever it is possible, training programs and hospitals should establish interdisciplinary team training.

6. Involve Patients in Their Care

Whenever possible, patients and their family members or other caregivers should be invited to become part of the care process. Clinicians must obtain accurate information about each patient's medications and allergies and make certain this information is readily available at the patient's bedside. In addition, safety improves when patients and their families know their condition, treatments (including medications), and technologies that are used in their care.

At the time of discharge, patients should receive a list of their medications, doses, dosing schedule, precautions about interactions, possible side effects, and any activities that should be avoided, such as driving. Patients also need clear written information about the next steps after discharge, such as followup visits to monitor their progress and whom to contact if problems or questions arise.

Family caregivers deserve special attention in terms of their ability to provide safe care, manage devices and medication, and to safely respond to patient needs. Yet they may, themselves, be affected by physical, health, and emotional challenges; lack of rest or respite; and other responsibilities (including work, finances, and other family members).

Attention is now being given to problems resulting from lack of patient and family health literacy. For example, information may be too complex to absorb or in a language unfamiliar (even to educated and English-speaking patients)—and frightening. A simple example is rapidly given instructions on home care of a Foley catheter when, as often occurs, the patient is being

discharged shortly after surgery and knows nothing about sterile technique or the design of the device. Another ubiquitous example is the warnings and dosage information on medication bottles, which many patients cannot understand how to apply.

7. Anticipate the Unexpected

The likelihood of error increases with reorganization, mergers, and other organization-wide changes that result in new patterns and processes of care. Some technologies, such as computerized physician order entry systems (CPOE), are engineered specifically to prevent error. Despite the best intentions of designers, however, all technology introduces new errors, even when its sole purpose is to prevent errors. Indeed, future failures cannot be forestalled by simply adding another layer of defense against failure.[17-19] Safe equipment design and use depend on a chain of involvement and commitment that begins with the manufacturer and continues with careful attention to the vulnerabilities of a new device or system. Health care professionals should expect any new technology to introduce new sources of error and should adopt the custom of automating cautiously, always alert to the possibility of unintended harm, and should test these technologies with users and modify as needed before widespread implementation.

8. Design for Recovery

The next strategy is to assume that errors will occur and to design and plan for recovery by duplicating critical functions and by making it easy to reverse operations and hard to carry out nonreversible ones. If an error occurs, examples of strategies to mitigate injury are keeping antidotes for high-risk drugs up to date and easily accessible and having standardized, well-rehearsed procedures in place for responding quickly to adverse events. Another strategy is to use simulation training, where learners practice tasks, processes, and rescues in lifelike circumstances using models or virtual reality.

9. Improve Access to Accurate, Timely Information

The final strategy for user-centered design is to improve access to information. Information for decision-making (e.g., patient history, medications, and current therapeutic strategies) should be available at the point of patient care. Examples include putting lab reports and medication administration records at the patient's bedside and putting protocols in the patient's chart. In a broader context, information is coordinated over time and across settings.

Conclusion

Now, 7 years after the release of *To Err is Human*, extensive efforts have been reported in journals, technical reports, and safety-oriented conferences. That literature described the magnitude of problems in a variety of care settings, the efforts to make change, and the results of those efforts in improving patient safety. Many of those studies are referenced and discussed throughout this book. Other authors have written incisively about what progress has and has not been made in the past 7 years and the challenges in creating cultures of safety.[20, 21] The greatest challenge we all face is to learn, use, and share better information about how to prevent harm to patients.

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Chapter 4. The Quality Chasm Series: Implications for Nursing

Mary K. Wakefield

Introduction and Background

Exhaustive research documents the fact that today in America, there is no guarantee that any individual will receive high-quality care for any particular health problem. Health care is plagued with inappropriate utilization of health services and errors in health care practice.[1] The quality and safety of health care in this nation were assessed through a series of 11 reports from the Institute of Medicine (IOM). Some of the most significant components of the first two reports are a set of aims to achieve high-quality care and new rules to guide the redesign of the broken health care system. The needed transformation and steps to achieving redesign are substantial because the chasm between what currently exists in health care and what should exist to achieve high-quality care is sizeable. While only four of the IOM reports will be discussed in this section—other reports are discussed in other chapters later in this book—each has significant implications for nursing and for how care should be delivered.

In 1999, the IOM released its landmark report, *To Err Is Human: Building a Safer Health System*.[2] The chilling conclusion of that report was that thousands of people were injured by the very health system from which they sought help. Tens of thousands of Americans die each year and hundreds of thousands are injured. That report and its companion, *Crossing the Quality Chasm*,[3] have had a profound impact on how health care is viewed. The information and perspectives moved conversations regarding patient safety and quality care from inside health care institutions to the mainstream of media, corporate America, and public policy. The reports raised awareness of the depth and complexity of quality challenges and prompted the marked expansion of quality improvement efforts through research and other means.

The most significant barrier to improving patient safety identified in *To Err Is Human* is a "lack of awareness of the extent to which errors occur daily in all health care settings and organizations. This lack of awareness exists because the vast majority of errors are not reported, and errors are not reported because personnel fear they will be punished"[2] (p. 155). While these statements describing the essence of the challenges facing health care are simple and straightforward, the level and complexity of effort needed to address them is not. Since the release of the two reports, broad-based efforts have begun to bring more sophistication and precision to measuring and improving the safety and quality of health care. Nevertheless, substantial work in both academic and practice settings remains to be done.

While the IOM reports initiated tectonic shifts in attention and effort, the reports were not the first set of clear statements of concern regarding safety and quality. Nor were these reports the first efforts at calling attention to the need for data, public reporting, and the consideration of health care quality in light of payment for care. More than 140 years earlier, Florence Nightingale, the founder of modern nursing, raised these same issues. In spite of the passage of well over a century between Nightingale and the release of the IOM reports, seemingly little attention was paid in the interim to creating safer health care environments.

Three comparisons of Nightingale's concerns and recommendations with those expressed in the IOM reports illustrate similar problem identification as well as a shared view regarding the building blocks essential to creating solutions. First, in her publication, *Notes on Hospitals*,[4] Nightingale identified the paradox of the problem at hand: "In practice a hospital may be found only to benefit a majority, and to inflict suffering on the remainder" (p. 20). Well over a century later, *To Err Is Human* says, "… a person … should not have to worry about being harmed by the health system itself"[2] (p. 5). Nightingale goes on to say, "Even admitting to the full extent the great value of hospital improvements of recent years, a vast deal of suffering, and some at least of the mortality, in these establishments is avoidable"[4] (p. 3). Similarly, *To Err Is Human* notes, "A substantial body of evidence points to medical errors as a leading cause of death and injury"[2] (p. 26).

Finally, in a search for solutions and with an eye toward measurement, developing evidence, public reporting, and linking payment with quantifiable performance, Nightingale advances[4] (p. 3), "It is impossible to resist the conviction that the sick are suffering from something quite other than the disease inscribed on their bed ticket—and the inquiry … arises in the mind, what can be the cause?" Related to this, *To Error Is Human* notes, "Sufficient attention must be devoted to analyzing and understanding the causes of errors in order to make improvements"[2] (p. 87). In addition, the report notes, "Group purchasers have the ability to consider safety issues in their contracting decisions"[2] (p. 152).

As is evident in the similarity of statements between Nightingale and the IOM, concerns about medical error and compromises in patient safety bridge a significant passage of time. It is difficult not to speculate about what safety in health care would look like today had Nightingale's calls to action been heeded. Rather than lagging behind, health care in the 21st century might have been the leader in safety among high-risk industries such as aviation and nuclear power production. Instead, clinicians, policymakers, and many others search for safety and quality lessons to apply in health care delivery from these and other high-risk but safer industries. Irony exists in that these industries, nonexistent during Nightingale's time, have made substantially more progress than health care in creating safe environments.

The Quality Chasm Series

Since the release of *To Err Is Human* and *Crossing the Quality Chasm*, the IOM has produced 9 additional related reports. The IOM Quality Chasm Series (see Table 1) includes reports linking quality to a range of issues, from health professions education, to health care in rural America, to improving health care quality for mental health and substance-abuse systems. Threaded through this series are key concepts of the framework presented in the original two reports. In each report, facets of the framework are expanded or applied to specific populations or system characteristics. The language of most of the reports tends to group members of health care disciplines by the terms "providers" or "clinicians," with an occasional mention of specific professional groups such as medicine or nursing. Generally speaking, the content of the reports are directly or indirectly applicable to all health care professionals. Consequently, each of the 11 reports has implications for aspects of nursing practice, research, education, and public policy engagement.

Table 1. The IOM Quality Chasm Series

- *To Err Is Human: Building a Safer Health System,* 2000[2]
- *Crossing the Quality Chasm,* 2001[3]
- *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality,* 2002[5]
- *Fostering Rapid Advances in Health Care: Learning From Systems Demonstrations,* 2002[6]
- *Priority Areas for National Action: Transforming Health Care Quality,* 2003[7]
- *Health Professions Education: A Bridge to Quality,* 2003[8]
- *Patient Safety: Achieving a New Standard for Care,* 2003[9]
- *Keeping Patients Safe: Transforming the Work Environment of Nurses,* 2004[10]
- *Quality Through Collaboration: The Future of Rural Health Care,* 2004[11]
- *Preventing Medication Errors: Quality Chasm Series,* 2006[12]
- *Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series,* 2006[13]

This section focuses on nursing implications associated with selected issues, concepts, findings, and recommendations specifically embedded in 4 of the 11 reports: *To Err Is Human*, *Crossing the Quality Chasm*, *Health Professions Education: A Bridge to Quality*, and *Quality Through Collaboration: The Future of Rural Health Care* (often referred to as the rural report). The identified nursing implications in these four reports give a sense of the relevance and utility of these reports to the nursing discipline. The first two reports discussed in this chapter established the scope of the problems associated with compromises in quality of health care and offered a framework for addressing those problems. The third report, on health professions education, described the critical role health professions education plays in facilitating or impeding the delivery of consistent, high-quality health care. The nursing profession, central to health care delivery, is a pivotal audience for this report.

The Future of Rural Health Care addresses the long-standing lack of attention brought to rural health care quality in spite of the fact that between one-fourth and one-fifth of the population resides in rural America. This report sheds light on the unique features of rural health care and tailored approaches to addressing quality shortcomings. Particularly relevant to nurses, however, is that *The Future of Rural Health Care* introduced innovative approaches that move beyond health care and focus on the quality of the health of populations. Whether viewed from a rural or urban context, the latter orientation is an important focus for nurses to consider in their future work and research.

To Err Is Human: Building a Safer Health System

As the first report in the IOM Quality Chasm series, *To Err Is Human* frames the scope of the challenge for improving safety in health care systems. Safety is defined as freedom from accidental injury.[2] Articulated in the report is the heavy toll associated with safety compromises and health care errors in terms of human lives, suffering, and financial burden of health care services. Financial burden is borne by individuals, employers, insurance companies, and governmental programs such as Medicare and Medicaid. Approximately 30 research studies

were reviewed and established the evidence base for the IOM's Committee on Quality of Health Care in America determination that error is a cause of very significant and widespread injury and mortality. Many of the research studies focused on activities that incorporated nursing functions such as medication processes. Additionally, a number of the reviewed studies helped to illuminate the predeterminants of error.

Due to the dearth of evidence to serve as the basis for some of the conclusions and recommendations in this report, the IOM acknowledged that current understanding of the epidemiology of errors was fragmented. Calls for research efforts were evident throughout the report. "Research and analysis are not luxuries in the operation of safety systems. They are essential steps in the effective redesign of systems"[2] (p. 181). Clearly there is opportunity for nurse researchers, along with others, to make significant and important contributions to address this knowledge deficit with needed evidence.

In addition to increasing awareness of the scope and significance of medical errors, a set of strategies and recommendations were advanced to encourage patient safety and quality improvement. Major emphasis is placed on (1) the essential role of leadership in addressing errors, (2) the need for and structure of error reporting systems, (3) the development of performance standards, and (4) recommendations regarding elements key to safety design in health care systems. The committee producing the report devoted considerable attention to making the case that perfection based on human performance—while a long-standing expectation of the work of nurses, physicians, and others—is both faulty and dangerous. In reorienting expectations from a focus on individuals to a focus on systems, the report clearly and firmly stated that to eliminate the source of a vast majority of errors and near misses, health care systems must be designed to make it very hard for nurses and others to make errors. This orientation runs directly counter to long-held views by both the public and health care providers themselves: that mistakes are solely the result of individual provider actions and that blame should be assigned accordingly. The report refocused attention on the need to construct systems that make it easy for nurses and others to engage in safe practices and difficult to execute actions that are unsafe.

External Drivers of Safety and Quality

The report described external drivers that can improve the safety and quality of health care, including nursing care. External drivers that influence the quality of nursing care included regulation and legislation, accrediting organizations, efforts to link payment with performance, the need for interdisciplinary guidelines, the commitment of professional organizations, and the level of public engagement. The report included a number of observations about the role that licensing and credentialing processes can have in building appropriate performance standards and expectations for all health professionals. Examples of regulation and legislation that impact nursing care quality included State scope-of-practice laws that govern what nurses are legally licensed to do and stipulate performance expectations. Subsequently, there are concerns about whether current methods of licensing and credentialing adequately assess the safety and competence of skills across health professionals, including nurses. More than 20 States now have laws requiring error reporting, and with recent Federal reporting legislation, serious errors that reflect nursing and other care processes are now governed by reporting expectations from outside the health care system.

Accrediting organizations influence nursing care quality through their safety and quality standards. Highly influential in this regard has been the marked expansion of safety expectations

of accrediting bodies, such as the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]). The Joint Commission National Patient Safety Goals (NPSGs) are very prescriptive and explicit in their impact on aspects of nursing practice. For example, the Joint Commission's safety goals include standardizing handoff communications, including an opportunity to ask and respond to questions, and a goal to encourage the active involvement of patients and their families in the patient's care as a patient safety strategy[14] (e.g., patient- and family-centered care).

External drivers also include steps being taken by the Centers for Medicare and Medicaid Services to link reporting performance on quality indicators with payment. These payment changes reward hospitals that publicly report their performance on a predetermined set of quality indicators, many of which are directly or indirectly influenced by nursing actions. Private sector entities such as insurance companies are moving in similar directions. The intense interest in aligning payment with performance (i.e., health sector income and patient outcome) has significant implications for nursing. Put simply, maintaining and strengthening the financial health of hospitals and other segments of the health care delivery system is linked in no small part to the practice of nursing in these facilities. Consequently, alignment of reimbursement with quality is redirecting the attention of health care administrators. To the extent that research continues to link nursing practices, staffing, and other characteristics (e.g., educational background and number of hours worked) to the quality of patient care, nursing will be positioned to receive considerably more attention from health care system leadership.

Recognizing that more could be done to improve patient outcomes the report called for the incorporation of patient safety considerations into clinical practice guidelines, as well as the development of guidelines specifically focused on patient safety. Particular attention is paid to the need for engaging interdisciplinary approaches to guideline development. Nurses' expertise and functions clearly overlap with a number of other disciplines in particular content areas (e.g., mental health care and critical care). This overlap makes this recommendation difficult to pursue, but appropriate to nursing as well as other disciplines. Nursing education, as well as State and national nursing organizations, can expand efforts to engage interdisciplinary partners in developing shared academic curricula and conference and meeting content. Additionally, nurse clinicians, researchers, and others should further the development of safety aspects of clinical guidelines development in concert with representatives of other health care disciplines.

Another report recommendation called for professional organizations to firmly commit to an agenda focused on patient safety, with specific efforts targeted toward health professions education. Efforts can emerge through curriculum development, the inclusion of safety content on conference agendas, and ongoing in-service education. Various nursing organizations have responded to aspects of this recommendation. However, in light of many competing priorities, expanding and sustaining this focus over time and across multiple venues will challenge nurses and the nursing profession.

The final external driver addressed in the report addressed whether or not the public is engaged in safety improvement efforts. Professional organizations, particularly those that represent nurses, can help to accomplish this by working with both the public and policymakers. Some national nursing organizations already have made safety part of their public policy agenda (e.g., the Association of Operating Room Nurses). Nevertheless, there is substantial work that could occur to create new efforts that educate and engage the broader public in health care safety activities. As a profession, nursing commands considerable trust from the American public. Also, nursing places high value on the importance of educating individuals, families, and communities

about health and health care in order to fully engage them as partners in their health. Consequently, nurses are particularly well positioned to engage in the challenging work of assisting the public to understand both the complexity of patient safety and error, and the actions they can engage in to help ensure they receive safe health care. Individual nurses can engage this type of effort in concert with other health team members. This work can also be done through nursing organizations and in tandem with insurers, employers, and others who recognize the pivotal role health care consumers can play in ensuring the delivery of safe care.

Principles for the Design of Safe Systems

Internal drivers that impact the safety and quality of care include policies, management decisions, and other organizational features that either help to prevent or predispose individuals to committing errors. The IOM report identified internal drivers as being most hazardous to safety in complex systems (e.g., health care), because generally speaking, the internal drivers' influence on error is not readily apparent.[2] Applied to nursing, quality and safety are products of interactions between nurses and others, between nurses and technology, and between nurses and care processes. To address threats to quality and safety by internal drivers, five principles for the design of safe systems are articulated in *To Err Is Human*, each of which has direct relevance to nursing practice.

- **Principle 1: The commitment of senior level managers and leaders of health care institutions is essential to moving a quality and safety agenda forward in care settings.**

Nurse leaders, in tandem with other institutional leaders, have a role in ensuring that patient safety is a priority corporate objective, a responsibility shared by everyone, and that expectations for safety oversight are clearly articulated and assigned. Efforts directed toward highlighting the importance and expectations of the quality and safety agenda need to reach up to boards of directors and across to all employees within health care settings. Nursing leadership has a core responsibility to help ensure that this orientation is pervasive within the institution and that it is firmly embraced by the senior ranks of the organization.

- **Principle 2: Human limits in care processes need to be explicitly identified and strategies put in place to minimize the likelihood that these limitations are expressed in the work environment.**

Nurses should be attuned to determining and addressing sources of potential error. Protocols and checklists that help guide nursing actions should be readily available and used. Determining ways to simplify processes, such as reducing the number of handoffs and standardizing actions, devices, or doses to minimize the likelihood of error, should involve all nurses.

- **Principle 3: Effective team functioning, promoted and fostered by the institution, is an essential component of health care systems that are quality and patient safety driven**.

This includes team training approaches as well as involving patients in safety design and care processes. Features of this principle are more fully developed in the IOM report, *Health Professions Education: A Bridge to Quality*, and will be discussed in that section.

- **Principle 4: The redesign of systems for safe care involves anticipating the unexpected and adopting proactive approaches to ensuring safe care.**

This principle covers such important attributes as improving access to accurate and timely information and designing for recovery. Since the release of *To Err Is Human*, specific evidence-based activities designed to anticipate the unexpected are being implemented. For example, the deployment of rapid response teams in health care environments is designed to prevent serious

adverse events such as cardiac or respiratory arrest.[15] With the help of nursing knowledge and research, other equally important high-impact care processes will be developed over time.

- **Principle 5: Creating a learning environment addresses the extremely complex work of changing organizational and academic cultures so that error is viewed as an opportunity to learn.**

A learning environment does not seek to fix blame, but ensures that reporting systems have well-developed approaches for communicating how identified problems will be addressed. Also important, given the historical power gradient among nurses and physicians and others, is the free flow of information without the inhibiting hierarchies.[2] Learning environments ensure that all staff have high comfort levels in communicating any and all safety concerns. Some of the most complex patient safety work involves creating organizational cultures and expectations that embrace these features. Redesigning the education of the next generation of nurses so they are capable of maximizing their contributions in these environments is a necessary component.

Nurse leaders should play key roles in ensuring that patient safety programs inside health care organizations are highly visible, implement nonpunitive reporting processes, and incorporate safety principles into daily practice, all of which are called for in the recommendations of *To Err Is Human*. The second report, *Crossing the Quality Chasm*, describes at greater length the use of internal and external approaches to meaningfully improve the quality of health care.

Crossing the Quality Chasm

Broader quality challenges described in *Crossing the Quality Chasm*[3] are equal to patient safety in their complexity. While the entire *Quality Chasm* report is highly relevant to nursing concerns, only a small set of key concepts with implications for nursing will be presented here. This discussion is for the purpose of illustrating the implications of this report for the nursing profession, and to highlight ways that nurses individually and collectively can align their efforts with the content of these highly regarded reports. Challenges to quality are divided into three types: (1) overuse, which refers to the application of health care services where the potential for harm exceeds the potential for benefit; (2) underuse, which is the absence of a service when it is indicated; and (3) misuse, which is in the provision of an appropriate service, a preventable injury occurs.[3]

The *Quality Chasm* report described the work of health care as being "characterized by more to know, more to manage, more to watch, more to do, and more people involved in doing it at any time in the nation's history"[3] (p. 25). The statement is certainly descriptive of nursing as well. All too familiar to nurses is the growing complexity of both health care and the nature of nursing knowledge and nursing practice. Given these complexities, individual nurses, as with other clinicians, cannot possibly recall and apply all knowledge necessary for the delivery of safe, high-quality patient, family, or community care. The complexity of nursing and medical practice has markedly increased, the technologies are more numerous and complex, and the evidence base underlying practice is rapidly expanding. Recognizing these challenges, the first recommendation in the *Quality Chasm* report restated the purpose of the health care system as articulated by President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry: "All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury and disability, and to improve the health and functioning of the people of the

United States."[3] (p. 39). In contemplating this statement, nurses might ask what the collective contribution of nursing is and should be to achieving this purpose. How do we pursue this goal? How do we know whether we and other stakeholders in the U.S. health care system are making progress toward achieving it? The *Quality Chasm* report adds more specificity to this recommendation by setting out six aims (see Table 2). To achieve the aims of the purpose statement articulated above, the *Quality Chasm* report suggests that these six aims should be the focus of nurses and other clinicians, and should be pursued in all health care settings.

Table 2. IOM's Six Aims for Improving Health Care Quality

Aim	Description
1. Safe care	Avoiding injuries to patients
2. Effective care	Providing care based on scientific knowledge
3. Patient-centered care	Providing respectful and responsive care that ensures that patient values guide clinical decisions
4. Timely care	Reducing waits for both recipients and providers of care
5. Efficient care	Avoiding waste
6. Equitable care	Ensuring that the quality of care does not vary because of characteristics such as gender, ethnicity, socioeconomic status, or geographic location.

Illustrations of the relevance and integral nature of nursing to achieving these aims are illustrated below.

- **Aim 1—Safe Care**

The Quality Chasm noted, "The health care environment should be safe for all patients, in all of its processes, all of the time. This standard of safety implies that organizations should not have different, lower standards of care on nights and weekends or during times of organizational change"[3] (p. 45). Recognizing the particular danger that handoffs can pose to patients, the report notes that handoffs are frequently the first place where patient safety is compromised. Clearly, part and parcel of the work of nurses are the transactions that occur among nurses and others as information, components of care processes, and patients themselves are handed off to others. Nursing work is punctuated by patient transfers from one environment to another (e.g., inter- and intra-institutional transfers of patients), from shift to shift, or communication from one clinician to another (e.g., information given by a nurse to different physical therapists caring for the same patient). Moreover, because of their ongoing contact with patients and their families, nurses are in pivotal positions to both inform and incorporate the observations and concerns of these individuals into creating safe care environments. To do so require nurses to consider all information conveyed to them by patients and family members and to encourage that communication.

- **Aim 2—Effective Care**

The provision of effective nursing care rests on the development and use of nursing evidence, as well as evidence produced by other disciplines with relevance to nursing practice. Effective care is based on evidence derived from four types of research: laboratory experiments, clinical trials, epidemiological research, and outcomes research, including case reports.[3] Outcomes research, critical to improving care quality, uses information about how well interventions work on a large, generalizable scale. Nurse researchers engage in all four types of research, and each

type is capable of informing aspects of care delivery and care quality. Nevertheless, there is a paucity of research to undergird the application of many interventions, nursing and non-nursing alike. Looking to the future, the *Quality Chasm* report suggests that "the knowledge base about effective care and its use in health settings will constantly expand through improved methods of accessing, summarizing and assessing information and making it available at the point of care for the patient"[3] (p. 48), Already, information technology systems in some health care settings provide immediate access to clinical guidelines, step-by-step approaches to procedures, and other information that is based on research evidence or, in its absence, expert judgment.

In addition to expecting the further development of and adherence to an evidence base, the *Quality Chasm* report also highlights the importance of nurses and other clinicians systematically and continually reviewing the outcomes of the care that they provide. Currently, care results are rolled up and reflected in overall performance indicators for nursing homes and hospitals. With some exceptions, there is relatively limited information that is currently collected, assessed, and fed back to nurses to help them better understand their individual impact on care quality and thereby assist them in improving their performance. Clearly, efforts that have resulted in the development of nursing indicators are a step in this direction. This is one more important area in which nurses can engage to further the quality improvement agenda.

- **Aim 3—Patient-Centered Care**

Aspects of patient-centered nursing care have long been incorporated in nursing education programs. However, the meaning of the term has evolved and the extent to which it is met is variable. Gerteis and colleagues[16] put forward a set of dimensions of patient-centered care, including respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support; and involvement of family and friends. Considerable nursing and other research remains to be done to better delineate the outline of this concept and strategies for addressing it. A related concept, population-centered care, is discussed extensively in the IOM report *Quality Through Collaboration: The Future of Rural Health.* This important concept has even less evidence-based approaches to help guide its achievement.

- **Aim 4—Timely Care**

Timeliness of care delivery is often compromised, almost regardless of where a consumer comes in contact with health care. From emergency rooms to schools, nurses see first hand the difficulties in providing timely access to care. Timeliness is compromised when patients needing immediate medical attention find themselves in overcrowded emergency rooms, or individuals without health insurance are delayed in accessing health care or there is a lack of available clinicians. Delays like these are too often the norm. Many factors, both internal and external to the care environment, impact timeliness. Internal to delivery systems, analyzing and refining the actual design of effective processes is overlooked. Instead, the blunt instrument used to drive timeliness is often the expectation for nurses and other clinicians to do more and, in some cases, faster. This approach itself can, at times, compromise care quality.

Efforts to improve timeliness are multifaceted. One of the essential tools to address parts of this challenge is technology. The expanded use of call-a-nurse lines, e-mail exchanges between clinicians and patients, and consumer access to telemedicine applications linking rural and urban facilities, are part of the developing technology-based toolkit needed to increase timely access to care.

- **Aim 5—Efficient Care**

Efficiency is not necessarily a hallmark of the U.S. health care system. In fact, some quality experts indicate that adding more financial resources to the health care delivery system is highly inefficient, given the high level of waste in current practices. Since nurses are on the front lines of health care, nurses are well positioned to work within their institutions at the local level as well as through their associations at the national level to develop and promote agendas designed to increase efficiency, ultimately making better use of the significant financial resources currently directed to health care.

Additionally, nurse researchers can play an exceedingly important role in achieving efficiency. For example, Naylor[17] found that elderly patients receiving a comprehensive intervention delivered by advanced practice nurses (APNs) in the hospital and followed in the home significantly decreased expensive hospitalizations. APN care resulted in average per capita expenditures of $6,152 compared to the control group expenditure of $9,618. As a result, efforts are underway to help move this intervention into the broader practice environment.

As the growth in health care expenditures continues to rise nationally, public policymakers, insurers, and others will be far more open to nursing practice models as well as other strategies that help to rein in high costs while sustaining or improving care quality. Efforts toward achieving this aim provide new opportunities for nurses to create models that maximize the contribution of nursing care and innovation in quality improvement.

- **Aim 6—Equitable Care**

Equity refers to universal access to health care services.[3] Challenges surrounding equity are reflected in disparities in health care by ethnic and socioeconomic groups, lack of health insurance or underinsurance, and geographic inequity that influences the services available. Equity as an aim tied to geographic access is discussed later in this section on the IOM report, *Quality Through Collaboration: The Future of Rural Health Care.*

Ten Rules of Health Care Redesign

In addition to advancing a core set of improvement aims, the *Quality Chasm* report also put forward 10 rules to guide the redesign of health care. The report recommended that this redesign effort incorporate the full complement of health care stakeholders, including patients, payers, clinicians, and others. Many of these rules have underlying evidence to support them. However, some of the rules do not, and in those cases, the report included supporting rationale. The current set of rules that guides health care delivery and the rules proposed to guide the redesign of health care are delineated in Table 3.

Table 3. Simple Rules for the 21st Century Health Care System

Current Approach	New Rule[3]
Care is based primarily on visits	Care based on continuous healing relationships
Professional autonomy drives variability	Customization based on patient needs and values
Professionals control care	The patient as the source of control
Information is a record	Shared knowledge and free flow of information

Current Approach	New Rule[3]
Decisionmaking is based on training and experience	Evidence-based decisionmaking
Do no harm is an individual responsibility	Safety as a system property
Secrecy is necessary	The need for transparency
The system reacts to needs	Anticipation of needs
Cost reduction is sought	Continuous decrease in waste
Preference is given to professional roles over the system	Cooperation among clinicians

As with the aims for improvement, implementing this entire set of rules in the redesign of health care systems has implications for nursing practice, education, and research. While nursing can be considered in the context of each of the current and new rules, only a few of the rules are discussed here in order to illustrate their relevance to nursing. For example, operationalizing the first new rule, care based on continuous healing relationships, focuses on ensuring that patients have the care they need when they need it. Continuity and coordination should trump fragmented, disconnected care efforts. Conceivably, this rule could directly influence where, how, and when nursing care is available to patients. Moreover, the Internet is likely to play a pivotal role in its application. Another example, the third rule—the patient is the source of control—is designed to facilitate decisionmaking by patients rather than authoritarian or paternalistic decisionmaking by health care providers. While often considered in the context of physician-patient communication, this rule has implications for the approaches nurses bring to patient engagement. However, in addition to individual nurse efforts to incorporate this orientation into patient care, major system-level changes will be needed to allow patients to exercise their preferred degree of control. Such system-level redesign, particularly as it relates to nurse-patient interactions, will benefit from nursing input.

Regarding new rule four, shared knowledge and free flow of information, *Quality Chasm* cited evidence that giving patients access to their own health and clinical information improves care processes and health outcomes. Clearly, electronic personal health records and Web-based information have considerable potential to enhance patient knowledge and stimulate healthy behavior. However, there is limited information about how nurses can help patients to fully harness these information resources. Nurses can lead efforts to make these rules actionable across health systems, particularly as they influence the redesign of nursing practice, the nurse-patient relationships, the relationships between nurses and other disciplines, and the relationship of nurses to care processes. Additionally, these expectations should be incorporated into nursing curricula to ensure that nurses are able to engage and support the refinement and application of important features of redesigned health care systems. In the process, nurses learn not just the changes necessary for improving quality of care, but also the skills and knowledge essential to fully participate in the change process associated with quality improvement efforts.

Deploying these rules requires the participation of virtually all stakeholders. Nursing is clearly a key partner in the convening of health profession associations as well as key industry and quality organization representatives to lead this transformation, expand the research underlying the rules, and develop an agenda to examine progress and next steps related to actions supporting the application of this rules set. A total of 7 years has passed since the release of the

Quality Chasm report. No doubt progress in health care redesign vis-à-vis the rules set has occurred during this time. However, there is considerably more work to be done in each of these areas.

Health Professions Education: A Bridge to Quality

Much of the national discussion about the health workforce, particularly nursing, has focused primarily on supply strategies to address current and anticipated workforce shortages. However, from a quality improvement perspective, there is also an imperative to focus on the capacity of the health care workforce to function in redesigned care systems. The purpose of the health care system articulated earlier will not be attained without significant attention to determining and disseminating the requisite skills and knowledge across the health care workforce. *Health Professions Education: A Bridge to Quality*[8] delineated the needed transformation skills and knowledge of the various health professions. As with predecessor reports, the call for change is clear and direct, beginning with the statement, "Education for the health professions is in need of a major overhaul"[8] (p. 1). This assertion and the subsequent observations and recommendations apply to all health professions, including nursing.

The *Health Professions Education* report described the shortcomings of today's health professions education programs. Among these shortcomings was the need for individuals to work effectively in interdisciplinary teams—something for which they rarely receive training. That is, "patients and families commonly report that caregivers appear not to coordinate their work or even to know what each other is doing"[8] (p. 31). This concern is particularly disconcerting given the increase in chronic disease burden and the clear necessity for collaboration across settings and provider types to meet the needs of patient populations. Another all-too-common educational shortcoming is the lack of an educational foundation in informatics. Future clinical practice will occur in health information technology-rich environments, in spite of the current slow uptake of information technology.[8]

The vision advanced in *Health Professions Education* stated, "All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality improvement approaches, and informatics"[8] (p. 45). Yet gaps exist between the needs and expectations for the workforce in health care environments and the preparation of those professionals in academic environments. This disconnect is highly problematic because, "At the core of a redesigned health care system are health professionals"[8] (p. 37). Attention to the educational preparation of the health professions workforce is essential to the meaningful engagement of the entire quality agenda.

New Competencies for Health Professionals

The set of five competencies reflected in the vision statement are considered highly applicable to all health care disciplines, including nursing, although the manner in which they are operationalized by each discipline will vary. As with some of the rules for redesign presented in the *Quality Chasm* report, the evidence base underlying some of these competencies is incomplete and additional research is needed. Where research findings are limited, expert rationale for the competency is provided.

- **Competency 1—Provide patient-centered care**

The report noted that patient-centered care includes knowledge of shared responsibility between patients and caregivers; communication approaches that allow patient access to information and achieve patient understanding; consideration of patients' individuality, values, and needs; and focus on the use of related population-based strategies to improve appropriate use of health services. The *Health Professions Education* report cites research related to some of these characteristics. For example, findings indicated that patients who were involved in decision making about their care have higher functional status, better outcomes, and lower costs.[8]

Additionally, health systems need to be analyzed to determine the extent to which the systems facilitate or constrain the deployment of skills and knowledge associated with this competency.

- **Competency 2—Work in interdisciplinary teams**

Interdisciplinary teams have been shown to enhance quality and lower costs. Substantially more research is needed to determine characteristics that facilitate team effectiveness, as well as the development of successful academic models capable of teaching and testing these performance attributes. Challenging the development of interdisciplinary educational content and the use of this competency in practice is the absence of a common language across disciplines, politics, and turf battles among the professions. Berwick captured the essence of interdisciplinary practice in a statement he offered in the development of the *Health Professions Education* report when he said[8] (p. 56), "System-mindedness means cooperation…. It means asking yourself … not what are the parts of me, not what do I do, but what am I part of?" For health professions educators, including nursing faculty, a corollary may be how do we help students acquire knowledge about their chosen profession as well as knowledge about how to effectively function in interprofessional teams of which they are destined to become part? Questions for nurse educators include how well are we instilling this competency in students and, how do we know?

Interdisciplinary approaches to research on the set of five competencies may be viewed as too challenging to build in academic environments. Yet it may be in this confluence of ideas, philosophies, and approaches that nurse researchers and others are better able to understand, test, and design interdisciplinary practices. In fact, the hard work of interdisciplinary practice may best be modeled through interdisciplinary education and research efforts that begin in academic environments. The culture of many academic environments, however, does not yet value the production of interdisciplinary education or research partnerships.

- **Competency 3—Employ evidence-based practices**

The IOM describes evidence-based practice as the integration of research evidence, clinical expertise, and patient values in making decisions about the care of individual patients. Each of these sources may be contributing factors relevant to decision making regarding patient care. In terms of the implications of this competency for nurses, the report indicated that the following knowledge and skills were necessary: knowing how to find the best sources of evidence, formulating clear clinical questions, and determining when and how to integrate new findings into practice. This knowledge requires bridging content between traditional nursing research courses and clinical courses. The *Health Professions Education* report noted that the evidence base for nursing and other disciplines is markedly limited, and the availability of data that captures information around nursing interventions in administrative and clinical records for research purposes is minimal. Some nurse researchers and nursing organizations are playing pivotal roles in attempting to address this deficit.

- **Competency 4—Apply quality improvement**

The science of quality improvement is expanding rapidly, and the competency of nurses to apply this science is important. Through academic and continuing education opportunities, nurses need to be competent in measuring quality of care, assessing and benchmarking practices to identify improvement opportunities, designing and testing interventions, identifying hazards and errors in care, implementing safety design principles such as standardization and human factors training, and participating as a member of interdisciplinary teams[8] (p. 59). A major challenge is the lack of quality improvement content expertise across faculty. Deans, other administrators, and faculty leaders need to focus on acquiring this expertise for their faculty as well as incorporating it into nursing education curricula, including clinical coursework.

- **Competency 5—Utilize informatics**

Health care informatics relates to the application of information technology (IT) systems to problems in health care and includes an array of applications from order entry to decision support systems. Research findings indicate that IT applications can enhance patient safety by standardizing, flagging errors, and eliminating handwritten data, among other functions.[8] Utilizing informatics can influence knowledge management, communication, and decisionmaking. Educational programming to target facets of this competency have increased in health care environments as well as in academic programs. However, considerable work remains to be done to prepare nurses to fully harness informatics to ensure safety and enhance care quality. Not the least of this work is the analysis of environmental attributes that contribute to successful informatics applications.

Much work remains in terms of teaching the five competencies in nursing education programs, applying the competencies in nursing practice, and focusing on the competencies through nursing research.

The *Health Professions Education* report gives extensive consideration to the purposes and limitations of accreditation, certification, and licensure and the relationship of these oversight processes to clinician competence and patient outcomes. Currently, most of these oversight processes do not address nurses' knowledge of any of the five competency areas. As with other disciplines, actually demonstrating competency is generally not part of the ongoing oversight of individual nurses. This report suggested that hard work on the part of oversight bodies (e.g., developing assessment tools) must be done to assure the public that nurses maintain minimum levels of competence throughout their careers.[8]

There is tremendous pressure on academic programs to ensure that students acquire other essential core content, making the addition of expectations such as those expressed in *Health Professions Education* difficult to accommodate. Nevertheless, the case is made. The inadequacy of educational preparation is reflected in the lack of skills and knowledge applied in current nursing practice. This report asserts, "The extent to which health professionals are implementing these competency areas does not meet the health care needs of the American public"[8] (p. 67).

Quality Through Collaboration: The Future of Rural Health

The last IOM report presented in this section addressed the unique circumstances of rural health care—rural populations and characteristics that influence the quality of rural health care. Based on a review of research findings as well as expert opinion, a number of specific recommendations are offered that build on rural health strengths and address their challenges. The IOM's *Quality Through Collaboration: The Future of Rural Health* highlighted a conclusion

important to nurses and others: that is, there is a paucity of research available on the quality of rural health care. As with urban health care, the limited rural research that does exist indicates variability of care quality.[11] This circumstance underscores the need for nurses and others with interest and expertise in rural health to further expand knowledge in this largely ignored area. One particular area needing nursing inquiry is the extent to which rural health care delivery reflects activity and progress toward achieving the six aims for improvement.

A unique contribution of the *Future of Rural Health* report is the application of the six aims to improve not just care quality delivered in health care organizations, as has been discussed in earlier reports, but also to target efforts that can improve the quality of health in the general population. Nurses in rural communities can be pivotal in helping to build a local community focus on both the quality of health and the quality of health care. The report provides illustrative examples of the application of each of the six aims and community level interventions to achieve those aims. Much of the work of targeting efforts toward improving the quality of population health will involve nurses and other leaders in rural health care settings working with community leaders in local schools, government, and other sectors. How to effectively engage this collective focus to advance population health should be a priority research area.

As with most of the reports in the IOM Quality Chasm series, the theme of leadership emerged in *The Future of Rural Health*. In this case, particular attention is given to the need for rural health system leaders to embrace and drive quality improvement within their organizations as well as the need to engage larger issues of population health quality. An identified strength of many rural communities is the familiarity that people have with each other and the various local community sectors. Also, often typical of rural communities is the orientation and practice of engaging across sectors to achieve community-level outcomes. This characteristic can help to facilitate new efforts around building quality into population health.[11]

The *Future of Rural Health* report pivots from the major components of the *Crossing the Quality Chasm* report and frames the issues in a rural context. For example, priority issues such as information technology applications, quality improvement infrastructure components, workforce considerations, and the aims for improvement are all viewed through the prism of a rural context. In addition, *The Future of Rural Health* cited relevant rural examples of each of the six aims, considering them in the context of the community as well as the context of health care delivery. Measures of the safety aim included measuring community characteristics such as occupational accident rates in rural areas and toxic environmental exposure/risk from pesticides. Brief discussions focused on community-level strategies for improving safety, effectiveness in community health improvement, and community-centered care that reflects responsiveness to the aggregated needs, values, and other characteristics of the local community. Clearly, the broadened application of the six aims for improvement in a rural community context offers an area for research and reconfigured interdisciplinary efforts that include stakeholders outside of traditional health care settings. The community-level application of the six aims, revamped to consider unique characteristics of urban areas, also should be highly relevant to urban communities and populations.

Too frequently, research conducted on quality and safety interventions in urban health care settings has been directly generalized to the often very different environments, staffing mix, and patient populations found in rural health care settings. For example, deploying rapid response teams in rural areas needs to take into consideration the different staff mix available on site in rural settings. Relevant research on functions common to rural health care settings is extremely limited. For example, there is minimal nursing research on the processes involved in patient

stabilization and transfer. This is a set of activities common to rural hospitals but far less frequently performed in urban hospitals. Research on patient outcomes associated with these processes is virtually nonexistent. More efforts need to be directed toward developing and determining relevant rural knowledge and tools, appropriate performance measures, and the development of data feedback capabilities. To begin to fill knowledge gaps and improve health care quality and population health, access to the science of quality improvement and acquiring related expertise is pivotal. This includes acquiring competence in evaluating, adopting, and adapting this new knowledge area for application in rural environments.[18]

In addition to identifying gaps in research knowledge and new framing of aims for application to quality improvement in rural population health, the *Future of Rural Health* report also addressed internal and external drivers of quality improvement specific to rural health systems. For example, unlike most urban hospitals, which are reimbursed through the prospective payment system, a large subset of rural hospitals are designated as critical access hospitals. These hospitals receive cost-based reimbursement, and there are currently no requirements linking Medicare payment to reporting on quality indicators, as is the case with prospective payment system hospitals. The report states that no providers, rural or urban, should be excluded from public reporting. However, mechanisms for linking cost-based reimbursement to quality indicators and eventually patient outcomes need to be developed for rural health care facilities. Additionally, determining how best to report and assign meaning to data extracted from small numbers of patient encounters remains a challenge.

In terms of drivers internal to rural health care settings, the job design of nurse leaders typically requires them to manage multiple roles and expectations. For example, frequently, the nurse responsible for quality assurance and improvement in a facility carries many other responsibilities as well. Given the limited numbers of nurses and other personnel in rural communities, efficiently acquiring and applying quality improvement knowledge and related skills can be particularly challenging. Conversely, because health care providers tend to be relatively few in number, information and new care approaches are often rapidly diffused throughout small rural facilities.

The report devoted significant attention to characteristics essential to the rural health care workforce. Building on the *Health Professions Education* report, *The Future of Rural Health* noted that the five identified competencies are all relevant to rural health care, but the applications may be different. Interdisciplinary teams may consist of individuals geographically separated, but who share involvement in the ongoing care of individuals. Electronic intensive care units are an example. Under these circumstances, applying team concepts may have special ramifications for nurses and others. While research findings from some of these practices indicated markedly improved patient morbidity and mortality, there was virtually no research base on which to guide the configuration and deployment of these types of teams.

The Future of Rural Health also advocated for educational preparation that includes rural-relevant practice knowledge and rural clinical experience. The role of rural consumers in acquiring quality care is also discussed, with attention given to the fact that their role in managing their health may be operationalized differently compared to their urban counterparts given resource availability, etc. For example, access to certain clinicians, including home health nurses and diabetes nurse educators, may be enabled through Web and other technology applications. Yet minimal study of the quality of these encounters has been undertaken. Although technology offers the promise of linking sparsely populated areas to health care services, there is a digital divide between rural and urban areas across the country. To the extent

that electronic connectivity is essential for care continuity, special effort needs to be made to overcome these challenges. Public policy is and will continue to play a major role in bridging this divide, offering nurses another area to engage in issues concerning rural access to quality health care.

Future Directions

In summary, the Quality Chasm series of reports emphasized a number of key attributes of the architecture needed to build a safe, consistently high-performing health care system. Expressed throughout the reports were serious concerns about the status of contemporary health care. Essential features of high-quality care systems—such as workforce competencies, effective application of internal and external drivers, progress toward achieving the six identified aims for improvement, and the application of a set of rules to systems redesign—are far from where they should be. The Quality Chasm series called for leadership in education, practice, and research to drive needed change. The series called for major overhaul of not just the organizations in which health care providers work, but the education of health care providers themselves. The series made a special effort to recognize the unique needs of specific populations, such as those in rural communities or those with mental health problems, and recommended approaches to more effectively deliver quality care to those populations. Based on the challenges and recommendations set forth, it is clear that significant work remains to be done.

Specific to the nursing profession, nurse educators, clinicians, and researchers need to help build state-of-the-art and state-of-the-science approaches for redesigning nursing care processes, using information technology between nurses and patients and nurses and other clinicians; acquiring, managing, and appropriately applying new knowledge and skills; preparing nurses to function effectively in teams; and evaluating nurses' performance in this regard. Regardless of the settings in which nurses practice, much more effort must be devoted to care coordination for individuals with chronic conditions, while diligently measuring both performance and outcomes. Nurses have a substantive and essential role in helping to apply the quality framework articulated in the IOM Quality Chasm series. And nurses clearly have a role in developing additional approaches and new features to the quality agenda. Active engagement in patient safety and quality improvement efforts is relevant to all nurses. Unlike the minimal progress from Nightingale's time until now, hopefully future nurses will be able to reflect back to the beginning of the 21st century and determine that nursing made significant strides. They will see improvement in both the quality of health and health care quality due to an improved role of nurses in providing quality care.

Research Implications

Every report in the Quality Chasm series calls for specific, targeted research to further develop the evidence base related to quality care. Research targeting quality improvement has been supported and implemented by various stakeholders, ranging from health profession organizations to Federal agencies to health providers themselves. Findings and implications are being applied in a variety of ways, from changing internal drivers of quality such as work structure (e.g., rapid response teams) to altering external drivers of quality (e.g., paying providers for performance based on evidence-based quality indicators). While nurses have been part of many of the research activities, significant research remains to be done.

The following is a compilation of some of the exemplar areas of research derived from the four reports reviewed in this section. These research areas are both relevant to nursing and are areas for which nursing's contribution is important.

- The role of leaders in addressing errors and designing safety and quality into health care systems is a common thread throughout the IOM Quality Chasm report series. Currently, the work design of practice in clinical settings introduces significant potential for executing unsafe actions. This is particularly relevant to nursing, given that much of the care delivered in health systems is nursing care.

  Research Focus: Identify how to effectively lead, design, test, and change safety structures and processes in health systems, in addition to researching the safety of structures and processes themselves (e.g., effective strategies for teaching and achieving consistent application of the Situation-Background-Assessment-Recommendation [SBAR] model of communication.) Research is needed that continues the work of determining high-risk structures, functions, and processes in various types of health care delivery settings, focusing on ways to make unsafe nursing activity and practices extremely difficult to carry out (e.g., identify potentially unsafe work-arounds). Design research to test the effectiveness of simulated team approaches to care processes that move beyond established simulations, such as responding to cardiac arrest.

- Public, standardized reporting of serious medical errors is recommended, and a number of States have implemented error reporting systems. Recently, Federal legislation related to reporting errors has been enacted.

  Research Focus: Policy research should determine effective means for conveying public information in ways that facilitate consumer choice of care settings and drive quality improvement at the level of care delivery.

- Encourage health care consumers to actively participate in ensuring the delivery of safe care.

  Research Focus: Determine effective strategies to inform and engage consumers in ways that help ensure their receipt of safe, high-quality care. Nurses, working with other stakeholders such as insurers and employers, should test messages and delivery structures designed to ensure that consumers receive safe care; for example, develop strategies for consumers to use when (1) querying clinicians about self-care processes, (2) making informed choices about health care interventions, (3) designing Web-based support groups for geographically dispersed consumers with chronic conditions.

- Using external factors such as paying for quality performance can drive quality improvement. Examples exist of health systems that have tested the intervention of using payment incentives to improve performance (e.g., Premier demonstration project funded by the Centers for Medicare & Medicaid Services).

  Research Focus: Successful pay-for-performance models should be replicated. To facilitate this initiative, research that isolates nursing characteristics contributing to performance improvement will be useful to informing dissemination and efficient adoption of these models.

- Creating learning environments is a prerequisite to systemwide delivery and improvement of care quality.

  Research Focus: Test approaches to construct and sustain organizational cultures oriented toward safe and high-quality care. This focus includes altering power gradients in clinical settings to ensure free flow of information and testing approaches to educating teams of health profession students in academic settings to maximize communication, problem identification, and systemwide corrections.

- Even when evidence exists regarding effective approaches to care delivery, this information is not consistently applied.

Research Focus: Research is needed to determine communication approaches and incentives that encourage behavior change and the adoption of evidence-based approaches to nursing care.

- The Quality Chasm report series proposes a set of new rules to guide health care systems, including rules such as the need for transparency, anticipation of patient needs, and the patient as the source of control.

Research Focus: More research is needed to assist with effective application of each of the new rules. For example, nurse researchers could consider how to restructure care relationships and processes to determine how to move from a system that reacts to patient needs to one that anticipates patient needs.

- Population-centered care is a concept central to *The Future of Rural Health*: In this report the six aims for improvement discussed in many of the other IOM reports were considered in a population rather than a health care system context. However, an evidence base needs to be developed to better understand how to construct this concept for the purpose of improving health and health care.

Research Focus: Significant research is needed to understand possible benefits as well as clarify population-centered care as a means to improve population health. A key area of focus is to determine how to effectively engage rural stakeholders—community leaders, educational leaders, and representatives from other sectors—to achieve measurable improvements in population health. Additionally, inquiry regarding the extent to which rural health care delivery systems reflect progress toward achieving the six aims for improvement is very limited. For example, minimal research exists on the process of patient stabilization and transfer from rural hospital emergency rooms to other facilities, and yet this is a common function of many rural facilities.

- *The Future of Rural Health* discusses the importance of linking facilities and providers across geographic distances as a means to build efficient quality improvement infrastructure. Connecting clinicians using IT to provide access to locally unavailable care has been implemented in terms of telemental health, e-Intensive Care, and other IT-based services.

Research Focus: Patient outcomes associated with some technology-based interventions (e.g., e-intensive care units) have been evaluated, but very little is known about how to guide the configuration and deployment of these virtual teams, the members of which exist at geographic distance from each other. Access to home health nurses, diabetes nurse educators, and others may be enabled through the Web and other technology applications, but the associated costs, patient outcomes, etc., are not yet well established through a body of research. Fairly limited efforts have been undertaken to support these technology-based interventions through payment methods as opposed to time-limited grant funding.

- The *Health Professions Education* report advances five competencies considered essential to the ability of providers to deliver high-quality care.

Research Focus: Educational research is needed to determine how to facilitate learning and adequately assess each of the core competencies in health profession students across disciplines (e.g., utilize evidence-based practices).

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Chapter 5. Understanding Adverse Events: A Human Factors Framework

Kerm Henriksen, Elizabeth Dayton, Margaret A. Keyes, Pascale Carayon, Ronda Hughes

Introduction

In addition to putting the spotlight on the staggering numbers of Americans that die each year as a result of preventable medical error, the Institute of Medicine's (IOM's) seminal report, *To Err is Human: Building a Safer Health System*, repeatedly underscored the message that the majority of the factors that give rise to preventable adverse events are systemic; that is, they are not the result of poorly performing individual nurses, physicians, or other providers.[1] Although it was not the intent of *To Err is Human* to treat systems thinking and human factors principles in great detail, it cited the work of many prominent human factors investigators and pointed out the impressive safety gains made in other high-risk industries such as aviation, chemical processing, and nuclear power. One of the beneficial consequences of the report is that it exposed a wide audience of health services researchers and practitioners to systems and human factors concepts to which they might not otherwise have been exposed. Similarly, the report brought to the attention of the human factors community serious health care problems that it could address. Today, both health care and human factors practitioners are venturing beyond their own traditional boundaries, working together in teams, and are benefiting from the sharing of new perspectives and clinical knowledge. The purpose of the present chapter is to further this collaboration between health care and human factors, especially as it is relevant to nursing, and continue the dialog on the interdependent system factors that underlie patient safety.

Human Factors—What Is It?

The study of human factors has traditionally focused on human beings and how we interact with products, devices, procedures, work spaces, and the environments encountered at work and in daily living.[2] Most individuals have encountered a product or piece of equipment or a work environment that leads to less than optimal human performance. If human strengths and limitations are not taken into account in the design process, devices can be confusing or difficult to use, unsafe, or inefficient. Work environments can be disruptive, stressful, and lead to unnecessary fatigue. For those who like comprehensive, formal definitions, consider the following, adapted from Chapanis and colleagues:[3]

> Human factors research discovers and applies information about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, systems, tasks, and jobs, and environments for productive, safe, comfortable, and effective human use.

This definition can be simplified as follows:

> Human factors research applies knowledge about human strengths and limitations to the design of interactive systems of people, equipment, and their environment to ensure their effectiveness, safety, and ease of use.

Such a definition means that the tasks that nurses perform, the technology they are called upon to use, the work environment in which they function, and the organizational policies

that shape their activities may or may not be a good fit for their strengths and limitations. When these system factors and the sensory, behavioral, and cognitive characteristics of providers are poorly matched, substandard outcomes frequently occur with respect to effort expended, quality of care, job satisfaction, and perhaps most important, the safety of patients.

Many nursing work processes have evolved as a result of local practice or personal preference rather than through a systematic approach of designing a system that leads to fewer errors and greater efficiency. Far too often, providers and administrators have fallen into a "status quo trap," doing things simply because they always have been done that way. Human factors practitioners, on the other hand, take into account human strengths and weaknesses in the design of systems, emphasizing the importance of avoiding reliance on memory, vigilance, and followup intentions—areas where human performance is less reliable. Key processes can be simplified and standardized, which leads to less confusion, gains in efficiency, and fewer errors. When care processes become standardized, nurses have more time to attend to individual patients' specialized needs, which typically are not subject to standardization. When medical devices and new technology are designed with the end user in mind, ease of use and error detection or preventability are possible, in contrast to many current "opaque" computer-controlled devices that prevent the provider from understanding their full functionality.

The field of human factors does not focus solely on devices and technology. Although human factors research emerged during World War II as a result of equipment displays and controls that were not well suited to the visual and motor abilities of human operators, each subsequent decade of human factors work has witnessed a broadening of the human performance issues considered worthy of investigation. More recently, a number of human factors investigators with interests in health care quality and safety advocated addressing a more comprehensive range of sociotechnical system factors, including not only patients, providers, the tasks performed, and teamwork, but also work environments or microsystems, organizational and management issues, and socioeconomic factors external to the institution.[4–7] One of the lessons stemming from a systems approach is that significant improvements in quality and safety are likely to be best achieved by attending to and correcting the misalignments among these interdependent levels of care. Managing the system interdependencies of care, as evidenced by continued major breakdowns such as inadequate transitions of patient care, is a major challenge faced by providers and their human factors partners alike.

Understanding Systems

At a very basic level, a system is simply a set of interdependent components interacting to achieve a common specified goal. Systems are such a ubiquitous part of our lives that we often fail to recognize that we are active participants in many systems throughout the day. When we get up in the morning, we are dependent on our household systems (e.g., plumbing, lighting, ventilation) to function smoothly; when we send our children off to school, we are participants in the school system; and when we get on the highway and commute to work, we are participants (and sometimes victims) of our transportation system. At work, we find ourselves engaged simultaneously in several systems at different levels. We might report to work in a somewhat self-contained setting such as the intensive care unit (ICU) or operating room (OR)—what human factors practitioners refer to as microsystems—yet the larger system is the hospital itself, which, in turn, is likely to be just one facility in yet a larger health care system or network, which in itself is just one of the threads that make up the fabric of our broader and quite diffuse national health care system. The key point is that we need to recognize and understand the functioning of the many systems that we are part of and

how policies and actions in one part of the overall system can impact the safety, quality, and efficiency of other parts of the system.

Systems thinking has not come naturally to health care professionals.[8] Although health care providers work together, they are trained in separate disciplines where the primary emphasis is the mastery of the skills and knowledge to diagnose ailments and render care. In the pursuit of becoming as knowledgeable and skillful as possible in their individual disciplines, a challenge facing nursing, medicine, and the other care specialties is to be aware of the reality that they are but one component of a very intricate and fragmented web of interacting subsystems of care where no single person or entity is in charge. This is how the authors of *To Err is Human* defined our health system:[1]

> Health care is composed of a large set of interacting systems—paramedic, and emergency, ambulatory, impatient care, and home health care; testing imaging laboratories; pharmacies; and so forth—that are coupled in loosely connected but intricate network of individuals, teams, procedures, regulations, communications, equipment, and devices that function with diffused management in a variable and uncertain environment. Physicians in community practice may be so tenuously connected that they do not even view themselves as part of the system of care.

A well-known expression in patient safety is that *each system is perfectly designed to achieve exactly the results that it gets.* It was made popular by a highly respected physician, Donald Berwick of the Institute of Healthcare Improvement, who understands the nature of systems. If we reap what we sow, as the expression connotes, and given that one does not have to be a systems engineer to understand systems, it makes sense for all providers to understand the workings of the systems of which they are a part. It is unfortunate that today one can receive an otherwise superb nursing or medical education and still receive very little instruction on the nature of systems that will shape and influence every moment of a provider's working life.

Sociotechnical System Models

With a systems perspective, the focus is on the interactions or interdependencies among the components and not just the components themselves. Several investigators have proposed slightly different models of important interrelated system factors, but they all seem to start with individual tasks performed at the point of patient care and then progressively expand to encompass other factors at higher organizational levels. Table 1 shows the similarity among three of these models. In an examination of system factors in the radiation oncology therapy environment, Henriksen and colleagues[4] examined the role of individual characteristics of providers (e.g., skills, knowledge, experience); the nature of the work performed (e.g., competing tasks, procedures/practices, patient load, complexity of treatment); the physical environment (e.g., lighting, noise, temperature, workplace layout, distractions); the human-system interfaces (e.g., equipment location, controls and displays, software, patient charts); the organizational/social environment (e.g., organizational climate, group norms, morale, communication); and management (e.g., staffing, organization structure, production schedule, resource availability, and commitment to quality). Vincent and colleagues[5] also proposed a hierarchical framework of factors influencing clinical practice that included patient characteristics, task factors, individual (staff) factors, team factors, work environment, and organizational and management factors. Carayon and Smith[6] proposed a work system model that is a collection of interacting subsystems made up of people (disciplines) performing tasks using various tools and technology within a physical environment in pursuit of organizational goals that serve as inputs to care processes and ultimately to outcomes for patients, providers,

and the organization alike. The similarity among these independently derived models is quite striking, in that they are all sociotechnical system models involving technical, environmental, and social components.

Table 1. Sociotechnical System Models

Authors	Elements of Model
Henriksen, Kaye, Morisseau 1993[4]	• Individual characteristics • Nature of the work • Physical environment • Human-system interfaces • Organizational/social/environmental • Management
Vincent 1998[5]	• Patient characteristics • Task factors • Individual factors • Team factors • Work environment • Organizational and management factors
Carayon, Smith 2000[6]	• People (disciplines) • Tools and technology • Physical environment • Organizational goals • Care processes

Human Error—A Troublesome Term

While one frequently finds references to human error in the mass media, the term has actually fallen into disfavor among many patient safety researchers. The reasons are fairly straightforward. The term lacks explanatory power by not explaining anything other than a human was involved in the mishap. Too often the term 'human error' connotes blame and a search for the guilty culprits, suggesting some sort of human deficiency or lack of attentiveness. When human error is viewed as a cause rather than a consequence, it serves as a cloak for our ignorance. By serving as an end point rather than a starting point, it retards further understanding. It is essential to recognize that errors or preventable adverse events are simply the symptoms or indicators that there are defects elsewhere in the system and not the defects themselves. In other words, the error is just the tip of the iceberg; it's what lies underneath that we need to worry about. When serious investigations of preventable adverse events are undertaken, the error serves as simply the starting point for a more careful examination of the contributing system defects that led to the error. However, a very common but misdirected response to managing error is to "put out the fire," identify the individuals involved, determine their culpability, schedule them for retraining or disciplinary action, introduce new procedures or retrofixes, and issue proclamations for greater vigilance. An approach aimed at the individual is the equivalent of swatting individual mosquitoes rather than draining the swamp to address the source of the problem.

A disturbing quality in many investigations of preventable adverse events is the hidden role that human bias can play. Despite the best of intentions, humans do not always make fair and impartial assessments of events and other people. A good example is hindsight bias.[9–12] As noted by Reason,[10] the most significant psychological difference between

individuals who were involved in events leading up to a mishap and those who are called upon to investigate it after it has occurred is knowledge of the outcome. Investigators have the luxury of hindsight in knowing how things are going to turn out; nurses, physicians, and technicians at the sharp end do not. With knowledge of the outcome, hindsight bias is the exaggerated extent to which individuals indicate they could have predicted the event before it occurred. Given the advantage of a known outcome, what would have been a bewildering array of nonconvergent events becomes assimilated into a coherent causal framework for making sense out of what happened. If investigations of adverse events are to be fair and yield new knowledge, greater focus and attention need to be directed at the precursory and antecedent circumstances that existed for sharp end personnel before the mishap occurred. The point of investigating preventable adverse health care events is primarily to make sense of the factors that contribute to the omissions and misdirected actions when they occur.[11, 12] This in no way denies the fact that well-intended providers do things that inflict harm on patients, nor does it lessen individual accountability. Quite simply, one has to look closely at the factors contributing to the adverse event and not just the most immediate individual involved.

In addition to hindsight bias, investigations of accidents are also susceptible to what social psychologists have termed the attribution error.[13] Human observers or investigators tend to make a fundamental error when they set out to determine the causal factors of someone's mistake. Rather than giving careful consideration to the prevailing situational and organizational factors that are present when misfortune befalls someone else, the observer tends to make dispositional attributions and views the mishap as evidence of some inherent character flaw or defect in the individual. For example, a nurse who administers the wrong medication to an emergency department (ED) patient at the end of a 10-hour shift may be judged by peers and the public as negligent or incompetent. On the other hand, when misfortune befalls individuals themselves, they are more likely to attribute the cause to situational or contextual factors rather than dispositional ones. To continue with the example, the nurse who actually administered incorrect medication in the ED may attribute the cause to the stressful and hurried work environment, the physician's messily scribbled prescription, or fatigue after 10 intense hours of work.

Pragmatic and System Characteristics

Rasmussen[14] points out the arbitrary and somewhat pragmatic aspects of investigations of human error and system performance. When system performance is below some specified standard, an effort is made to back-track the chain of events and circumstances to find the causes. How far back to go or when to stop are open questions, the answers to which are likely to vary among different investigators. One could stop at the provider's actions and claim medical error, or one could seek to identify other reasons—poor communication, confusing equipment interfaces, lack of standardized procedures, interruptions in the care environment, diffusion of responsibility, management neglect—that may have served as contributing factors. Rasmussen notes that the search for causes will stop when one comes across one or more factors that are familiar (that will therefore serve as acceptable explanations) and for which there are available corrections or cures. Since there is no well-defined start point to which one is progressively working backward through the causal chain, how far back one is willing to search is likely to depend on pragmatic considerations such as resources, time constrains, and internal political ramifications. Rasmussen also observes that some human actions become classified as human error simply because they are performed in unkind work environments; that is, work environments where there is not much tolerance for individual experimentation and where it is not possible for individuals to correct

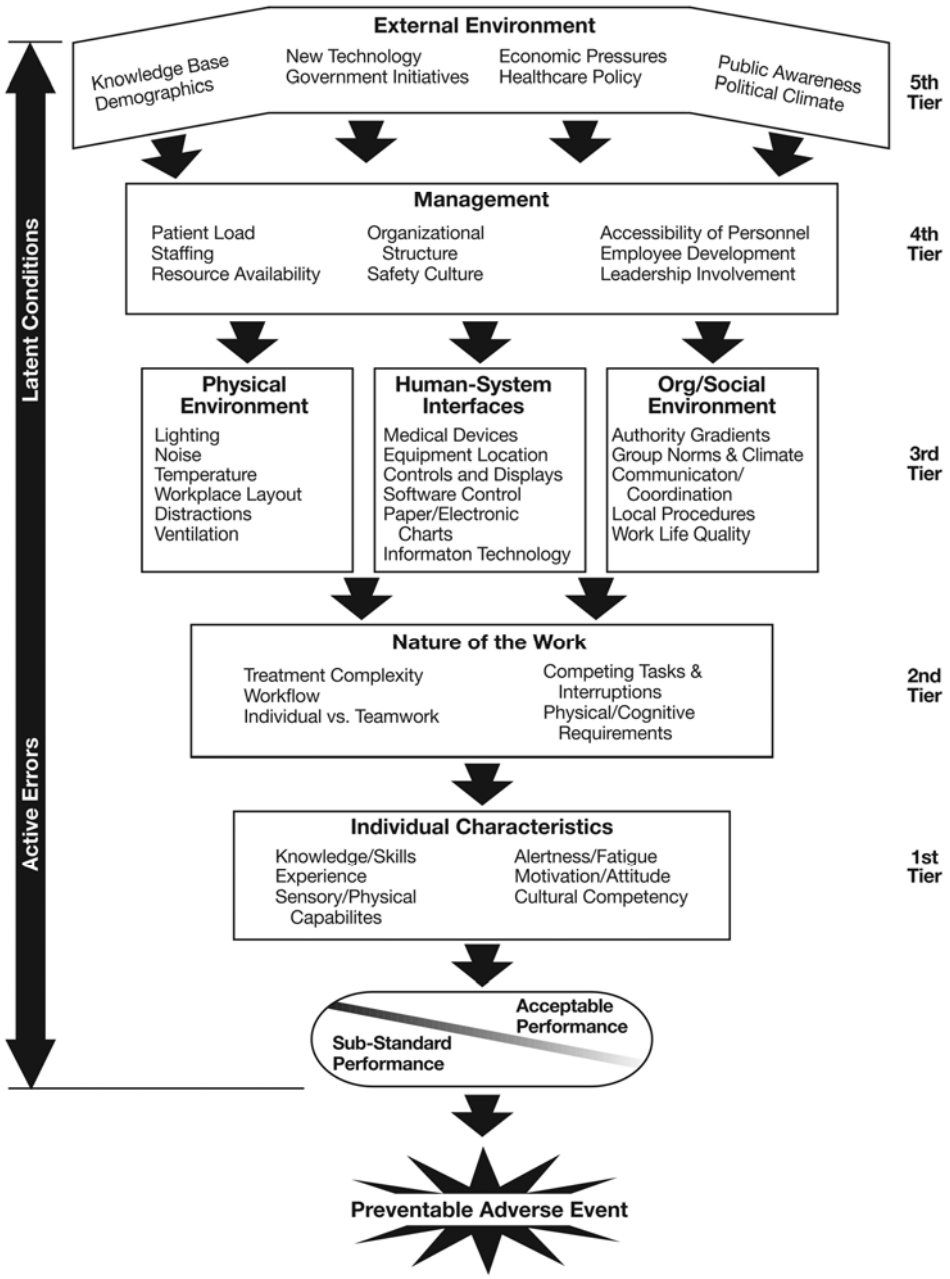
inappropriate actions before they lead to undesirable consequences. In some unkind environments, it may not be possible to reverse the inappropriate actions, while in others it may not be possible to foresee the undesirable consequences. Rasmussen's unkind work environment is quite similar to Perrow's notion of *tightness of coupling* in complex systems.[15]

Perrow's analysis of system disasters in high-risk industries shifts the burden of responsibility from the front-line operator of the system to actual properties of the system. Using the concepts of *tightness of coupling* and *interactive complexity*, Perrow focuses on the inherent characteristics of systems that make some industries more prone to accidents.[15] Tightness of coupling refers to dependencies among operational sequences that are relatively intolerant of delays and deviations, while interactive complexity refers to the number of ways system components (i.e., equipment, procedures, people) can interact, especially unexpectedly. It is the multiple and unexpected interactions of malfunctioning parts, inadequate procedures, and unanticipated actions—each innocuous by themselves—in tightly coupled systems that give rise to accidents. Such accidents are rare but inevitable, even "normal," to use Perrow's terminology. By understanding the special characteristics of high-risk systems, decisionmakers might be able to avoid blaming the wrong components of the system and also refrain from technological fixes that serve only to make the system riskier.

A Human Factors Framework

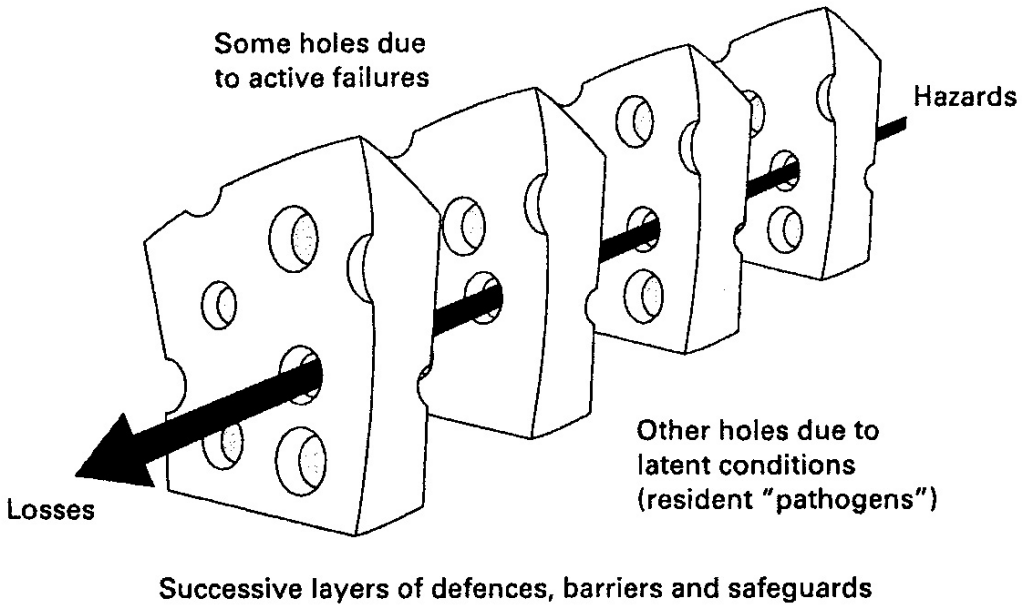
Figure 1 shows many of the components or major factors that need to be addressed to gain a better understanding of the nature of preventable adverse events. What the figure does not portray very well is the way in which these major factors can interact with one another. A basic tenet of any systems approach to adverse events is that changes in one part of the system will surely have repercussions on another part of the system. Hence, it is important to focus on the way these components can interact and influence one another and not just the components themselves. When these components are functioning well together, they serve collectively as a set of barriers or system of defenses to the occurrence of preventable adverse events. However, it is when weaknesses or vulnerabilities exist within these components and they interact or align themselves in such a way that the weaknesses overlap that preventable adverse events occur. This way of describing "holes" that exist in the successive components or layers of defenses has more light-heartedly been dubbed the "Swiss cheese" model of accident causation, made popular by James Reason, a prominent British psychologist who has dramatically influenced the way we think about patient safety.[16] Figure 2 shows the Swiss cheese model of accident causation and how the trajectory of hazards can result in losses or adverse events.

Figure 1. Contributing Factors to Adverse Events in Health Care



In brief, many adverse events result from this unique interaction or alignment of several necessary but singly insufficient factors. Weaknesses in these factors typically are present in the system long before the occurrence of an adverse event. All that is needed is for a sufficient number to become aligned for a serious adverse event to occur.

Figure 2. The "Swiss Cheese" Model of Accident Causation



Source: Reason J, Carthey J, deLeval M. Diagnosing "vulnerable system syndrome": An essential prerequisite to effective risk management. Qual Health Care, 2001; 10(Suppl. II):ii21-ii25. Reprinted with permission of the BMJ Publishing Group.

The distinction made by Reason between *latent conditions* and *active errors*, shown along the left margin of Figure 1, also is very important.[11, 17] In health care, active errors are committed by those providers (e.g., nurses, physicians, technicians) who are in the middle of the action, responding to patient needs at the *sharp end*.[18] Latent conditions are the potential contributing factors that are hidden and lie dormant in the health care delivery system, occurring upstream at the more remote tiers, far removed from the active end. These latent conditions—more organizational, contextual, and diffuse in nature or design related—have been dubbed the *blunt end*.[18] The distinction between latent conditions and active errors is important because it allows us to clearly see that nurses, who have the greatest degree of patient contact, are actually the last line of defense against medical error (and hence the most vulnerable). As such, nurses can inherit the less recognized sins of omission and commission of everyone else who has played a role in the design of the health care delivery system. Reason perhaps makes this point best:[10]

> Rather than being the main instigators of an accident, operators tend to be inheritors of system defects created by poor design, incorrect installation, faulty maintenance and bad management decisions. Their part is usually that of adding a final garnish to a lethal brew whose ingredients have already been long in the cooking.

The human factors framework outlined here allows us to examine a wide range of latent conditions that are part of the health care sociotechnical system in which providers reside.

Individual Characteristics

Figure 1 identifies *individual characteristics* as a first-tier factor that has a direct impact on provider performance and whether that performance is likely to be considered acceptable or substandard. Individual characteristics include all the qualities that individuals bring with them to the job—things such as knowledge, skill level, experience, intelligence, sensory capabilities, training and education, and even organismic and attitudinal states such as alertness, fatigue, and motivation, just to mention a few. The knowledge and skills that health

care providers develop prior to employment through accredited training programs is fundamental to their ability to perform their work. At the same time, organismic factors such as fatigue resulting from long hours and stress can influence the ability of providers to apply their specialized knowledge optimally. Communication ability and cultural competency skills should also be included at this level. Fortunately, few critics would argue that the skills and abilities mentioned here are unimportant in having an impact on optimal health care delivery and outcomes.

The Nature of the Work

The second-tier factor in Figure 1, *the nature of the work*, refers to characteristics of the work itself and includes the extent to which well-defined procedures are utilized, the nature of the workflow, peak and nonpeak patient loads, the presence or absence of teamwork, the complexity of treatments, equipment functioning and downtime, interruptions and competing tasks, and the physical/cognitive requirements for performing the work. Although empirical studies on the impact of these work-related factors in health care settings are not as plentiful as they are in the human factors literature, they indeed exist. For example, a review of the external beam radiation therapy literature[19] found fewer treatment administration errors when therapists worked in pairs[20]and greater numbers of treatment administration errors at the higher patient census levels.[21] If management becomes overly ambitious in directing a high volume of patients to be treated in a fixed period of time, the consequence for radiation therapists is a high-pressure work environment and an increase in the number of adverse events. With respect to the human factors literature, there is an abundance of research on the effects of work-related factors on human performance drawn largely from defense-related operations and that of other highly hazardous industries where proficient human performance plays a critical role.[22–25]

Human-System Interfaces

The *human-system interface* refers to the manner in which two subsystems— typically human and equipment—interact or communicate within the boundaries of the system. This is shown as a third-tier factor in Figure 1. Nurses use medical devices and equipment extensively and thus have plentiful first-hand experience with the poor fit that frequently exists between the design of the devices' controls and displays and the capabilities and knowledge of users. One approach for investigating the mismatches between devices and people is to recognize there is an expanding progression of interfaces in health care settings, each with their own vulnerabilities and opportunities for confusion.[26, 27] Starting at the very center with the patient, a *patient-device interface* needs to be recognized. Does the device or accessory attachment need to be fitted or adapted to the patient? What physical, cognitive, and affective characteristics of the patient need to be taken into account in the design and use of the device? What sort of understanding does the patient need to have of device operation and monitoring? With the increasing migration of sophisticated devices into the home as a result of strong economic pressures to move patients out of hospitals as soon as possible, safe home care device use becomes a serious challenge, especially with elderly patients with comorbidities who may be leaving the hospital sicker as a result of shorter stays, and where the suitability of the home environment may be called into question (e.g., home caregivers are also likely to be aged, and the immediate home environment layout may not be conducive to device use). In brief, the role of the patient in relation to the device and its immediate environment necessitates careful examination. At the same time, the migration of devices into the home nicely illustrates the convergence of several system factors—health care economics,

shifting demographics, acute and chronic needs of patients, competency of home caregivers, supportiveness of home environments for device use—that in their collective interactivity and complexity can bring about threats to patient safety and quality of care.

Providers of care are subject to a similar set of device use issues. Human factors practitioners who focus on the *provider (user)–device interface* are concerned about the provider's ability to operate, maintain, and understand the overall functionality of the device, as well as its connections and functionality in relation to other system components. In addition to controls and displays that need to be designed with human motor and sensory capabilities in mind, the device needs to be designed in a way that enables the nurse or physician to quickly determine the state of the device. Increasing miniaturization of computer-controlled devices has increased their quality but can leave providers with a limited understanding of the full functionality of the device. With a poor understanding of device functionality, providers are at a further loss when the device malfunctions and when swift decisive action may be critical for patient care. The design challenge is in creating provider-device interfaces that facilitate the formation of appropriate mental models of device functioning and that encourage meaningful dialogue and sharing of tasks between user and device. Providers also have a role in voicing their concerns regarding poorly designed devices to their managers, purchasing officers, and to manufacturers.

The next interface level in our progression of interfaces is the *microsystem-device interface*. At the microsystem level (i.e., contained organizational units such as EDs and ICUs), it is recognized that medical equipment and devices frequently do not exist in stand-alone form but are tied into and coupled with other components and accessories that collectively are intended to function as a seamless, integrated system. Providers, on the other hand, are quick to remind us that this is frequently not the case, given the amount of time they spend looking for appropriate cables, lines, connectors, and other accessories. In many ORs and ICUs, there is an eclectic mix of monitoring systems from different vendors that interface with various devices that increases the cognitive workload placed on provider personnel. Another microsystem interface problem, as evidenced by several alerts from health safety organizations, are medical gas mix-ups, where nitrogen and carbon dioxide have been mistakenly connected to the oxygen supply system. Gas system safeguards using incompatible connectors have been overridden with adapters and other retrofitted connections. The lesson for providers here is to be mindful that the very need for an adaptor is a warning signal that a connection is being sought that may not be intended by the device manufacturer and that may be incorrect and harmful.[28]

Yet other device-related concerns are sociotechnical in nature, and hence we refer to a *sociotechnical-device interface*. How well are the technical requirements for operating and maintaining the device supported by the physical and socio-organizational environment of the user? Are the facilities and workspaces where the device is used adequate? Are quality assurance procedures in place that ensure proper operation and maintenance of the device? What sort of training do providers receive in device operation before using the device with patients? Are chief operating officers and nurse managers committed to safe device use as an integral component of patient safety? As health information technology (HIT) plays an increasing role in efforts to improve patient safety and quality of care, greater scrutiny needs to be directed at discerning the optimal and less-than-optimal conditions in the sociotechnical environment for the intelligent and proper use of these devices and technologies.

The Physical Environment

The benefits of a *physical work environment* that is purposefully designed for the nature of the work that is performed have been well understood in other high-risk industries for a

number of years. More recently, the health care profession has begun to appreciate the relationship between the physical environment (e.g., design of jobs, equipment, and physical layout) and employee performance (e.g., efficiency, reduction of error, and job satisfaction). The third tier in Figure 1 also emphasizes the importance of the physical environment in health care delivery.

There is a growing evidence base from health care architecture, interior design, and environmental and human factors engineering that supports the assertion that safety and quality of care can be designed into the physical construction of facilities. An extensive review by Ulrich and colleagues[29] found more than 600 studies that demonstrated the impact of the design of the physical environment of hospitals on safety and quality outcomes for patients and staff. A diverse range of design improvements include better use of space for improved patient vigilance and reduced steps to the point of patient care; mistake proofing and forcing functions that preclude the initiation of potentially harmful actions; standardization of facility systems, equipment, and patient rooms; in-room placement of sinks for hand hygiene; single-bed rooms for reducing infections; better ventilation systems for pathogen control; improved patient handling, transport, and prevention of falls; HIT for quick and reliable access to patient information and enhanced medication safety; appropriate and adjustable lighting; noise reduction for lowering stress; simulation suites with sophisticated mannequins that enable performance mastery of critical skills; improved signage; use of affordances and natural mapping; and greater accommodation and sensitivity to the needs of families and visitors. Reiling and colleagues[30] described the design and building of a new community hospital that illustrates the deployment of patient safety-driven design principles.

A basic premise of sound design is that it starts with a thorough understanding of user requirements. A focus on the behavioral and performance requirements of a building's occupants has generally been accepted in architecture since the early 1970s.[31–33] Architects have devised methods—not dissimilar to function and task analysis techniques developed by human factors practitioners—that inventory all the activities that are performed by a building's occupants as well as visitors. Table 2 lists just a small sample of questions that need to be asked.[34, 35]

Table 2. Determining Activities Performed by Building Occupants and Visitors

• Who will be using the facility? • What are the characteristic activities of user groups? • What can be learned about the extent, time of occurrence, and duration of anticipated activities?
• What are the relationships and exchanges between building dwellers and visitors? • How many people will be moving about within the facility, for what purpose, and how frequently? • What are the demographics (e.g., age, gender) and special characteristics of building users?
• What user groups require special equipment, fixtures, furnishings, placement, signage, safety features, and security components?
• What spaces are needed to support user activities? • What special provisions are needed in these spaces to ensure safety and quality of the services rendered? • How can the spaces be designed to facilitate human performance on the required tasks?

• What are the recommended circulation patterns for facilitating information, equipment, and supply flow between spaces? • What are the design provisions for advances in health information technology? • What space adjacency requirements exist?
• What provisions with respect to user groups need to be made for temperature, humidity, ventilation, illumination, noise, distraction, hazards, and climatic conditions?

Given the vast amounts of time spent on hospital units and the number of repetitive tasks performed, nurses as an occupational group are especially sensitive to building and workplace layout features that have a direct bearing on the quality and safety of care provided. When designing workplaces in clinical settings, human capabilities and limitations need to be considered with respect to distances traveled, standing and seated positions, work surfaces, the lifting of patients, visual requirements for patient monitoring, and spaces for provider communication and coordination activities. Traveling unnecessary distances to retrieve needed supplies or information is a waste of valuable time. Repetitious motor activity facilitates fatigue. Information needed by several people can be made easily accessible electronically, communication and coordination among providers can be maximized by suitable spatial arrangements, and clear lines of sight where needed can be designed for monitoring tasks.

At the time of this chapter's writing, the U.S. hospital industry is in the midst of a major building boom for the next decade, with an estimated $200 billion earmarked for new construction. Nursing has an opportunity to play a key role in serving on design teams that seek to gain a better understanding of the tasks performed by provider personnel. By employing the accumulating evidence base, hospitals can be designed to be more effective, safe, efficient, and patient-centered. Or they can be designed in a way that repeats the mistakes of the past. Either way, the physical attributes that hospitals take will impact the quality and safety of health care delivery for years to come.

Organizational/Social Environment

As shown in the third tier of Figure 1, the organizational/social environment represents another set of latent conditions that can lie dormant for some time; yet when combined with other pathogens (to use Reason's metaphor[10]), can thwart the system's defenses and lead to error. Adverse events that have been influenced by organizational and social factors have been poorly understood due, in large part, to their delayed and dormant consequences. These are the omnipresent, but difficult to quantify factors—organizational climate, group norms, morale, authority gradients, local practices—that often go unrecognized by individuals because they are so deeply immersed in them. However, over time these factors are sure to have their impact.

In her analysis of the *Challenger* disaster, Vaughn[36] discovered a pattern of small, incremental erosions to safety and quality that over time became the norm. She referred to this organizational/social phenomenon as *normalization of deviance*. Disconfirming information (i.e., information that the launch mission was not going as well as it should) was minimized and brought into the realm of acceptable risk. This served to reduce any doubt or uneasy feelings about the status of the mission and preserved the original belief that their systems were essentially safe. A similar normalization of deviance seems to have happened in health care with the benign acceptance of shortages and adverse working conditions for nurses. If a hospital can get by with fewer and fewer nurses and other needed resources without the occurrence of serious adverse consequences, these unfavorable conditions may

continue to get stretched, creating thinner margins of safety, until a major adverse event occurs.

Another form of organizational fallibility is the *good provider fallacy*.[37, 38] Nurses as a group have well-deserved professional reputations as a result of their superb work ethic, commitment, and compassion. Many, no doubt, take pride in their individual competence, resourcefulness, and ability to solve problems on the run during the daily processes of care. Yet, as fine as these qualities are, there is a downside to them. In a study of hospital work process failures (e.g., missing supplies, malfunctioning equipment, incomplete/inaccurate information, unavailable personnel), Tucker and Edmondson[39] found that the failures elicited work-arounds and quick fixes by nurses 93 percent of the time, and reports of the failure to someone who might be able to do something about it 7 percent of the time. While this strategy for problem-solving satisfies the immediate patient care need, from a systems perspective it is sheer folly to focus only on the first-order problem and do nothing about the second-order problem—the contributing factors that create the first-order problem. By focusing only on first-order fixes or work-arounds and not the contributing factors, the problems simply reoccur on subsequent shifts as nurses repeat the cycle of trying to keep up with the crisis of the day. To change this shortsightedness, it is time for nurse managers and those who shape organizational climate to value some new qualities. Rather than simply valuing nurses who take the initiative, who roll with the punches while attempting quick fixes, and who otherwise "stay in their place," it is time to value nurses who ask penetrating questions, who present evidence contrary to the view that things are alright, and who step out of a traditionally compliant role and help solve the problem-behind-the-problem. Given the vast clinical expertise and know-how of nurses, it is a great loss when organizational and social norms in the clinical work setting create a culture of low expectations and inhibit those who can so clearly help the organization learn to deliver safer, higher quality, and more patient-centered care.

Management

Conditions of poor planning, indecision, or omission, associated with managers and those in decisionmaking positions, are termed latent because they occur further upstream in Figure 1 (tier four), far away from the sharp-end activities of nurses and other providers. Decisions are frequently made in a loose, diffuse, somewhat disorderly fashion. Because decisionmaking consequences accrue gradually, interact with other variables, and are not that easy to isolate and determine, those who make organizational policy, shape organizational culture, and implement managerial decisions are rarely held accountable for the consequences of their actions. Yet managerial dictum and organizational practices regarding staffing, communication, workload, patient scheduling, accessibility of personnel, insertion of new technology, and quality assurance procedures are sure to have their impact. As noted earlier, providers are actually the last line of defense, for it is the providers who ultimately must cope with the shortcomings of everyone else who has played a role in the design of the greater sociotechnical system. For example, the absence of a serious commitment to higher quality and safe care at the management level is a latent condition that may become apparent in terms of adverse consequences only when this "error of judgment" aligns itself with other system variables such as overworked personnel, excessive interruptions, poorly designed equipment interfaces, a culture of low expectations, and rapid-paced production schedules for treating patients.

Compared to providers, managers and decisionmakers are much better positioned to actually address the problems-behind-the-problem and be mindful of the interdependencies of care. Managers and decisionmakers have the opportunity to work across organizational units

of care and address the discontinuities. With perhaps a few exceptions, there is very little evidence that managers and leaders actually spend much time in attending to the complex interdependencies of care and areas of vulnerability in their institutions. While they may not have the same clinical know-how as sharp end personnel, they certainly have the corporate authority to involve those with clinical expertise in needed change efforts. Thus, a new role for health care leaders and managers is envisioned, placing a high value on understanding system complexity and focusing on the interdependencies—not just the components.[38] In this new role, leaders recognize that superb clinical knowledge and dedication of providers is no match for the toll that flawed and poorly performing interdependent systems of care can take. In brief, they aim to do something about the misalignments.

The External Environment

Lest it seem that the authors are being a bit harsh on management, it needs to be recognized that there are external forces exerting their influence at this level. From a systems perspective, one must not simply repeat the blame game and lay all the responsibility for health care delivery problems at the feet of management. Health care is an open system, and, as shown in Figure 1, each system level subsumes lower systems and gets subsumed by higher systems in return. Subsuming the management level and the more distal downstream levels is the external environment, which perhaps is best portrayed as a shifting mosaic of economic pressures, political climates and policies, scientific and technological advancements, and changing demographics. For those that toil at the sharp end, these diffuse, broad-based, and shifting forces may seem less relevant because of their more remote or indirect impact. While this is understandable, the impact of these forces is undeniable. The external environment influences patient safety and quality of care by shaping the context in which care is provided. A salient characteristic of our dynamic 21st-century society is that these external forces are stronger and change more frequently than ever before.[7] For providers and health care decisionmakers to stay ahead of these forces (rather than getting rolled over by them) and gain more proactive leverage to help shape the ensuing changes, it is first necessary to gain a better understanding of the external forces that are operating.

Not only is the scientific foundation of nursing and medicine expanding significantly (e.g., consider advances in genomics, neuroscience, immunology, and the epidemiology of disease), there is a corresponding need to master different procedures associated with new drug armamentariums, new imaging technologies, and new minimally invasive surgical interventions.[40] The groundwork is currently being laid for pay-for-performance to become a reality in the near future. Safety, efficiency, and high-quality care will serve as a basis for medical reimbursement, not just services rendered, as is currently the case. Two demographic trends are converging causing serious alarm. Nursing, as a profession, continues to experience shortages and discontent just as an aging baby boom population with a plethora of chronic and acute care needs starts to occupy a wide range of care settings. Medical practice has been steadily shifting from inpatient to outpatient settings. Economic incentives to move patients out of hospitals as soon as possible continue, and as noted earlier, there is a concurrent migration of sophisticated medical devices into the home despite fears that the home care environment may not be suitable for safe and effective medical device use. With continued cost-containment concerns and pressures on clinicians to be as productive as possible, the clinical setting becomes a less ideal place to acquire clinical skills from senior staff. Currently simulation techniques are receiving active investigation and may provide an alternative means of acquiring and maintaining clinical skills. At the same time, with a growing proportion of the population composed of minorities, greater sensitivity and tailored approaches directed toward those less well served by the health system will be needed.

Unlike other sectors of the economy, health care remained untouched for too long by advances in information technology (except, perhaps, for billing purposes). That is no longer the case, given the recent implementation of electronic health records, computer physician order entry systems, barcoding systems, and other technologies by early adopters. However, lofty expectations that usher in new technology are quickly dampened by unintended consequences.[41, 42] One of the early lessons learned is that successful implementation involves more than just technical considerations—the nature of clinical work, the design of well-conceived interfaces, workflow considerations, user acceptance and adoption issues, training, and other organizational support requirements all need to be taken into account. Still another external development that will likely have an impact on clinical practice in the years to come is the passage of the Patient Safety and Quality Improvement Act of 2005. It provides confidentiality protections and encourages providers to contract with patient safety organizations (PSOs) for the purpose of collecting and analyzing data on patient safety events so that information can be fed back to providers to help reduce harm to patients. With the confidentiality protections mandated by the act, providers should be able to report patient safety events freely without fear of reprisal or litigation. Finally, given the availability of numerous medical Web sites and a national press network sensitized to instances of substandard clinical care and medical error, today's patients are better informed and a bit less trusting with respect to their encounters with the health system.

What Can Nurses Do?

Considering all the system factors (and we have only identified some of them), a normal reaction probably is to feel a bit overwhelmed by the demanding and complex clinical environment in which nurses find themselves. Given the hierarchical and complex nature of system factors identified and the unanticipated ways they can interact, a reasonable question is, “What can nurses do?” The answer, in part, comes from learning to manage the unexpected[1]—a quality of high-reliability organizations (HROs) that many health care organizations are currently learning to adopt. In brief, HROs are those organizations that have sustained very impressive safety records while operating in very complex and unkind environments (e.g., aircraft carriers, nuclear power, firefighting crews), where the risk of injury to people and damage to expensive equipment or the environment is high. A key characteristic on the part of workers in HROs is that of *mindfulness*—a set of cognitive processes that allows individuals to be highly attuned to the many ways things can go wrong in unkind environments and ways to recover from them. Workers in HROs are qualitatively different and continuously mindful of different things compared to workers in less reliable organizations. Table 3 describes the five mindfulness processes that define the core components of HROs and the implications for nursing. For a fuller account of HROs, interested readers are encouraged to access the original source.[43]

Table 3. A State of Mindfulness for Nurses

Core process	Explanation/Implication for Nursing
Preoccupation with failure	Adverse events are rare in HROs, yet these organizations focus incessantly on ways the system can fail them. Rather than letting success breed complacency, they worry about success and know that adverse events will indeed occur. They treat close calls as a sign of danger lurking in the system. Hence, it is a good thing when nurses are preoccupied with the many ways things can go wrong and when they share that "inner voice of concern" with others.

Core process	Explanation/Implication for Nursing
Reluctance to simplify interpretations	When things go wrong, less reliable organizations find convenient ways to circumscribe and limit the scope of the problem. They simplify and do not spend much energy on investigating all the contributing factors. Conversely, HROs resist simplified interpretations, do not accept conventional explanations that are readily available, and seek out information that can disconfirm hunches and popular stereotypes. Nurses who develop good interpersonal, teamwork, and critical-thinking skills will enhance their organization's ability to accept disruptive information that disconfirms preconceived ideas.
Sensitivity to operations	Workers in HROs do an excellent job of maintaining a big picture of current and projected operations. Jet fighter pilots call it *situational awareness*; surface Navy personnel call it *maintaining the bubble*. By integrating information about operations and the actions of others into a coherent picture, they are able to stay ahead of the action and can respond appropriately to minor deviations before they result in major threats to safety and quality. Nurses also demonstrate excellent sensitivity to operations when they process information regarding clinical procedures beyond their own jobs and stay ahead of the action rather than trying to catch up to it.
Commitment to resilience	Given that errors are always going to occur, HROs commit equal resources to being mindful about errors that have already occurred and to correct them before they worsen. Here the idea is to reduce or mitigate the adverse consequences of untoward events. Nursing already shows resilience by putting supplies and recovery equipment in places that can be quickly accessed when patient conditions go awry. Since foresight always lags hindsight, nursing resilience can be honed by creating simulations of care processes that start to unravel (e.g., failure to rescue).
Deference to expertise	In managing the unexpected, HROs allow decisions to migrate to those with the expertise to make them. Decisions that have to be made quickly are made by knowledgeable front-line personnel who are closest to the problem. Less reliable organizations show misplaced deference to authority figures. While nurses, no doubt, can cite many examples of misplaced deference to physicians, there are instances where physicians have assumed that nurses have the authority to make decisions and act, resulting in a diffusion of responsibility. When it comes to decisions that need to be made quickly, implicit assumptions need to be made explicit; rules of engagement need to be clearly established; and deference must be given to those with the expertise, resources, and availability to help the patient.

It should be noted that not everyone in health care has been receptive to comparisons between health care delivery and the activities that take place in other high-risk industries such as aircraft carrier operations or nuclear power. Health care is not aviation; it is more complex and qualitatively different. While all of this may be true, it probably also is true that health care is the most poorly managed of all the high-risk industries and very late in coming to recognize the importance of system factors that underlie adverse events. The one thing that the other high-risk industries clearly have in common with health care is the human component. Sailors that work the decks of aircraft carriers have the same physiologies as those who work the hospital floor. They get fatigued from excessive hours of operation in the same way as those who occupy the nurses' station. When the technology and equipment they

use is poorly designed and confusing to use, they get frustrated and make similar types of mistakes as those in health care who have to use poorly designed medical devices. When the pace of operations pick up and they are bombarded with interruptions, short-term memory fails them in exactly the same way that it fails those who work in hectic EDs and ICUs. They respond to variations in the physical environment (e.g., lighting, noise, workplace layout) and to social/organizational pressures (e.g., group norms, culture, authority gradients) in a very similar fashion to those in health care who are exposed to the same set of factors. While the nature of the work may be dramatically different, the types of system factors that influence human performance are indeed very similar. The take-home message of all this is that the human factors studies that have been conducted in the other high-risk industries are very relevant to health care, and nursing in particular, as we continue to learn to improve the skills, processes, and system alignments that are needed for higher quality and safer care.

Conclusion

The complex and demanding clinical environment of nurses can be made a bit more understandable and easier in which to deliver care by accounting for a wide range of human factors concerns that directly and indirectly impact human performance. Human factors is the application of scientific knowledge about human strengths and limitations to the design of systems in the work environment to ensure safe and satisfying performance. A human factors framework such as that portrayed in Figure 1 helps us become aware of the salient components and their relationships that shape and influence the quality of care that is provided to patients. The concept of human error is a somewhat loaded term. Rather than falling into the trap of uncritically focusing on human error and searching for individuals to blame, a systems approach attempts to identify the contributing factors to substandard performance and find ways to better detect, recover from, or preclude problems that could result in harm to patients. Starting with the individual characteristics of providers such as their knowledge, skills, and sensory/physical capabilities, we examined a hierarchy of system factors, including the nature of the work performed, the physical environment, human-system interfaces, the organizational/social environment, management, and external factors. In our current fragmented health care system, where no single individual or entity is in charge, these multiple factors seem to be continuously misaligned and interact in a manner that leads to substandard care. These are the proverbial accidents in the system waiting to happen. Nurses serve in a critical role at the point of patient care; they are in an excellent position to not only identify the problems, but to help identify the problems-behind-the-problems. Nurses can actively practice the tenets of high-reliability organizations. It is recognized, of course, that nursing cannot address the system problems all on its own. Everyone who has a potential impact on patient care, no matter how remote (e.g., device manufacturers, administrators, nurse managers), needs to be mindful of the interdependent system factors that they play a role in shaping. Without a clear and strong nursing voice and an organizational climate that is conducive to candidly addressing system problems, efforts to improve patient safety and quality will fall short of their potential.

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Chapter 6. Clinical Reasoning, Decisionmaking, and Action: Thinking Critically and Clinically

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Background

This chapter examines multiple thinking strategies that are needed for high-quality clinical practice. Clinical reasoning and judgment are examined in relation to other modes of thinking used by clinical nurses in providing quality health care to patients that avoids adverse events and patient harm. The clinician's ability to provide safe, high-quality care can be dependent upon their ability to reason, think, and judge, which can be limited by lack of experience. The expert performance of nurses is dependent upon continual learning and evaluation of performance.

Critical Thinking

Nursing education has emphasized critical thinking as an essential nursing skill for more than 50 years.[1] The definitions of critical thinking have evolved over the years. There are several key definitions for critical thinking to consider. The American Philosophical Association (APA) defined critical thinking as purposeful, self-regulatory judgment that uses cognitive tools such as interpretation, analysis, evaluation, inference, and explanation of the evidential, conceptual, methodological, criteriological, or contextual considerations on which judgment is based.[2] A more expansive general definition of critical thinking is

> . . . in short, self-directed, self-disciplined, self-monitored, and self-corrective thinking. It presupposes assent to rigorous standards of excellence and mindful command of their use. It entails effective communication and problem solving abilities and a commitment to overcome our native egocentrism and sociocentrism. Every clinician must develop rigorous habits of critical thinking, but they cannot escape completely the situatedness and structures of the clinical traditions and practices in which they must make decisions and act quickly in specific clinical situations.[3]

There are three key definitions for nursing, which differ slightly. Bittner and Tobin defined critical thinking as being "influenced by knowledge and experience, using strategies such as reflective thinking as a part of learning to identify the issues and opportunities, and holistically synthesize the information in nursing practice"[4] (p. 268). Scheffer and Rubenfeld[5] expanded on the APA definition for nurses through a consensus process, resulting in the following definition:

> Critical thinking in nursing is an essential component of professional accountability and quality nursing care. Critical thinkers in nursing exhibit these habits of the mind: confidence, contextual perspective, creativity, flexibility, inquisitiveness, intellectual integrity, intuition, openmindedness, perseverance, and reflection. Critical thinkers in nursing practice the cognitive skills of analyzing, applying standards, discriminating, information seeking, logical reasoning, predicting, and transforming knowledge[6] (Scheffer & Rubenfeld, p. 357).

The National League for Nursing Accreditation Commission (NLNAC) defined critical thinking as:

> the deliberate nonlinear process of collecting, interpreting, analyzing, drawing conclusions about, presenting, and evaluating information that is both factually and belief based. This is demonstrated in nursing by clinical judgment, which includes ethical, diagnostic, and therapeutic dimensions and research[7] (p. 8).

These concepts are furthered by the American Association of Colleges of Nurses' definition of critical thinking in their *Essentials of Baccalaureate Nursing*:

> Critical thinking underlies independent and interdependent decision making. Critical thinking includes questioning, analysis, synthesis, interpretation, inference, inductive and deductive reasoning, intuition, application, and creativity[8] (p. 9).
>
> Course work or ethical experiences should provide the graduate with the knowledge and skills to:
>
> - Use nursing and other appropriate theories and models, and an appropriate ethical framework;
> - Apply research-based knowledge from nursing and the sciences as the basis for practice;
> - Use clinical judgment and decision-making skills;
> - Engage in self-reflective and collegial dialogue about professional practice;
> - Evaluate nursing care outcomes through the acquisition of data and the questioning of inconsistencies, allowing for the revision of actions and goals;
> - Engage in creative problem solving[8] (p. 10).

Taken together, these definitions of critical thinking set forth the scope and key elements of thought processes involved in providing clinical care. Exactly how critical thinking is defined will influence how it is taught and to what standard of care nurses will be held accountable.

Professional and regulatory bodies in nursing education have required that critical thinking be central to all nursing curricula, but they have not adequately distinguished critical reflection from ethical, clinical, or even creative thinking for decisionmaking or actions required by the clinician. Other essential modes of thought such as clinical reasoning, evaluation of evidence, creative thinking, or the application of well-established standards of practice—all distinct from critical reflection—have been subsumed under the rubric of critical thinking. In the nursing education literature, clinical reasoning and judgment are often conflated with critical thinking. The accrediting bodies and nursing scholars have included decisionmaking and action-oriented, practical, ethical, and clinical reasoning in the rubric of critical reflection and thinking. One might say that this harmless semantic confusion is corrected by actual practices, except that students need to understand the distinctions between critical reflection and clinical reasoning, and they need to learn to discern when each is better suited, just as students need to also engage in applying standards, evidence-based practices, and creative thinking.

The growing body of research, patient acuity, and complexity of care demand higher-order thinking skills. Critical thinking involves the application of knowledge and experience to identify patient problems and to direct clinical judgments and actions that result in positive patient outcomes. These skills can be cultivated by educators who display the virtues of critical thinking, including independence of thought, intellectual curiosity, courage, humility, empathy, integrity, perseverance, and fair-mindedness.[9]

The process of critical thinking is stimulated by integrating the essential knowledge, experiences, and clinical reasoning that support professional practice. The emerging paradigm for clinical thinking and cognition is that it is social and dialogical rather than monological and individual.[10–12] Clinicians pool their wisdom and multiple perspectives, yet some clinical knowledge can be demonstrated only in the situation (e.g., how to suction an extremely fragile patient whose oxygen saturations sink too low). Early warnings of problematic situations are made possible by clinicians comparing their observations to that of other providers. Clinicians form practice communities that create styles of practice, including ways of doing things, communication styles and mechanisms, and shared expectations about performance and expertise of team members.

By holding up critical thinking as a large umbrella for different modes of thinking, students can easily misconstrue the logic and purposes of different modes of thinking. Clinicians and scientists alike need multiple thinking strategies, such as critical thinking, clinical judgment, diagnostic reasoning, deliberative rationality, scientific reasoning, dialogue, argument, creative thinking, and so on. In particular, clinicians need forethought and an ongoing grasp of a patient's health status and care needs trajectory, which requires an assessment of their own clarity and understanding of the situation at hand, critical reflection, critical reasoning, and clinical judgment.

Critical Reflection, Critical Reasoning, and Judgment

Critical reflection requires that the thinker examine the underlying assumptions and radically question or doubt the validity of arguments, assertions, and even facts of the case. Critical reflective skills are essential for clinicians; however, these skills are not sufficient for the clinician who must decide how to act in particular situations and avoid patient injury. For example, in everyday practice, clinicians cannot afford to critically reflect on the well-established tenets of "normal" or "typical" human circulatory systems when trying to figure out a particular patient's alterations from that typical, well-grounded understanding that has existed since Harvey's work in 1628.[13] Yet critical reflection can generate new scientifically based ideas. For example, there is a lack of adequate research on the differences between women's and men's circulatory systems and the typical pathophysiology related to heart attacks. Available research is based upon multiple, taken-for-granted starting points about the general nature of the circulatory system. As such, critical reflection may not provide what is needed for a clinician to act in a situation. This idea can be considered reasonable since critical reflective thinking is not sufficient for good clinical reasoning and judgment. The clinician's development of skillful critical reflection depends upon being taught what to pay attention to, and thus gaining a sense of salience that informs the powers of perceptual grasp. The powers of noticing or perceptual grasp depend upon noticing what is salient and the capacity to respond to the situation.

Critical reflection is a crucial professional skill, but it is not the only reasoning skill or logic clinicians require. The ability to think critically uses reflection, induction, deduction, analysis, challenging assumptions, and evaluation of data and information to guide decisionmaking.[9, 14, 15] Critical reasoning is a process whereby knowledge and experience are applied in considering multiple possibilities to achieve the desired goals,[16] while considering the patient's situation.[14] It is a process where both inductive and deductive cognitive skills are used.[17] Sometimes clinical reasoning is presented as a form of evaluating scientific knowledge, sometimes even as a form of scientific reasoning. Critical thinking is inherent in making sound clinical reasoning.[18]

An essential point of tension and confusion exists in practice traditions such as nursing and medicine when clinical reasoning and critical reflection become entangled, because the clinician must have some established bases that are not questioned when engaging in clinical decisions and actions, such as standing orders. The clinician must act in the particular situation and time with the best clinical and scientific knowledge available. The clinician cannot afford to indulge in either ritualistic unexamined knowledge or diagnostic or therapeutic nihilism caused by radical doubt, as in critical reflection, because they must find an intelligent and effective way to think and act in particular clinical situations. Critical reflection skills are essential to assist practitioners to rethink outmoded or even wrong-headed approaches to health care, health promotion, and prevention of illness and complications, especially when new evidence is available. Breakdowns in practice, high failure rates in particular therapies, new diseases, new scientific discoveries, and societal changes call for critical reflection about past assumptions and no-longer-tenable beliefs.

Clinical reasoning stands out as a situated, practice-based form of reasoning that requires a background of scientific and technological research-based knowledge about general cases, more so than any particular instance. It also requires practical ability to discern the relevance of the evidence behind general scientific and technical knowledge and how it applies to a particular patient. In dong so, the clinician considers the patient's particular clinical trajectory, their concerns and preferences, and their particular vulnerabilities (e.g., having multiple comorbidities) and sensitivities to care interventions (e.g., known drug allergies, other conflicting comorbid conditions, incompatible therapies, and past responses to therapies) when forming clinical decisions or conclusions.

Situated in a practice setting, clinical reasoning occurs within social relationships or situations involving patient, family, community, and a team of health care providers. The expert clinician situates themselves within a nexus of relationships, with concerns that are bounded by the situation. Expert clinical reasoning is socially engaged with the relationships and concerns of those who are affected by the caregiving situation, and when certain circumstances are present, the adverse event. Halpern[19] has called excellent clinical ethical reasoning "emotional reasoning" in that the clinicians have emotional access to the patient/family concerns and their understanding of the particular care needs. Expert clinicians also seek an optimal perceptual grasp, one based on understanding and as undistorted as possible, based on an attuned emotional engagement and expert clinical knowledge.[19, 20]

Clergy educators[21] and nursing and medical educators have begun to recognize the wisdom of broadening their narrow vision of rationality beyond simple rational calculation (exemplified by cost-benefit analysis) to reconsider the need for character development—including emotional engagement, perception, habits of thought, and skill acquisition—as essential to the development of expert clinical reasoning, judgment, and action.[10, 22–24] Practitioners of engineering, law, medicine, and nursing, like the clergy, have to develop a place to stand in their discipline's tradition of knowledge and science in order to recognize and evaluate salient evidence in the moment. Diagnostic confusion and disciplinary nihilism are both threats to the clinician's ability to act in particular situations. However, the practice and practitioners will not be self-improving and vital if they cannot engage in critical reflection on what is not of value, what is outmoded, and what does not work. As evidence evolves and expands, so too must clinical thought.

Clinical judgment requires clinical reasoning across time about the particular, and because of the relevance of this immediate historical unfolding, clinical reasoning can be very different from the scientific reasoning used to formulate, conduct, and assess clinical experiments. While

scientific reasoning is also socially embedded in a nexus of social relationships and concerns, the goal of detached, critical objectivity used to conduct scientific experiments minimizes the interactive influence of the research on the experiment once it has begun. Scientific research in the natural and clinical sciences typically uses formal criteria to develop "yes" and "no" judgments at prespecified times. The scientist is always situated in past and immediate scientific history, preferring to evaluate static and predetermined points in time (e.g., snapshot reasoning), in contrast to a clinician who must always reason about transitions over time.[25, 26]

Techne and Phronesis

Distinctions between the mere scientific making of things and practice was first explored by Aristotle as distinctions between techne and phronesis.[27] Learning to be a good practitioner requires developing the requisite moral imagination for good practice. If, for example, patients exercise their rights and refuse treatments, practitioners are required to have the moral imagination to understand the probable basis for the patient's refusal. For example, was the refusal based upon catastrophic thinking, unrealistic fears, misunderstanding, or even clinical depression?

Techne, as defined by Aristotle, encompasses the notion of formation of character and habitus[28] as embodied beings. In Aristotle's terms, techne refers to the making of things or producing outcomes.[11] Joseph Dunne defines techne as "the activity of producing outcomes," and it "is governed by a means-ends rationality where the *maker or producer* governs the thing or outcomes produced or made through gaining mastery over the means of producing the outcomes, to the point of being able to separate means and ends"[11] (p. 54). While some aspects of medical and nursing practice fall into the category of techne, much of nursing and medical practice falls outside means-ends rationality and must be governed by concern for doing good or what is best for the patient in particular circumstances, where being in a relationship and discerning particular human concerns at stake guide action.

Phronesis, in contrast to techne, includes reasoning about the particular, across time, through changes or transitions in the patient's and/or the clinician's understanding. As noted by Dunne, phronesis is "characterized at least as much by a perceptiveness with regard to concrete particulars as by a knowledge of universal principles"[11] (p. 273). This type of practical reasoning often takes the form of puzzle solving or the evaluation of immediate past "hot" history of the patient's situation. Such a particular clinical situation is necessarily particular, even though many commonalities and similarities with other disease syndromes can be recognized through signs and symptoms and laboratory tests.[11, 29, 30] Pointing to knowledge embedded in a practice makes no claim for infallibility or "correctness." Individual practitioners can be mistaken in their judgments because practices such as medicine and nursing are inherently underdetermined.[31]

While phronetic knowledge must remain open to correction and improvement, real events, and consequences, it cannot consistently transcend the institutional setting's capacities and supports for good practice. Phronesis is also dependent on ongoing experiential learning of the practitioner, where knowledge is refined, corrected, or refuted. The Western tradition, with the notable exception of Aristotle, valued knowledge that could be made universal and devalued practical know-how and experiential learning. Descartes codified this preference for formal logic and rational calculation.

Aristotle recognized that when knowledge is underdetermined, changeable, and particular, it cannot be turned into the universal or standardized. It must be perceived, discerned, and judged, all of which require experiential learning. In nursing and medicine, perceptual acuity in physical

assessment and clinical judgment (i.e., reasoning across time about changes in the particular patient or the clinician's understanding of the patient's condition) fall into the Greek Aristotelian category of phronesis. Dewey[32] sought to rescue knowledge gained by practical activity in the world. He identified three flaws in the understanding of experience in Greek philosophy: (1) empirical knowing is the opposite of experience with science; (2) practice is reduced to techne or the application of rational thought or technique; and (3) action and skilled know-how are considered temporary and capricious as compared to reason, which the Greeks considered as ultimate reality.

In practice, nursing and medicine require both techne and phronesis. The clinician standardizes and routinizes what can be standardized and routinized, as exemplified by standardized blood pressure measurements, diagnoses, and even charting about the patient's condition and treatment.[27] Procedural and scientific knowledge can often be formalized and standardized (e.g., practice guidelines), or at least made explicit and certain in practice, except for the necessary timing and adjustments made for particular patients.[11, 22]

Rational calculations available to techne—population trends and statistics, algorithms—are created as decision support structures and can improve accuracy when used as a stance of inquiry in making clinical judgments about particular patients. Aggregated evidence from clinical trials and ongoing working knowledge of pathophysiology, biochemistry, and genomics are essential. In addition, the skills of phronesis (clinical judgment that reasons across time, taking into account the transitions of the particular patient/family/community and transitions in the clinician's understanding of the clinical situation) will be required for nursing, medicine, or any helping profession.

Thinking Critically

Being able to think critically enables nurses to meet the needs of patients within their context and considering their preferences; meet the needs of patients within the context of uncertainty; consider alternatives, resulting in higher-quality care;[33] and think reflectively, rather than simply accepting statements and performing tasks without significant understanding and evaluation.[34] Skillful practitioners can think critically because they have the following cognitive skills: information seeking, discriminating, analyzing, transforming knowledge, predicating, applying standards, and logical reasoning.[5] One's ability to think critically can be affected by age, length of education (e.g., an associate vs. a baccalaureate decree in nursing), and completion of philosophy or logic subjects.[35–37] The skillful practitioner can think critically because of having the following characteristics: motivation, perseverance, fair-mindedness, and deliberate and careful attention to thinking.[5, 9]

Thinking critically implies that one has a knowledge base from which to reason and the ability to analyze and evaluate evidence.[38] Knowledge can be manifest by the logic and rational implications of decisionmaking. Clinical decisionmaking is particularly influenced by interpersonal relationships with colleagues,[39] patient conditions, availability of resources,[40] knowledge, and experience.[41] Of these, experience has been shown to enhance nurses' abilities to make quick decisions[42] and fewer decision errors,[43] support the identification of salient cues, and foster the recognition and action on patterns of information.[44, 45]

Clinicians must develop the character and relational skills that enable them to perceive and understand their patient's needs and concerns. This requires accurate interpretation of patient data that is relevant to the specific patient and situation. In nursing, this formation of moral agency focuses on learning to be responsible in particular ways demanded by the practice, and to

pay attention and intelligently discern changes in patients' concerns and/or clinical condition that require action on the part of the nurse or other health care workers to avert potential compromises to quality care.

Formation of the clinician's character, skills, and habits are developed in schools and particular practice communities within a larger practice tradition. As Dunne notes,

> A practice is not just a surface on which one can display instant virtuosity. It grounds one in a tradition that has been formed through an elaborate development and that exists at any juncture only in the dispositions (slowly and perhaps painfully acquired) of its recognized practitioners. The question may of course be asked whether there are *any* such practices in the contemporary world, whether the wholesale encroachment of Technique has not obliterated them—and whether this is not the whole point of MacIntyre's recipe of withdrawal, as well as of the post-modern story of dispossession[11] (p. 378).

Clearly Dunne is engaging in critical reflection about the conditions for developing character, skills, and habits for skillful and ethical comportment of practitioners, as well as to act as moral agents for patients so that they and their families receive safe, effective, and compassionate care.

Professional socialization or professional values, while necessary, do not adequately address character and skill formation that transform the way the practitioner exists in his or her world, what the practitioner is capable of noticing and responding to, based upon well-established patterns of emotional responses, skills, dispositions to act, and the skills to respond, decide, and act.[46] The need for character and skill formation of the clinician is what makes a practice stand out from a mere technical, repetitious manufacturing process.[11, 30, 47]

In nursing and medicine, many have questioned whether current health care institutions are designed to promote or hinder enlightened, compassionate practice, or whether they have deteriorated into commercial institutional models that focus primarily on efficiency and profit. MacIntyre points out the links between the ongoing development and improvement of practice traditions and the institutions that house them:

> Lack of justice, lack of truthfulness, lack of courage, lack of the relevant intellectual virtues—these corrupt traditions, just as they do those institutions and practices which derive their life from the traditions of which they are the contemporary embodiments. To recognize this is of course also to recognize the existence of an additional virtue, one whose importance is perhaps most obvious when it is least present, the virtue of having an adequate sense of the traditions to which one belongs or which confront one. This virtue is not to be confused with any form of conservative antiquarianism; I am not praising those who choose the conventional conservative role of *laudator temporis acti.* It is rather the case that an adequate sense of tradition manifests itself in a grasp of those future possibilities which the past has made available to the present. Living traditions, just because they continue a not-yet-completed narrative, confront a future whose determinate and determinable character, so far as it possesses any, derives from the past[30] (p. 207).

It would be impossible to capture all the situated and distributed knowledge outside of actual practice situations and particular patients. Simulations are powerful as teaching tools to enable nurses' ability to think critically because they give students the opportunity to practice in a simplified environment. However, students can be limited in their inability to convey underdetermined situations where much of the information is based on perceptions of many

aspects of the patient and changes that have occurred over time. Simulations cannot have the sub-cultures formed in practice settings that set the social mood of trust, distrust, competency, limited resources, or other forms of situated possibilities.

Experience

One of the hallmark studies in nursing providing keen insight into understanding the influence of experience was a qualitative study of adult, pediatric, and neonatal intensive care unit (ICU) nurses, where the nurses were clustered into advanced beginner, intermediate, and expert level of practice categories. The advanced beginner (having up to 6 months of work experience) used procedures and protocols to determine which clinical actions were needed. When confronted with a complex patient situation, the advanced beginner felt their practice was unsafe because of a knowledge deficit or because of a knowledge application confusion. The transition from advanced beginners to competent practitioners began when they first had experience with actual clinical situations and could benefit from the knowledge gained from the mistakes of their colleagues. Competent nurses continuously questioned what they saw and heard, feeling an obligation to know more about clinical situations. In doing do, they moved from only using care plans and following the physicians' orders to analyzing and interpreting patient situations. Beyond that, the proficient nurse acknowledged the changing relevance of clinical situations requiring action beyond what was planned or anticipated. The proficient nurse learned to acknowledge the changing needs of patient care and situation, and could organize interventions "by the situation as it unfolds rather than by preset goals[48] (p. 24). Both competent and proficient nurses (that is, intermediate level of practice) had at least two years of ICU experience.[48] Finally, the expert nurse had a more fully developed grasp of a clinical situation, a sense of confidence in what is known about the situation, and could differentiate the precise clinical problem in little time.[48]

Expertise is acquired through professional experience and is indicative of a nurse who has moved beyond mere proficiency. As Gadamer[29] points out, experience involves a turning around of preconceived notions, preunderstandings, and extends or adds nuances to understanding. Dewey[49] notes that experience requires a prepared "creature" and an enriched environment. The opportunity to reflect and narrate one's experiential learning can clarify, extend, or even refute experiential learning.

Experiential learning requires time and nurturing, but time alone does not ensure experiential learning. Aristotle linked experiential learning to the development of character and moral sensitivities of a person learning a practice.[50] New nurses/new graduates have limited work experience and must experience continuing learning until they have reached an acceptable level of performance.[51] After that, further improvements are not predictable, and years of experience are an inadequate predictor of expertise.[52]

The most effective knower and developer of practical knowledge creates an ongoing dialogue and connection between lessons of the day and experiential learning over time. Gadamer, in a late life interview, highlighted the open-endedness and ongoing nature of experiential learning in the following interview response:

> Being experienced does not mean that one now knows something once and for all and becomes rigid in this knowledge; rather, one becomes more open to new experiences. A person who is experienced is undogmatic. Experience has the effect of freeing one to be open to new experience … In our experience we bring

> nothing to a close; we are constantly learning new things from our experience … this I call the interminability of all experience[32] (p. 403).

Practical endeavor, supported by scientific knowledge, requires experiential learning, the development of skilled know-how, and perceptual acuity in order to make the scientific knowledge relevant to the situation. Clinical perceptual and skilled know-how helps the practitioner discern when particular scientific findings might be relevant.[53]

Often experience and knowledge, confirmed by experimentation, are treated as oppositions, an either-or choice. However, in practice it is readily acknowledged that experiential knowledge fuels scientific investigation, and scientific investigation fuels further experiential learning. Experiential learning from particular clinical cases can help the clinician recognize future similar cases and fuel new scientific questions and study. For example, less experienced nurses—and it could be argued experienced as well—can use nursing diagnoses practice guidelines as part of their professional advancement. Guidelines are used to reflect their interpretation of patients' needs, responses, and situation,[54] a process that requires critical thinking and decisionmaking.[55, 56] Using guidelines also reflects one's problem identification and problem-solving abilities.[56] Conversely, the ability to proficiently conduct a series of tasks without nursing diagnoses is the hallmark of expertise.[39, 57]

Experience precedes expertise. As expertise develops from experience and gaining knowledge and transitions to the proficiency stage, the nurses' thinking moves from steps and procedures (i.e., task-oriented care) toward "chunks" or patterns[39] (i.e., patient-specific care). In doing so, the nurse thinks reflectively, rather than merely accepting statements and performing procedures without significant understanding and evaluation.[34] Expert nurses do not rely on rules and logical thought processes in problem-solving and decisionmaking.[39] Instead, they use abstract principles, can see the situation as a complex whole, perceive situations comprehensively, and can be fully involved in the situation.[48] Expert nurses can perform high-level care without conscious awareness of the knowledge they are using,[39, 58] and they are able to provide that care with flexibility and speed. Through a combination of knowledge and skills gained from a range of theoretical and experiential sources, expert nurses also provide holistic care.[39] Thus, the best care comes from the combination of theoretical, tacit, and experiential knowledge.[59, 60]

Experts are thought to eventually develop the ability to intuitively know what to do and to quickly recognize critical aspects of the situation.[22] Some have proposed that expert nurses provide high-quality patient care,[61, 62] but that is not consistently documented—particularly in consideration of patient outcomes—and a full understanding between the differential impact of care rendered by an "expert" nurse is not fully understood. In fact, several studies have found that length of professional experience is often unrelated and even negatively related to performance measures and outcomes.[63, 64]

In a review of the literature on expertise in nursing, Ericsson and colleagues[65] found that focusing on challenging, less-frequent situations would reveal individual performance differences on tasks that require speed and flexibility, such as that experienced during a code or an adverse event. Superior performance was associated with extensive training and immediate feedback about outcomes, which can be obtained through continual training, simulation, and processes such as root-cause analysis following an adverse event. Therefore, efforts to improve performance benefited from continual monitoring, planning, and retrospective evaluation. Even then, the nurse's ability to perform as an expert is dependent upon their ability to use intuition or insights gained through interactions with patients.[39]

Intuition and Perception

Intuition is the instant understanding of knowledge without evidence of sensible thought.[66] According to Young,[67] intuition in clinical practice is a process whereby the nurse recognizes something about a patient that is difficult to verbalize. Intuition is characterized by factual knowledge, "immediate possession of knowledge, and knowledge independent of the linear reasoning process"[68] (p. 23). When intuition is used, one filters information initially triggered by the imagination, leading to the integration of all knowledge and information to problem solve.[69] Clinicians use their interactions with patients and intuition, drawing on tacit or experiential knowledge,[70, 71] to apply the correct knowledge to make the correct decisions to address patient needs. Yet there is a "conflated belief in the nurses' ability to know what is best for the patient"[72] (p. 251) because the nurses' and patients' identification of the patients' needs can vary.[73]

A review of research and rhetoric involving intuition by King and Appleton[62] found that all nurses, including students, used intuition (i.e., gut feelings). They found evidence, predominately in critical care units, that intuition was triggered in response to knowledge and as a trigger for action and/or reflection with a direct bearing on the analytical process involved in patient care. The challenge for nurses was that rigid adherence to checklists, guidelines, and standardized documentation,[62] ignored the benefits of intuition. This view was furthered by Rew and Barrow[68, 74] in their reviews of the literature, where they found that intuition was imperative to complex decisionmaking,[68] difficult to measure and assess in a quantitative manner, and was not linked to physiologic measures.[74]

Intuition is a way of explaining professional expertise.[75] Expert nurses rely on their intuitive judgment that has been developed over time.[39, 76] Intuition is an informal, nonanalytically based, unstructured, deliberate calculation that facilitates problem solving,[77] a process of arriving at salient conclusions based on relatively small amounts of knowledge and/or information.[78] Experts can have rapid insight into a situation by using intuition to recognize patterns and similarities, achieve commonsense understanding, and sense the salient information combined with deliberative rationality.[10] Intuitive recognition of similarities and commonalities between patients are often the first diagnostic clue or early warning, which must then be followed up with critical evaluation of evidence among the competing conditions. This situation calls for intuitive judgment that can distinguish "expert human judgment from the decisions" made by a novice[79] (p. 23).

Shaw[80] equates intuition with direct perception. Direct perception is dependent upon being able to detect complex patterns and relationships that one has learned through experience are important. Recognizing these patterns and relationships generally occurs rapidly and is complex, making it difficult to articulate or describe. Perceptual skills, like those of the expert nurse, are essential to recognizing current and changing clinical conditions. Perception requires attentiveness and the development of a sense of what is salient. Often in nursing and medicine, means and ends are fused, as is the case for a "good enough" birth experience and a peaceful death.

Applying Practice Evidence

Research continues to find that using evidence-based guidelines in practice, informed through research evidence, improves patients' outcomes.[81–83] Research-based guidelines are

intended to provide guidance for specific areas of health care delivery.[84] The clinician—both the novice and expert—is expected to use the best available evidence for the most efficacious therapies and interventions in particular instances, to ensure the highest-quality care, especially when deviations from the evidence-based norm may heighten risks to patient safety. Otherwise, if nursing and medicine were exact sciences, or consisted only of techne, then a 1:1 relationship could be established between results of aggregated evidence-based research and the best path for all patients.

Evaluating Evidence

Before research should be used in practice, it must be evaluated. There are many complexities and nuances in evaluating the research evidence for clinical practice. Evaluation of research behind evidence-based medicine requires critical thinking and good clinical judgment. Sometimes the research findings are mixed or even conflicting. As such, the validity, reliability, and generalizability of available research are fundamental to evaluating whether evidence can be applied in practice. To do so, clinicians must select the best scientific evidence relevant to particular patients—a complex process that involves intuition to apply the evidence. Critical thinking is required for evaluating the best available scientific evidence for the treatment and care of a particular patient.

Good clinical judgment is required to select the most relevant research evidence. The best clinical judgment, that is, reasoning across time about the particular patient through changes in the patient's concerns and condition and/or the clinician's understanding, are also required. This type of judgment requires clinicians to make careful observations and evaluations of the patient over time, as well as know the patient's concerns and social circumstances. To evolve to this level of judgment, additional education beyond clinical preparation if often required.

Sources of Evidence

Evidence that can be used in clinical practice has different sources and can be derived from research, patient's preferences, and work-related experience.[85, 86] Nurses have been found to obtain evidence from experienced colleagues believed to have clinical expertise and research-based knowledge[87] as well as other sources.

For many years now, randomized controlled trials (RCTs) have often been considered the best standard for evaluating clinical practice. Yet, unless the common threats to the validity (e.g., representativeness of the study population) and reliability (e.g., consistency in interventions and responses of study participants) of RCTs are addressed, the meaningfulness and generalizability of the study outcomes are very limited. Relevant patient populations may be excluded, such as women, children, minorities, the elderly, and patients with multiple chronic illnesses. The dropout rate of the trial may confound the results. And it is easier to get positive results published than it is to get negative results published. Thus, RCTs are generalizable (i.e., applicable) only to the population studied—which may not reflect the needs of the patient under the clinicians care. In instances such as these, clinicians need to also consider applied research using prospective or retrospective populations with case control to guide decisionmaking, yet this too requires critical thinking and good clinical judgment.

Another source of available evidence may come from the gold standard of aggregated systematic evaluation of clinical trial outcomes for the therapy and clinical condition in question, be generated by basic and clinical science relevant to the patient's particular pathophysiology or

care need situation, or stem from personal clinical experience. The clinician then takes all of the available evidence and considers the particular patient's known clinical responses to past therapies, their clinical condition and history, the progression or stages of the patient's illness and recovery, and available resources.

In clinical practice, the particular is examined in relation to the established generalizations of science. With readily available summaries of scientific evidence (e.g., systematic reviews and practice guidelines) available to nurses and physicians, one might wonder whether deep background understanding is still advantageous. Might it not be expendable, since it is likely to be out of date given the current scientific evidence? But this assumption is a false opposition and false choice because without a deep background understanding, the clinician does not know how to best find and evaluate scientific evidence for the particular case in hand. The clinician's sense of salience in any given situation depends on past clinical experience and current scientific evidence.

Evidence-Based Practice

The concept of evidence-based practice is dependent upon synthesizing evidence from the variety of sources and applying it appropriately to the care needs of populations and individuals. This implies that evidence-based practice, indicative of expertise in practice, appropriately applies evidence to the specific situations and unique needs of patients.[88, 89] Unfortunately, even though providing evidence-based care is an essential component of health care quality, it is well known that evidence-based practices are not used consistently.

Conceptually, evidence used in practice advances clinical knowledge, and that knowledge supports independent clinical decisions in the best interest of the patient.[90, 91] Decisions must prudently consider the factors not necessarily addressed in the guideline, such as the patient's lifestyle, drug sensitivities and allergies, and comorbidities. Nurses who want to improve the quality and safety of care can do so though improving the consistency of data and information interpretation inherent in evidence-based practice.

Initially, before evidence-based practice can begin, there needs to be an accurate clinical judgment of patient responses and needs. In the course of providing care, with careful consideration of patient safety and quality care, clinicians must give attention to the patient's condition, their responses to health care interventions, and potential adverse reactions or events that could harm the patient. Nonetheless, there is wide variation in the ability of nurses to accurately interpret patient responses[92] and their risks.[93] Even though variance in interpretation is expected, nurses are obligated to continually improve their skills to ensure that patients receive quality care safely.[94] Patients are vulnerable to the actions and experience of their clinicians, which are inextricably linked to the quality of care patients have access to and subsequently receive.

The judgment of the patient's condition determines subsequent interventions and patient outcomes. Attaining accurate and consistent interpretations of patient data and information is difficult because each piece can have different meanings, and interpretations are influenced by previous experiences.[95] Nurses use knowledge from clinical experience[96, 97] and—although infrequently—research.[98–100]

Once a problem has been identified, using a process that utilizes critical thinking to recognize the problem, the clinician then searches for and evaluates the research evidence[101] and evaluates potential discrepancies. The process of using evidence in practice involves "a problem-solving approach that incorporates the best available scientific evidence, clinicians' expertise, and

patient's preferences and values"[102] (p. 28). Yet many nurses do not perceive that they have the education, tools, or resources to use evidence appropriately in practice.[103]

Reported barriers to using research in practice have included difficulty in understanding the applicability and the complexity of research findings, failure of researchers to put findings into the clinical context, lack of skills in how to use research in practice,[104, 105] amount of time required to access information and determine practice implications,[105–107] lack of organizational support to make changes and/or use in practice,[104, 97, 105, 107] and lack of confidence in one's ability to critically evaluate clinical evidence.[108]

When Evidence Is Missing

In many clinical situations, there may be no clear guidelines and few or even no relevant clinical trials to guide decisionmaking. In these cases, the latest basic science about cellular and genomic functioning may be the most relevant science, or by default, guestimation. Consequently, good patient care requires more than a straightforward, unequivocal application of scientific evidence. The clinician must be able to draw on a good understanding of basic sciences, as well as guidelines derived from aggregated data and information from research investigations.

Practical knowledge is shaped by one's practice discipline and the science and technology relevant to the situation at hand. But scientific, formal, discipline-specific knowledge are not sufficient for good clinical practice, whether the discipline be law, medicine, nursing, teaching, or social work. Practitioners still have to learn how to discern generalizable scientific knowledge, know how to use scientific knowledge in practical situations, discern what scientific evidence/knowledge is relevant, assess how the particular patient's situation differs from the general scientific understanding, and recognize the complexity of care delivery—a process that is complex, ongoing, and changing, as new evidence can overturn old.

Practice communities like individual practitioners may also be mistaken, as is illustrated by variability in practice styles and practice outcomes across hospitals and regions in the United States. This variability in practice is why practitioners must learn to critically evaluate their practice and continually improve their practice over time. The goal is to create a living self-improving tradition.

Within health care, students, scientists, and practitioners are challenged to learn and use different modes of thinking when they are conflated under one term or rubric, using the best-suited thinking strategies for taking into consideration the purposes and the ends of the reasoning. Learning to be an effective, safe nurse or physician requires not only technical expertise, but also the ability to form helping relationships and engage in practical ethical and clinical reasoning.[50] Good ethical comportment requires that both the clinician and the scientist take into account the notions of good inherent in clinical and scientific practices. The notions of good clinical practice must include the relevant significance and the human concerns involved in decisionmaking in particular situations, centered on clinical grasp and clinical forethought.

The Three Apprenticeships of Professional Education

We have much to learn in comparing the pedagogies of formation across the professions, such as is being done currently by the Carnegie Foundation for the Advancement of Teaching. The Carnegie Foundation's broad research program on the educational preparation of the profession focuses on three essential apprenticeships:

> To capture the full range of crucial dimensions in professional education, we developed the idea of a three-fold apprenticeship: (1) intellectual training to learn the academic knowledge base and the capacity to think in ways important to the profession; (2) a skill-based apprenticeship of practice; and (3) an apprenticeship to the ethical standards, social roles, and responsibilities of the profession, through which the novice is introduced to the meaning of an integrated practice of all dimensions of the profession, grounded in the profession's fundamental purposes.[109]

This framework has allowed the investigators to describe tensions and shortfalls as well as strengths of widespread teaching practices, especially at articulation points among these dimensions of professional training.

Research has demonstrated that these three apprenticeships are taught best when they are integrated so that the intellectual training includes skilled know-how, clinical judgment, and ethical comportment. In the study of nursing, exemplary classroom and clinical teachers were found who do integrate the three apprenticeships in all of their teaching, as exemplified by the following anonymous student's comments:

> With that as well, I enjoyed the class just because I do have clinical experience in my background and I enjoyed it because it took those practical applications and the knowledge from pathophysiology and pharmacology, and all the other classes, and it tied it into the actual aspects of like what is going to happen at work. For example, I work in the emergency room and question: Why am I doing this procedure for this particular patient? Beforehand, when I was just a tech and I wasn't going to school, I'd be doing it because I was told to be doing it—or I'd be doing CPR because, you know, the doc said, start CPR. I really enjoy the Care and Illness because now I know the process, the pathophysiological process of why I'm doing it and the clinical reasons of why they're making the decisions, and the prioritization that goes on behind it. I think that's the biggest point. Clinical experience is good, but not everybody has it. Yet when these students transition from school and clinicals to their job as a nurse, they will understand what's going on and why.

The three apprenticeships are equally relevant and intertwined. In the Carnegie *National Study of Nursing Education* and the companion study on medical education as well as in cross-professional comparisons, teaching that gives an integrated access to professional practice is being examined. Once the three apprenticeships are separated, it is difficult to reintegrate them. The investigators are encouraged by teaching strategies that integrate the latest scientific knowledge and relevant clinical evidence with clinical reasoning about particular patients in unfolding rather than static cases, while keeping the patient and family experience and concerns relevant to clinical concerns and reasoning.

Clinical judgment or phronesis is required to evaluate and integrate techne and scientific evidence.

Within nursing, professional practice is wise and effective usually to the extent that the professional creates relational and communication contexts where clients/patients can be open and trusting. Effectiveness depends upon mutual influence between patient and practitioner, student and learner. This is another way in which clinical knowledge is dialogical and socially distributed. The following articulation of practical reasoning in nursing illustrates the social,

dialogical nature of clinical reasoning and addresses the centrality of perception and understanding to good clinical reasoning, judgment and intervention.

Clinical Grasp*

Clinical grasp describes clinical inquiry in action. Clinical grasp begins with perception and includes problem identification and clinical judgment across time about the particular transitions of particular patients. Garrett Chan[20] described the clinician's attempt at finding an "optimal grasp" or vantage point of understanding. Four aspects of clinical grasp, which are described in the following paragraphs, include (1) making qualitative distinctions, (2) engaging in detective work, (3) recognizing changing relevance, and (4) developing clinical knowledge in specific patient populations.

Making Qualitative Distinctions

Qualitative distinctions refer to those distinctions that can be made only in a particular contextual or historical situation. The context and sequence of events are essential for making qualitative distinctions; therefore, the clinician must pay attention to transitions in the situation and judgment. Many qualitative distinctions can be made only by observing differences through touch, sound, or sight, such as the qualities of a wound, skin turgor, color, capillary refill, or the engagement and energy level of the patient. Another example is assessing whether the patient was more fatigued after ambulating to the bathroom or from lack of sleep. Likewise the quality of the clinician's touch is distinct as in offering reassurance, putting pressure on a bleeding wound, and so on.[110]

Engaging in Detective Work, Modus Operandi Thinking, and Clinical Puzzle Solving

Clinical situations are open ended and underdetermined. Modus operandi thinking keeps track of the particular patient, the way the illness unfolds, the meanings of the patient's responses as they have occurred in the particular time sequence. Modus operandi thinking requires keeping track of what has been tried and what has or has not worked with the patient. In this kind of reasoning-in-transition, gains and losses of understanding are noticed and adjustments in the problem approach are made.

We found that teachers in a medical surgical unit at the University of Washington deliberately teach their students to engage in "detective work." Students are given the daily clinical assignment of "sleuthing" for undetected drug incompatibilities, questionable drug dosages, and unnoticed signs and symptoms. For example, one student noted that an unusual dosage of a heart medication was being given to a patient who did not have heart disease. The student first asked her teacher about the unusually high dosage. The teacher, in turn, asked the

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* This section of the paper was condensed and paraphrased from Benner, Hooper-Kyriakidis, and Stannard.[23] Patricia Hooper-Kyriakidis wrote the section on clinical grasp, and Patricia Benner wrote the section on clinical forethought.

student whether she had asked the nurse or the patient about the dosage. Upon the student's questioning, the nurse did not know why the patient was receiving the high dosage and assumed the drug was for heart disease. The patient's staff nurse had not questioned the order. When the student asked the patient, the student found that the medication was being given for tremors and that the patient and the doctor had titrated the dosage for control of the tremors. This deliberate approach to teaching detective work, or modus operandi thinking, has characteristics of "critical reflection," but stays situated and engaged, ferreting out the immediate history and unfolding of events.

Recognizing Changing Clinical Relevance

The meanings of signs and symptoms are changed by sequencing and history. The patient's mental status, color, or pain level may continue to deteriorate or get better. The direction, implication, and consequences for the changes alter the relevance of the particular facts in the situation. The changing relevance entailed in a patient transitioning from primarily curative care to primarily palliative care is a dramatic example, where symptoms literally take on new meanings and require new treatments.

Developing Clinical Knowledge in Specific Patient Populations

Extensive experience with a specific patient population or patients with particular injuries or diseases allows the clinician to develop comparisons, distinctions, and nuanced differences within the population. The comparisons between many specific patients create a matrix of comparisons for clinicians, as well as a tacit, background set of expectations that create population- and patient-specific detective work if a patient does not meet the usual, predictable transitions in recovery. What is in the background and foreground of the clinician's attention shifts as predictable changes in the patient's condition occurs, such as is seen in recovering from heart surgery or progressing through the predictable stages of labor and delivery. Over time, the clinician develops a deep background understanding that allows for expert diagnostic and interventions skills.

Clinical Forethought

Clinical forethought is intertwined with clinical grasp, but it is much more deliberate and even routinized than clinical grasp. Clinical forethought is a pervasive habit of thought and action in nursing practice, and also in medicine, as clinicians think about disease and recovery trajectories and the implications of these changes for treatment. Clinical forethought plays a role in clinical grasp because it structures the practical logic of clinicians. At least four habits of thought and action are evident in what we are calling clinical forethought: (1) future think, (2) clinical forethought about specific patient populations, (3) anticipation of risks for particular patients, and (4) seeing the unexpected.

Future think. Future think is the broadest category of this logic of practice. Anticipating likely immediate futures helps the clinician make good plans and decisions about preparing the environment so that responding rapidly to changes in the patient is possible. Without a sense of salience about anticipated signs and symptoms and preparing the environment, essential clinical judgments and timely interventions would be impossible in the typically fast pace of acute and intensive patient care. Future think governs the style and content of the nurse's attentiveness to

the patient. Whether in a fast-paced care environment or a slower-paced rehabilitation setting, thinking and acting with anticipated futures guide clinical thinking and judgment. Future think captures the way judgment is suspended in a predictive net of anticipation and preparing oneself and the environment for a range of potential events.

Clinical forethought about specific diagnoses and injuries. This habit of thought and action is so second nature to the experienced nurse that the new or inexperienced nurse may have difficulty finding out about what seems to other colleagues as "obvious" preparation for particular patients and situations. Clinical forethought involves much local specific knowledge about who is a good resource and how to marshal support services and equipment for particular patients.

Examples of preparing for specific patient populations are pervasive, such as anticipating the need for a pacemaker during surgery and having the equipment assembled ready for use to save essential time. Another example includes forecasting an accident victim's potential injuries, and recognizing that intubation might be needed.

Anticipation of crises, risks, and vulnerabilities for particular patients. This aspect of clinical forethought is central to knowing the particular patient, family, or community. Nurses situate the patient's problems almost like a topography of possibilities. This vital clinical knowledge needs to be communicated to other caregivers and across care borders. Clinical teaching could be improved by enriching curricula with narrative examples from actual practice, and by helping students recognize commonly occurring clinical situations in the simulation and clinical setting. For example, if a patient is hemodynamically unstable, then managing life-sustaining physiologic functions will be a main orienting goal. If the patient is agitated and uncomfortable, then attending to comfort needs in relation to hemodynamics will be a priority. Providing comfort measures turns out to be a central background practice for making clinical judgments and contains within it much judgment and experiential learning.

When clinical teaching is too removed from typical contingencies and strong clinical situations in practice, students will lack practice in active thinking-in-action in ambiguous clinical situations. In the following example, an anonymous student recounted her experiences of meeting a patient:

> I was used to different equipment and didn't know how things went, didn't know their routine, really. You can explain all you want in class, this is how it's going to be, but when you get there … . Kim was my first instructor and my patient that she assigned me to—I walked into the room and he had every tube imaginable. And so I was a little overwhelmed. It's not necessarily even that he was that critical … . She asked what tubes here have you seen? Well, I know peripheral lines. You taught me PICC [peripherally inserted central catheter] lines, and we just had that, but I don't really feel comfortable doing it by myself, without you watching to make sure that I'm flushing it right and how to assess it. He had a chest tube and I had seen chest tubes, but never really knew the depth of what you had to assess and how you make sure that it's all kosher and whatever. So she went through the chest tube and explained, it's just bubbling a little bit and that's okay. The site, check the site. The site looked okay and that she'd say if it wasn't okay, this is what it might look like … . He had a feeding tube. I had done feeding tubes but that was like a long time ago in my LPN experiences schooling. So I hadn't really done too much with the feeding stuff either … . He had a [nasogastric] tube, and knew pretty much about that and I think at the time it was

> clamped. So there were no issues with the suction or whatever. He had a Foley catheter. He had a feeding tube, a chest tube. I can't even remember but there were a lot.

As noted earlier, a central characteristic of a practice discipline is that a self-improving practice requires ongoing experiential learning. One way nurse educators can enhance clinical inquiry is by increasing pedagogies of experiential learning. Current pedagogies for experiential learning in nursing include extensive preclinical study, care planning, and shared postclinical debriefings where students share their experiential learning with their classmates. Experiential learning requires open learning climates where students can discuss and examine transitions in understanding, including their false starts, or their misconceptions in actual clinical situations. Nursing educators typically develop open and interactive clinical learning communities, so that students seem committed to helping their classmates learn from their experiences that may have been difficult or even unsafe. One anonymous nurse educator described how students extend their experiential learning to their classmates during a postclinical conference:

> So for example, the patient had difficulty breathing and the student wanted to give the meds instead of addressing the difficulty of breathing. Well, while we were sharing information about their patients, what they did that day, I didn't tell the student to say this, but she said, 'I just want to tell you what I did today in clinical so you don't do the same thing, and here's what happened.' Everybody's listening very attentively and they were asking her some questions. But she shared that. She didn't have to. I didn't tell her, you must share that in postconference or anything like that, but she just went ahead and shared that, I guess, to reinforce what she had learned that day but also to benefit her fellow students in case that thing comes up with them.

The teacher's response to this student's honesty and generosity exemplifies her own approach to developing an open community of learning. Focusing *only* on performance and on "being correct" prevents learning from breakdown or error and can dampen students' curiosity and courage to learn experientially.

Seeing the unexpected. One of the keys to becoming an expert practitioner lies in how the person holds past experiential learning and background habitual skills and practices. This is a skill of foregrounding attention accurately and effectively in response to the nature of situational demands. Bourdieu[29] calls the recognition of the situation central to practical reasoning. If nothing is routinized as a habitual response pattern, then practitioners will not function effectively in emergencies. Unexpected occurrences may be overlooked. However, if expectations are held rigidly, then subtle changes from the usual will be missed, and habitual, rote responses will inappropriately rule. The clinician must be flexible in shifting between what is in background and foreground. This is accomplished by staying curious and open. The clinical "certainty" associated with perceptual grasp is distinct from the kind of "certainty" achievable in scientific experiments and through measurements. Recognition of similar or paradigmatic clinical situations is similar to "face recognition" or recognition of "family resemblances." This concept is subject to faulty memory, false associative memories, and mistaken identities; therefore, such perceptual grasp is the beginning of curiosity and inquiry and not the end. Assessment and validation are required. In rapidly moving clinical situations, perceptual grasp is the starting point for clarification, confirmation, and action. Having the clinician say out loud how he or she is understanding the situation gives an opportunity for confirmation and disconfirmation from other clinicians present.[111] The relationship between foreground and

background of attention needs to be fluid, so that missed expectations allow the nurse to *see* the unexpected. For example, when the background rhythm of a cardiac monitor changes, the nurse notices, and what had been background tacit awareness becomes the foreground of attention. A hallmark of expertise is the ability to notice the unexpected.[20] Background expectations of usual patient trajectories form with experience. Tacit expectations for patient trajectories form that enable the nurse to notice subtle failed expectations and pay attention to early signs of unexpected changes in the patient's condition. Clinical expectations gained from caring for similar patient populations form a tacit clinical forethought that enable the experienced clinician to notice missed expectations. Alterations from implicit or explicit expectations set the stage for experiential learning, depending on the openness of the learner.

Conclusion

Learning to provide safe and quality health care requires technical expertise, the ability to think critically, experience, and clinical judgment. The high-performance expectation of nurses is dependent upon the nurses' continual learning, professional accountability, independent and interdependent decisionmaking, and creative problem-solving abilities.

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Chapter 7. The Evidence for Evidence-Based Practice Implementation

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Background

Overview of Evidence-Based Practice

Evidence-based health care practices are available for a number of conditions such as asthma, heart failure, and diabetes. However, these practices are not always implemented in care delivery, and variation in practices abound.[1–4] Traditionally, patient safety research has focused on data analyses to identify patient safety issues and to demonstrate that a new practice will lead to improved quality and patient safety.[5] Much less research attention has been paid to how to implement practices. Yet, only by putting into practice what is learned from research will care be made safer.[5] Implementing evidence-based safety practices are difficult and need strategies that address the complexity of systems of care, individual practitioners, senior leadership, and—ultimately—changing health care cultures to be evidence-based safety practice environments.[5]

Nursing has a rich history of using research in practice, pioneered by Florence Nightingale.[6–9] Although during the early and mid-1900s, few nurses contributed to this foundation initiated by Nightingale,[10] the nursing profession has more recently provided major leadership for improving care through application of research findings in practice.[11]

Evidence-based practice (EBP) is the conscientious and judicious use of current best evidence in conjunction with clinical expertise and patient values to guide health care decisions.[12–15] Best evidence includes empirical evidence from randomized controlled trials; evidence from other scientific methods such as descriptive and qualitative research; as well as use of information from case reports, scientific principles, and expert opinion. When enough research evidence is available, the practice should be guided by research evidence in conjunction with clinical expertise and patient values. In some cases, however, a sufficient research base may not be available, and health care decisionmaking is derived principally from nonresearch evidence sources such as expert opinion and scientific principles.[16] As more research is done in a specific area, the research evidence must be incorporated into the EBP.[15]

Models of Evidence-Based Practice

Multiple models of EBP are available and have been used in a variety of clinical settings.[16–36] Although review of these models is beyond the scope of this chapter, common elements of these models are selecting a practice topic (e.g., discharge instructions for individuals with heart failure), critique and syntheses of evidence, implementation, evaluation of the impact on patient care and provider performance, and consideration of the context/setting in which the practice is implemented.[15, 17] The learning that occurs during the process of translating research into practice is valuable information to capture and feed back into the process, so that others can adapt the evidence-based guideline and/or the implementation strategies.

A recent conceptual framework for maximizing and accelerating the transfer of research results from the Agency for Healthcare Research and Quality (AHRQ) patient safety research portfolio to health care delivery was developed by the dissemination subcommittee of the AHRQ Patient Safety Research Coordinating Committee.[37] This model is a synthesis of concepts from scientific information on knowledge transfer, social marketing, social and organizational innovation, and behavior change (see Figure 1).[37] Although the framework is portrayed as a series of stages, the authors of this framework do not believe that the knowledge transfer process is linear; rather, activities occur simultaneously or in different sequences, with implementation of EBPs being a multifaceted process with many actors and systems.

Steps of Evidence-Based Practice

Steps of promoting adoption of EBPs can be viewed from the perspective of those who conduct research or generate knowledge,[23, 37] those who use the evidence-based information in practice,[16, 31] and those who serve as boundary spanners to link knowledge generators with knowledge users.[19]

Steps of knowledge transfer in the AHRQ model[37] represent three major stages: (1) knowledge creation and distillation, (2) diffusion and dissemination, and (3) organizational adoption and implementation. These stages of knowledge transfer are viewed through the lens of researchers/creators of new knowledge and begin with determining what findings from the patient safety portfolio or individual research projects ought to be disseminated.

Knowledge creation and distillation is conducting research (with expected variation in readiness for use in health care delivery systems) and then packaging relevant research findings into products that can be put into action—such as specific practice recommendations—thereby increasing the likelihood that research evidence will find its way into practice.[37] It is essential that the knowledge distillation process be informed and guided by end users for research findings to be implemented in care delivery. The criteria used in knowledge distillation should include perspectives of the end users (e.g., transportability to the real-world health care setting, feasibility, volume of evidence needed by health care organizations and clinicians), as well as traditional knowledge generation considerations (e.g., strength of the evidence, generalizability).

Diffusion and dissemination involves partnering with professional opinion leaders and health care organizations to disseminate knowledge that can form the basis of action (e.g., essential elements for discharge teaching for hospitalized patient with heart failure) to potential users. Dissemination partnerships link researchers with intermediaries that can function as knowledge brokers and connectors to the practitioners and health care delivery organizations. Intermediaries can be professional organizations such as the National Patient Safety Foundation or multidisciplinary knowledge transfer teams such as those that are effective in disseminating research-based cancer prevention programs. In this model, dissemination partnerships provide an authoritative seal of approval for new knowledge and help identify influential groups and communities that can create a demand for application of the evidence in practice. Both mass communication and targeted dissemination are used to reach audiences with the anticipation that early users will influence the latter adopters of the new usable, evidence-based research findings. Targeted dissemination efforts must use multifaceted dissemination strategies, with an emphasis on channels and media that are most effective for particular user segments (e.g., nurses, physicians, pharmacists).

End user adoption, implementation, and institutionalization is the final stage of the knowledge transfer process.[37] This stage focuses on getting organizations, teams, and individuals

to adopt and consistently use evidence-based research findings and innovations in everyday practice. Implementing and sustaining EBPs in health care settings involves complex interrelationships among the EBP topic (e.g., reduction of medication errors), the organizational social system characteristics (such as operational structures and values, the external health care environment), and the individual clinicians.[35, 37–39] A variety of strategies for implementation include using a change champion in the organization who can address potential implementation challenges, piloting/trying the change in a particular patient care area of the organization, and using multidisciplinary implementation teams to assist in the practical aspects of embedding innovations into ongoing organizational processes.[35, 37] Changing practice takes considerable effort at both the individual and organizational level to apply evidence-based information and products in a particular context.[22] When improvements in care are demonstrated in the pilot studies and communicated to other relevant units in the organization, key personnel may then agree to fully adopt and sustain the change in practice. Once the EBP change is incorporated into the structure of the organization, the change is no longer considered an innovation but a standard of care.[22, 37]

In comparison, other models of EBP (e.g., Iowa Model of Evidence-based Practice to Promote Quality of Care[16]) view the steps of the EBP process from the perspective of clinicians and/or organizational/clinical contexts of care delivery. When viewing steps of the EBP process through the lens of an end user, the process begins with selecting an area for improving care based on evidence (rather than asking what findings ought to be disseminated); determining the priority of the potential topic for the organization; formulating an EBP team composed of key stakeholders; finding, critiquing, and synthesizing the evidence; setting forth EBP recommendations, with the type and strength of evidence used to support each clearly documented; determining if the evidence findings are appropriate for use in practice; writing an EBP standard specific to the organization; piloting the change in practice; implementing changes in practice in other relevant practice areas (depending on the outcome of the pilot); evaluating the EBP changes; and transitioning ongoing quality improvement (QI) monitoring, staff education, and competency review of the EBP topic to appropriate organizational groups as defined by the organizational structure.[15, 40] The work of EBP implementation from the perspective of the end user is greatly facilitated by efforts of AHRQ, professional nursing organizations (e.g., Oncology Nursing Society), and others that distill and package research findings into useful products and tools for use at the point of care delivery.

When the clinical questions of end users can be addressed through use of existing evidence that is packaged with end users in mind, steps of the EBP process take less time and more effort can be directed toward the implementation, evaluation, and sustainability components of the process. For example, finding, critiquing, and synthesizing the evidence; setting forth EBP recommendations with documentation of the type and strength of evidence for each recommendation; and determining appropriateness of the evidence for use in practice are accelerated when the knowledge-based information is readily available. Some distilled research findings also include quick reference guides that can be used at the point of care and/or integrated into health care information systems, which also helps with implementation.[41, 42]

Translation Science: An Overview

Translation science is the investigation of methods, interventions, and variables that influence adoption by individuals and organizations of EBPs to improve clinical and operational decisionmaking in health care.[35, 43–46] This includes testing the effect of interventions on

promoting and sustaining adoption of EBPs. Examples of translation studies include describing facilitators and barriers to knowledge uptake and use, organizational predictors of adherence to EBP guidelines, attitudes toward EBPs, and defining the structure of the scientific field.[11, 47–49]

Translation science must be guided by a conceptual model that organizes the strategies being tested, elucidates the extraneous variables (e.g., behaviors and facilitators) that may influence adoption of EBPs (e.g., organizational size, characteristics of users), and builds a scientific knowledge base for this field of inquiry.[15, 50] Conceptual models used in the translating-research-into-practice studies funded by AHRQ were adult learning, health education, social influence, marketing, and organizational and behavior theories.[51] Investigators have used Rogers's Diffusion of Innovation model,[35, 39, 52–55] the Promoting Action on Research Implementation in Health Services (PARIHS) model,[29] the push/pull framework,[23, 56, 57] the decisionmaking framework,[58] and the Institute for Healthcare Improvement (IHI) model[59] in translation science.

Study findings regarding evidence-based practices in a diversity of health care settings are building an empirical foundation of translation science.[19, 43, 51, 60–83] These investigations and others[18, 84–86] provide initial scientific knowledge to guide us in how to best promote use of evidence in practice. To advance knowledge about promoting and sustaining adoption of EBPs in health care, translation science needs more studies that test translating research into practice (TRIP) interventions: studies that investigate what TRIP interventions work, for whom, in what circumstances, in what types of settings; and studies that explain the underlying mechanisms of effective TRIP interventions.[35, 49, 79, 87] Partnership models, which encourage ongoing interaction between researchers and practitioners, may be the way forward to carry out such studies.[56] Challenges, issues, methods, and instruments used in translation research are described elsewhere.[11, 19, 49, 78, 88–97]

Research Evidence

What Is Known About Implementing Evidence-Based Practices?

Multifaceted implementation strategies are needed to promote use of research evidence in clinical and administrative health care decisionmaking.[15, 22, 37, 45, 64, 72, 77, 79, 98, 99] Although Grimshaw and colleagues[65] suggest that multifaceted interventions are no more effective than single interventions, context (site of care delivery) was not incorporated in the synthesis methodology. As noted by others, the same TRIP intervention may meet with varying degrees of effectiveness when applied in different contexts.[35, 49, 79, 80, 87, 100, 101] Implementation strategies also need to address *both* the individual practitioner and organizational perspective.[15, 22, 37, 64, 72, 77, 79, 98] When practitioners decide individually what evidence to use in practice, considerable variability in practice patterns result,[71] potentially resulting in adverse patient outcomes.

For example, an "individual" perspective of EBP would leave the decision about use of evidence-based endotracheal suctioning techniques to each nurse and respiratory therapist. Some individuals may be familiar with the research findings for endotracheal suctioning while others may not. This is likely to result in different and conflicting practices being used as people change shifts every 8 to 12 hours. From an organizational perspective, endotracheal suctioning policies and procedures based on research are written, the evidence-based information is integrated into the clinical information systems, and adoption of these practices by nurses and other practitioners is systematically promoted in the organization. This includes assuring that practitioners have the

necessary knowledge, skills, and equipment to carry out the evidence-based endotracheal suctioning practice. The organizational governance supports use of these practices through various councils and committees such as the Practice Committee, Staff Education Committee, and interdisciplinary EBP work groups.

The Translation Research Model,[35] built on Rogers's seminal work on diffusion of innovations,[39] provides a guiding framework for testing and selecting strategies to promote adoption of EBPs. According to the Translation Research Model, adoption of innovations such as EBPs are influenced by the nature of the innovation (e.g., the type and strength of evidence, the clinical topic) and the manner in which it is communicated (disseminated) to members (nurses) of a social system (organization, nursing profession).[35] Strategies for promoting adoption of EBPs must address these four areas (nature of the EBP topic; users of the evidence; communication; social system) within a context of participative change (see Figure 2)**.** This model provided the framework for a multisite study that tested the effectiveness of a multifaceted TRIP intervention designed to promote adoption of evidence-based acute pain management practices for hospitalized older adults. The intervention improved the quality of acute pain management practices and reduced costs.[81] The model is currently being used to test the effectiveness of a multifaceted TRIP intervention to promote evidence-based cancer pain management of older adults in home hospice settings.[*] This guiding framework is used herein to overview what is known about implementation interventions to promote use of EBPs in health care systems (see Evidence Table).

Nature of the Innovation or Evidence-Based Practice

Characteristics of an innovation or EBP topic that affect adoption include the relative advantage of the EBP (e.g., effectiveness, relevance to the task, social prestige); the compatibility with values, norms, work, and perceived needs of users; and complexity of the EBP topic.[39] For example, EBP topics that are perceived by users as relatively simple (e.g., influenza vaccines for older adults) are more easily adopted in less time than those that are more complex (acute pain management for hospitalized older adults). Strategies to promote adoption of EBPs related to characteristics of the topic include practitioner review and "reinvention" of the EBP guideline to fit the local context, use of quick reference guides and decision aids, and use of clinical reminders.[53, 59, 60, 65, 74, 82, 102–107] An important principle to remember when planning implementation of an EBP is that the attributes of the EBP topic as perceived by users and stakeholders (e.g., ease of use, valued part of practice) are neither stable features nor sure determinants of their adoption. Rather it is the interaction among the characteristics of the EBP topic, the intended users, and a particular context of practice that determines the rate and extent of adoption.[22, 35, 39]

Studies suggest that clinical systems, computerized decision support, and prompts that support practice (e.g., decisionmaking algorithms, paper reminders) have a positive effect on aligning practices with the evidence base.[15, 51, 65, 74, 80, 82, 102, 104, 107–110] Computerized knowledge management has consistently demonstrated significant improvements in provider performance and patient outcomes.[82] Feldman and colleagues, using a just-in-time e-mail reminder in home health care, have demonstrated (1) improvements in evidence-based care and outcomes for patients with heart failure,[64, 77] and (2) reduced pain intensity for cancer patients.[75] Clinical information systems should deploy the evidence base to the point of care and incorporate

[*] Principal Investigator: Keela Herr (R01 grant no. CA115363-01; National Cancer Institute (NCI))

computer decision-support software that integrates evidence for use in clinical decisionmaking about individual patients.[40, 104, 111–114] There is still much to learn about the "best" manner of deploying evidence-based information through electronic clinical information systems to support evidence-based care.[115]

Methods of Communication

Interpersonal communication channels, methods of communication, and influence among social networks of users affect adoption of EBPs.[39] Use of mass media, opinion leaders, change champions, and consultation by experts along with education are among strategies tested to promote use of EBPs. Education is necessary but not sufficient to change practice, and didactic continuing education alone does little to change practice behavior.[61, 116] There is little evidence that interprofessional education as compared to discipline-specific education improves EBP.[117] Interactive education, used in combination with other practice-reinforcing strategies, has more positive effects on improving EBP than didactic education alone.[66, 68, 71, 74, 118, 119] There is evidence that mass media messages (e.g., television, radio, newspapers, leaflets, posters and pamphlets), targeted at the health care consumer population, have some effect on use of health services for the targeted behavior (e.g., colorectal cancer screening). However, little empirical evidence is available to guide framing of messages communicated through planned mass media campaigns to achieve the intended change.[120]

Several studies have demonstrated that opinion leaders are effective in changing behaviors of health care practitioners,[22, 68, 79, 100, 116, 121–123] especially in combination with educational outreach or performance feedback. Opinion leaders are from the local peer group, viewed as a respected source of influence, considered by associates as technically competent, and trusted to judge the fit between the innovation and the local situation.[39, 116, 121, 124–127] With their wide sphere of influence across several microsystems/units, opinion leaders' use of the innovation influences peers and alters group norms.[39,128] The key characteristic of an opinion leader is that he or she is trusted to evaluate new information in the context of group norms. Opinion leadership is multifaceted and complex, with role functions varying by the circumstances, but few successful projects to implement innovations in organizations have managed without the input of identifiable opinion leaders.[22, 35, 39, 81, 96] Social interactions such as "hallway chats," one-on-one discussions, and addressing questions are important, yet often overlooked components of translation.[39, 59] Thus, having local opinion leaders discuss the EBPs with members of their peer group is necessary to translate research into practice. If the EBP that is being implemented is interdisciplinary in nature, discipline-specific opinion leaders should be used to promote the change in practice.[39]

Change champions are also helpful for implementing innovations.[39, 49, 81, 129–131] They are practitioners within the local group setting (e.g., clinic, patient care unit) who are expert clinicians, passionate about the innovation, committed to improving quality of care, and have a positive working relationship with other health care professionals.[39, 125, 131, 132] They circulate information, encourage peers to adopt the innovation, arrange demonstrations, and orient staff to the innovation.[49, 130] The change champion believes in an idea; will not take "no" for an answer; is undaunted by insults and rebuffs; and, above all, persists.[133] Because nurses prefer interpersonal contact and communication with colleagues rather than Internet or traditional sources of practice knowledge,[134–137] it is imperative that one or two change champions be identified for each patient care unit or clinic where the change is being made for EBPs to be enacted by direct care providers.[81, 138] Conferencing with opinion leaders and change champions

periodically during implementation is helpful to address questions and provide guidance as needed.[35, 66, 81, 106]

Because nurses' preferred information source is through peers and social interactions,[134–137, 139, 140] using a core group in conjunction with change champions is also helpful for implementing the practice change.[16, 110, 141] A core group is a select group of practitioners with the mutual goal of disseminating information regarding a practice change and facilitating the change by other staff in their unit/microsystem.[142] Core group members represent various shifts and days of the week and become knowledgeable about the scientific basis for the practice; the change champion educates and assists them in using practices that are aligned with the evidence. Each member of the core group, in turn, takes the responsibility for imparting evidence-based information and effecting practice change with two or three of their peers. Members assist the change champion and opinion leader with disseminating the EBP information to other staff, reinforce the practice change on a daily basis, and provide positive feedback to those who align their practice with the evidence base.[15] Using a core-group approach in conjunction with a change champion results in a critical mass of practitioners promoting adoption of the EBP.[39]

Educational outreach, also known as academic detailing, promotes positive changes in practice behaviors of nurses and physicians.[22, 64, 66, 71, 74, 75, 77, 81, 119, 143] Academic detailing is done by a topic expert, knowledgeable of the research base (e.g., cancer pain management), who may be external to the practice setting; he or she meets one-on-one with practitioners in their setting to provide information about the EBP topic. These individuals are able to explain the research base for the EBPs to others and are able to respond convincingly to challenges and debates.[22] This strategy may include providing feedback on provider or team performance with respect to selected EBP indicators (e.g., frequency of pain assessment).[66, 81, 119]

Users of the Innovation or Evidence-Based Practice

Members of a social system (e.g., nurses, physicians, clerical staff) influence how quickly and widely EBPs are adopted.[39] Audit and feedback, performance gap assessment (PGA), and trying the EBP are strategies that have been tested.[15, 22, 65, 66, 70–72, 81, 98, 124, 144] PGA and audit and feedback have consistently shown a positive effect on changing practice behavior of providers.[65, 66, 70, 72, 81, 98, 124, 144, 145] PGA (baseline practice performance) informs members, at the *beginning* of change, about a practice performance and opportunities for improvement. Specific practice indicators selected for PGA are related to the practices that are the focus of evidence-based practice change, such as every-4-hour pain assessment for acute pain management.[15, 66, 81]

Auditing and feedback are ongoing processes of using and assessing performance indicators (e.g., every-4-hour pain assessment), aggregating data into reports, and discussing the findings with practitioners *during* the practice change.[22, 49, 66, 70, 72, 81, 98, 145] This strategy helps staff know and see how their efforts to improve care and patient outcomes are progressing throughout the implementation process. Although there is no clear empirical evidence for how to provide audit and feedback,[70, 146] effects may be larger when clinicians are active participants in implementing change and discuss the data rather than being passive recipients of feedback reports.[67, 70] Qualitative studies provide some insight into use of audit and feedback.[60, 67] One study on use of data feedback for improving treatment of acute myocardial infarction found that (1) feedback data must be perceived by physicians as important and valid, (2) the data source and timeliness of data feedback are critical to perceived validity, (3) time is required to establish credibility of data within a hospital, (4) benchmarking improves the validity of the data feedback, and (5) physician leaders can enhance the effectiveness of data feedback. Data feedback that profiles an

individual physician's practices can be effective but may be perceived as punitive; data feedback must persist to sustain improved performance; and effectiveness of data feedback is intertwined with the organizational context, including physician leadership and organizational culture.[60] Hysong and colleagues[67] found that high-performing institutions provided timely, individualized, nonpunitive feedback to providers, whereas low performers were more variable in their timeliness and nonpunitiveness and relied more on standardized, facility-level reports. The concept of useful feedback emerged as the core concept around which timeliness, individualization, nonpunitiveness, and customizability are important.

Users of an innovation usually try it for a period of time before adopting it in their practice.[22, 39, 147] When "trying an EBP" (piloting the change) is incorporated as part of the implementation process, users have an opportunity to use it for a period of time, provide feedback to those in charge of implementation, and modify the practice if necessary.[148] Piloting the EBP as part of implementation has a positive influence on the extent of adoption of the new practice.[22, 39, 148]

Characteristics of users such as educational preparation, practice specialty, and views on innovativeness may influence adoption of an EBP, although findings are equivocal.[27, 39, 130, 149–153] Nurses' disposition to critical thinking is, however, positively correlated with research use,[154] and those in clinical educator roles are more likely to use research than staff nurses or nurse managers.[155]

Social System

Clearly, the social system or context of care delivery matters when implementing EBPs.[2, 30, 33, 39, 60, 84, 85, 91, 92, 101, 156–163] For example, investigators demonstrated the effectiveness of a prompted voiding intervention for urinary incontinence in nursing homes, but sustaining the intervention in day-to-day practice was limited when the responsibility of carrying out the intervention was shifted to nursing home staff (rather than the investigative team) and required staffing levels in excess of a majority of nursing home settings.[164] This illustrates the importance of embedding interventions into ongoing processes of care.

Several organizational factors affect adoption of EBPs.[22, 39, 79, 134, 165–167] Vaughn and colleagues[101] demonstrated that organizational resources, physician full-time employees (FTEs) per 1,000 patient visits, organizational size, and whether the facility was located in or near a city affected use of evidence in the health care system of the Department of Veterans Affairs (VA). Large, mature, functionally differentiated organizations (e.g., divided into semiautonomous departments and units) that are specialized, with a focus of professional knowledge, slack resources to channel into new projects, decentralized decisionmaking, and low levels of formalization will more readily adopt innovations such as new practices based on evidence. Larger organizations are generally more innovative because size increases the likelihood that other predictors of innovation adoption—such as slack financial and human resources and differentiation—will be present. However, these organizational determinants account for only about 15 percent of the variation in innovation adoption between comparable organizations.[22] Adler and colleagues[168] hypothesize that while more structurally complex organizations may be more innovative and hence adopt EBPs relatively early, less structurally complex organizations may be able to diffuse EBPs more effectively. Establishing semiautonomous teams is associated with successful implementation of EBPs, and thus should be considered in managing organizational units.[168–170]

As part of the work of implementing EBPs, it is important that the social system—unit, service line, or clinic—ensures that policies, procedures, standards, clinical pathways, and documentation systems support the use of the EBPs.[49, 68, 72, 73, 103, 140, 171] Documentation forms or clinical information systems may need revision to support changes in practice; documentation systems that fail to readily support the new practice thwart change.[82]

Absorptive capacity for new knowledge is another social system factor that affects adoption of EBPs. Absorptive capacity is the knowledge and skills to enact the EBPs; the strength of evidence alone will not promote adoption. An organization that is able to systematically identify, capture, interpret, share, reframe, and recodify new knowledge, and put it to appropriate use, will be better able to assimilate EBPs.[82, 103, 172, 173] A learning organizational culture and proactive leadership that promotes knowledge sharing are important components of building absorptive capacity for new knowledge.[66, 139, 142, 174] Components of a receptive context for EBP include strong leadership, clear strategic vision, good managerial relations, visionary staff in key positions, a climate conducive to experimentation and risk taking, and effective data capture systems. Leadership is critical in encouraging organizational members to break out of the convergent thinking and routines that are the norm in large, well-established organizations.[4, 22, 39, 122, 148, 163, 175]

An organization may be generally amenable to innovations but not ready or willing to assimilate a particular EBP. Elements of system readiness include tension for change, EBP-system fit, assessment of implications, support and advocacy for the EBP, dedicated time and resources, and capacity to evaluate the impact of the EBP during and following implementation. If there is tension around specific work or clinical issues and staff perceive that the situation is intolerable, a potential EBP is likely to be assimilated if it can successfully address the issues, and thereby reduce the tension.[22, 175]

Assessing and structuring workflow to fit with a potential EBP is an important component of fostering adoption. If implications of the EBP are fully assessed, anticipated, and planned for, the practice is more likely to be adopted.[148, 162, 176] If supporters for a specific EBP outnumber and are more strategically placed within the organizational power base than opponents, the EBP is more likely to be adopted by the organization.[60, 175] Organizations that have the capacity to evaluate the impact of the EBP change are more likely to assimilate it. Effective implementation needs both a receptive climate and a good fit between the EBP and intended adopters' needs and values.[22, 60, 140, 175, 177]

Leadership support is critical for promoting use of EBPs.[33, 59, 72, 85, 98, 122, 178–181] This support, which is expressed verbally, provides necessary resources, materials, and time to fulfill assigned responsibilities.[148, 171, 182, 183] Senior leaders need to create an organizational mission, vision, and strategic plan that incorporate EBP; implement performance expectations for staff that include EBP work; integrate the work of EBP into the governance structure of the health care system; demonstrate the value of EBPs through administrative behaviors; and establish explicit expectations that nurse leaders will create microsystems that value and support clinical inquiry.[122, 183, 184]

A recent review of organizational interventions to implement EBPs for improving patient care examined five major aspects of patient care. The review suggests that revision of professional roles (changing responsibilities and work of health professionals such as expanding roles of nurses and pharmacists) improved processes of care, but it was less clear about the effect on improvement of patient outcomes. Multidisciplinary teams (collaborative practice teams of physicians, nurses, and allied health professionals) treating mostly patients with prevalent

chronic diseases resulted in improved patient outcomes. Integrated care services (e.g., disease management and case management) resulted in improved patient outcomes and cost savings. Interventions aimed at knowledge management (principally via use of technology to support patient care) resulted in improved adherence to EBPs and patient outcomes. The last aspect, quality management, had the fewest reviews available, with the results uncertain. A number of organizational interventions were not included in this review (e.g., leadership, process redesign, organizational learning), and the authors note that the lack of a widely accepted taxonomy of organizational interventions is a problem in examining effectiveness across studies.[82]

An organizational intervention that is receiving increasing attention is tailored interventions to overcome barriers to change.[162, 175, 185] This type of intervention focuses on first assessing needs in terms of what is causing the gap between current practice and EBP for a specified topic, what behaviors and/or mechanism need to change, what organizational units and persons should be involved, and identification of ways to facilitate the changes. This information is then used in tailoring an intervention for the setting that will promote use of the specified EBP. Based on a recent systematic review, effectiveness of tailored implementation interventions remains uncertain.[185]

In summary, making an evidence-based change in practice involves a series of action steps and a complex, nonlinear process. Implementing the change will take several weeks to months, depending on the nature of the practice change. Increasing staff knowledge about a specific EBP and passive dissemination strategies are not likely to work, particularly in complex health care settings. Strategies that seem to have a positive effect on promoting use of EBPs include audit and feedback, use of clinical reminders and practice prompts, opinion leaders, change champions, interactive education, mass media, educational outreach/academic detailing, and characteristics of the context of care delivery (e.g., leadership, learning, questioning). It is important that senior leadership and those leading EBP improvements are aware of change as a process and continue to encourage and teach peers about the change in practice. The new practice must be continually reinforced and sustained or the practice change will be intermittent and soon fade, allowing more traditional methods of care to return.[15]

Practice Implications From Translation Science

Principles of Evidence-Based Practice for Patient Safety

Several translation science principles are informative for implementing patient safety initiatives:

- First, consider the context and engage health care personnel who are at the point of care in selecting and prioritizing patient safety initiatives, clearly communicating the evidence base (strength and type) for the patient safety practice topic(s) and the conditions or setting to which it applies. These communication messages need to be carefully designed and targeted to each stakeholder user group.
- Second, illustrate, through qualitative or quantitative data (e.g., near misses, sentinel events, adverse events, injuries from adverse events), the reason the organization and individuals within the organization should commit to an evidence-based safety practice topic. Clinicians tend to be more engaged in adopting patient safety initiatives when they understand the evidence base of the practice, in contrast to administrators saying, "We must do this because it is an external regulatory requirement." For example, it is critical

to converse with busy clinicians about the evidence-based rationale for doing fall-risk assessment, and to help them understand that fall-risk assessment is an external regulatory agency expectation because the strength of the evidence supports this patient safety practice.

- Third, didactic education alone is never enough to change practice; one-time education on a specific safety initiative is not enough. Simply improving knowledge does not necessarily improve practice. Rather, organizations must invest in the tools and skills needed to create a culture of evidence-based patient safety practices where questions are encouraged and systems are created to make it easy to do the right thing.
- Fourth, the context of EBP improvements in patient safety need to be addressed at each step of the implementation process; piloting the change in practice is essential to determine the fit between the EBP patient safety information/innovation and the setting of care delivery. There is no one way to implement, and what works in one agency may need modification to fit the organizational culture of another context.
- Finally, it is important to evaluate the processes and outcomes of implementation. Users and stakeholders need to know that the efforts to improve patient safety have a positive impact on quality of care. For example, if a new barcoding system is being used to administer blood products, it is imperative to know that the steps in the process are being followed (process indicators) and that the change in practice is resulting in fewer blood product transfusion errors (outcome indicators).

Research Implications

Translation science is young, and although there is a growing body of knowledge in this area, we have, to date, many unanswered questions. These include the type of audit and feedback (e.g., frequency, content, format) strategies that are most effective, the characteristics of opinion leaders that are critical for success, the role of specific context variables, and the combination of strategies that are most effective. We also know very little about use of tailored implementation interventions, or the key context attributes to assess and use in developing and testing tailored interventions. The types of clinical reminders that are most effective for making EBP knowledge available at the point of care require further empirical explanation. We also know very little about the intensity and intervention dose of single and multifaceted strategies that are effective for promoting and sustaining use of EBPs or how the effectiveness differs by type of topic (e.g., simple versus complex). Only recently has the context of care delivery been acknowledged as affecting use of evidence, and further empirical work is needed in this area to understand how complex adaptive systems of practice incorporate knowledge acquisition and use. Lastly, we do not know what strategies or combination of strategies work for whom, in what context, why they work in some settings or cases and not others, and what is the mechanism by which these strategies or combination of strategies work.

This is an exciting area of investigation that has a direct impact on implementing patient safety practices. In planning investigations, researchers must use a conceptual model to guide the research and add to the empirical and theoretical understanding of this field of inquiry. Additionally, funding is needed for implementation studies that focus on evidence-based patient safety practices as the topic of concern. To generalize empirical findings from patient safety implementation studies, we must have a better understanding of what implementation strategies work, with whom, and in what types of settings, and we must investigate the underlying

mechanisms of these strategies. This is likely to require mixed methods, a better understanding of complexity science, and greater appreciation for nontraditional methods and realistic inquiry.[87]

Conclusion

Although the science of translating research into practice is fairly new, there is some guiding evidence of what implementation interventions to use in promoting patient safety practices. However, there is no magic bullet for translating what is known from research into practice. To move evidence-based interventions into practice, several strategies may be needed. Additionally, what works in one context of care may or may not work in another setting, thereby suggesting that context variables matter in implementation.[80]

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Search Strategy

Several electronic databases were searched (MEDLINE®, CINAHL®, PubMed®) using terms of evidence-based practice research, implementation research, and patient safety. (The terms "quality improvement" or "quality improvement intervention research" were not used.) The Cochrane Collaboration–Cochrane Reviews was also searched to look for systematic reviews of specific implementation strategies, and the *Journal of Implementation Science* was also reviewed. I also requested the final reports of the TRIP I and TRIP II studies funded by AHRQ. Classic articles known to the author were also included in this chapter (e.g., Locock et al.[123]).

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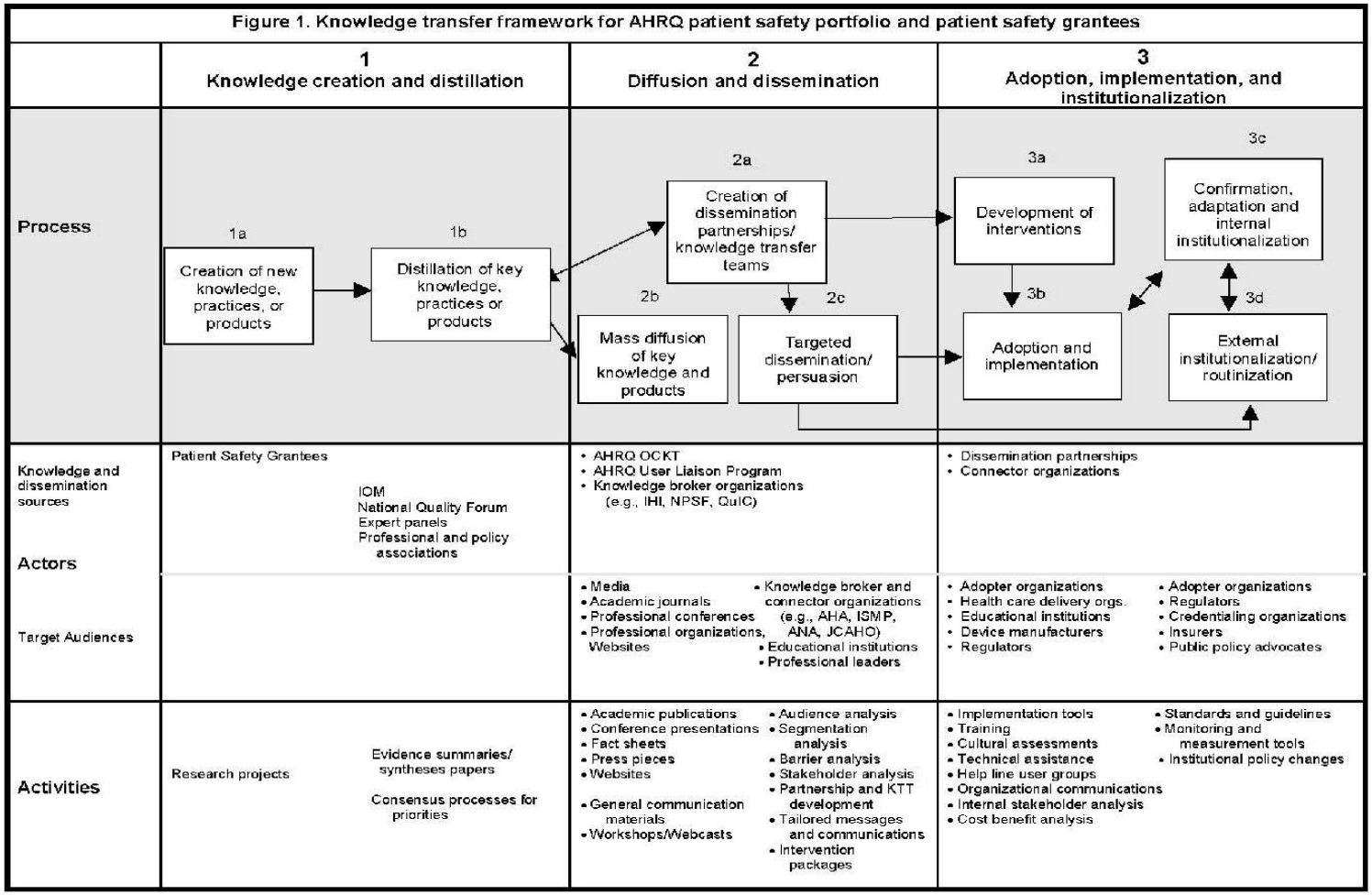
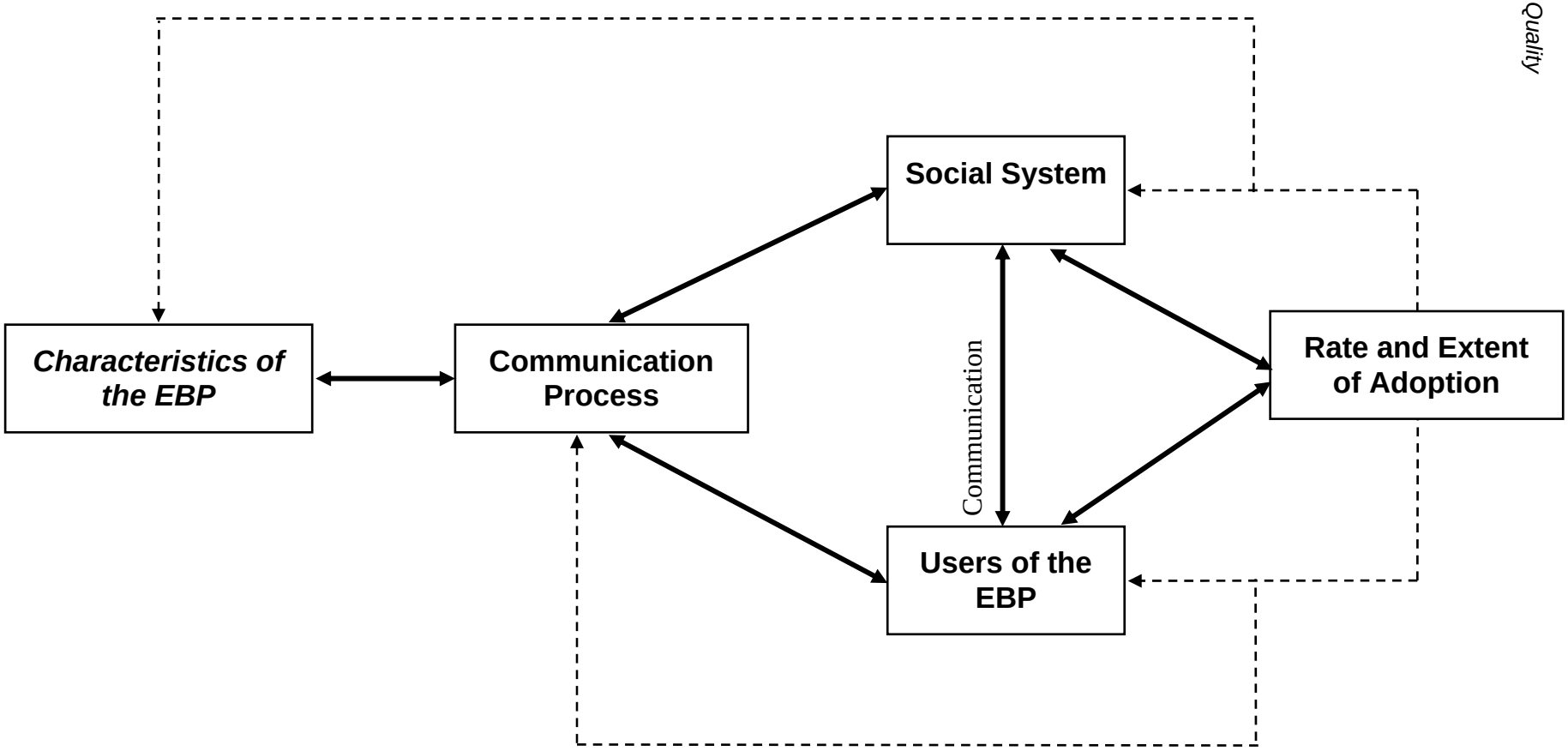
Figure 1. AHRQ Model of Knowledge Transfer



Adapted from Nieva, V., Murphy, R., Ridley, N., et al.[37] Used with permission. http://www.ahrq.gov/qual/advances/

Figure 2.* Implementation Model

Redrawn from Rogers EM. Diffusion of innovations. 5th ed. New York: The Free Press; 2003; Titler MG, Everett LQ. Translating research into practice: considerations for critical care investigators. Crit Care Nurs Clin North Am 2001a;13(4):587-604. (Copyright of this model retained by Marita Titler.)



Evidence Table. Evidence-Based Practice in Nursing

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Berner 2003[121]	Local opinion leaders.	Group randomized controlled trial (RCT). Evidence level 2.	RCT 3 study arms: no intervention, traditional health care QI; opinion leader (OL) plus QI (level 2). Outcomes = 6 evidence-based quality indicators for 1994 unstable angina guidelines (level 2).	Hospitals in Alabama. Patients admitted to an Alabama hospital during 1997–98 (baseline) and 1999–2000 (followup) with ICD-9 CM codes of unstable angina, angina pectoris, coronary artery disease, and chest pain unspecified. Mean age of patients was >70 years of age.	Peer nominated opinion leader added to a Centers for Medicare and Medicaid Services (CMS) QI intervention.	OL treatment effects (over QI group) found for antiplatelet medication within 24 hours and heparin use (2 of 5 indicators).

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Bootsmiller 2004[103]	Assess the implementation methods for 4 clinical practice guidelines (CPGs) in the VA health care system.	Retrospective cohort study. Evidence level 5.	Survey methods with questionnaire sent to 416 quality managers, primary care administrators, or others involved with guideline implementation in primary care at 143 VA medical centers with primary care clinics (level 9). Modified Dillman method was used. Outcomes: methods used to implement guidelines (level 4).	Primary care clinics of VA medical centers. Study population is individual responsible for guideline implementation. 242 surveys returned from 130 hospitals. CPGs were chronic obstructive pulmonary disease (COPD), diabetes, heart failure, and major depressive disorder.	Total number of interventions used were counted and type of interventions used to implement CPGs were categorized as consistently effective, variably effective, and minimally effective, based on Bero's categories: Consistently effective: - Forms created/revised - Computer interactive education - Internet discussion groups - Responsibilities of nonphysicians changed academic detailing Variably effective: - CPG workgroup - Clinical meetings to discuss CPG Minimally effective: - Providers receive brief summary - Providers receive CPG - Providers receive pocket guide - Storyboards - Instructional tape of CPG - Grand rounds	Commonly used approaches were clinical meetings to discuss guidelines (variably effective/Bero's classification), provider receipt of brief summary (minimally effective classification), forms created or revised (consistently effective classification), responsibilities of nonphysicians revised (consistently effective classification). Most facilities used 4–7 approaches. Consistently and minimally effective approaches were used most frequently. Strategies used together almost always included one consistently effective approach.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Bradley 2004[60]	Describe the implementation process for the Hospital Elder Life Program (HELP)—an evidence-based program for improving care of older patients.	Descriptive prospective study.	Qualitative analyses of implementation process at the beginning of implementation and every 6 months for up to 18 months.	8 hospitals implementing HELP. In-depth, open-ended interviews were conducted by telephone with physicians, nurses, volunteers, and administrative staff involved in the HELP implementation.		Major themes in implementing the HELP program were (1) gain internal support for the program, recognizing diverse requirements and goals; (2) ensure effective clinical leadership in multiple roles; (3) integrate with existing geriatric programs to foster coordination rather than competition; (4) balance program fidelity with hospital-specific circumstances; (5) document and publicize positive outcomes; (6) maintain momentum while changing practice and shifting organizational culture.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Bradley 2004[177]	Identify key themes about effective approaches for data feedback as well as pitfalls to avoid in using data feedback to support performance improvement efforts.	Retrospective cohort study. Evidence level 5.	Qualitative study with open-ended interviews of clinical and administrative staff at 8 hospitals representing a range of sizes, geographical regions, and beta-blocker use rate after AMI (level 9). Outcomes = key themes in use of data feedback.	8 hospitals. Interviewed physicians (n = 14), nurses (n = 15), quality management (n = 11), and administrative (n = 5) staff who were identified as key in improving care of patients with AMI.	Data feedback for improving performance of beta-blocker use after AMI.	7 major themes: Data must be perceived by physicians as valid to motivate change. It takes time to develop credibility of data within a hospital. The source and timeliness of the data are critical to perceived validity. Benchmarking improves the validity of the data feedback. Physician leaders can enhance the effectiveness of data feedback. Data feedback that profiles an individual physician's practices can be effective but may be perceived as punitive. Data feedback must persist to sustain improved performance. Effectiveness of data feedback might be intertwined with the organizational context, including physician leadership and organizational culture.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Carter 2005[61]	Evaluation of the relationship between physicians' knowledge of hypertension guidelines and blood pressure (BP) control in their patients.	Cross-sectional study	Cross-sectional study of physicians' knowledge about Joint National Committee (JNC) 7 hypertension guidelines (level 4). Outcomes were BP values of patients each physician treated.	Study setting was two academic primary care clinics located in the same academic medical center. The sample was 32 primary care physicians and 613 patients they treated. Mean age of physicians was 41 years (Standard Deviation [SD]. = 10.9), majority were men (66%).	Association between physician knowledge and BP control. Covariates of presence of diabetes, patient age.	There was a strong inverse relationship between BP control rates and correct responses by physicians on the knowledge test (r = -0.524; *p* = .002). Strong correlation was also found between correct responses on the knowledge survey and a higher mean systolic BP (r = 0.453; *p* = .009). When the covariates of patient age and diabetes were added to the model, there was no longer a significant association between physician knowledge and BP control. However, the correlation (in the multivariate model) was still in the same direction; for every 5 points better on the knowledge test, there was a 16% decrease in the rate of BP control (*p* = .13), and for every 10 years increase in patient age, there was a 16% decrease in BP control (*p* = .04).

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Chin 2004[62, 186]	To determine the additive effect of additional support for organizational change techniques and chronic care management as they are added to the Health Disparities Collaborative initiatives to improve diabetes care in community health centers.	RCT	34 centers were randomized to a standardized intensity arm (Health Disparities Collaborative initiatives) or high intensity arm. (level 2). Outcomes included process of care measures; laboratory values based on American Diabetes Association (ADA) recommendations; and patient surveys of satisfaction with provider's communication style and overall care, attitudes about interacting with providers, knowledge of ADA recommendations, and provider performance of key processes of care (levels 1 and 2).	34 community health centers from the Midwest or West Central clusters that participated in the 1998–99 or 1999–2000 Diabetes Collaborative of the Bureau of Primary Health Care in Improving Diabetes Care Collaboratively in the Community. These centers care for the medically underserved. In the standard arm, there were 843 patients at baseline and 665 in the followup standard intensity group. 993 patients were in the high intensity arm at baseline and 818 postinterventions high intensity group. Mean age of subjects ranged from 56 to 58, a majority were female, and white.	All 34 centers were community health centers that are overseen by the Bureau of Primary Health Care and had participated in the Health Disparities Collaborative to improve diabetes care. Interventions included forming a QI team, adoption of the Plan-Do-Study-Act (PDSA) cycle for QI, learning sessions, data feedback, monthly teleconferences, and regional meetings over a year. The centers randomized to the standard intensity arm continued to receive quarterly data-feedback reports, conference calls with other centers, and a yearly in-person meeting with other health centers. The high intensity sites received the standard intensity interventions plus additional support in organizational change strategies, chronic care management, and strategies to engage patients in behavioral change designed to get them to be more active in their care.	Centers in the high intensity arm showed higher rates of Hgb A1c and urine microalbumin assessment, eye exam, foot exam, dental referral, and increased prescription of home glucose monitoring postintervention as compared to the standard intensity arm. No significant differences by treatment arm were noted for patient survey data.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Davey 2005[187]	To estimate the effectiveness of persuasive interventions, restrictive interventions, and structural interventions (alone or in combination) in promoting prudent antibiotic prescribing to hospital inpatients.	Systematic literature review. Evidence level 1. (Table 3.1)	RCTs, quasi-randomized controlled trials, controlled before and after studies, and interrupted time series studies (levels 2 and 3). Outcomes were appropriate antibiotic prescribing and patient outcomes, including length of stay, inpatient mortality, and 28-day mortality (levels 1 and 2).	66 studies (43 interrupted time series studies, 13 RCTs, 6 controlled before/after studies, 2 controlled clinical trials, 1 cluster clinical trial, 1 cluster randomized trial. The majority of studies (42) were from the United States. Study participants were health care professionals who prescribe antibiotics to hospitalized inpatients receiving acute care.	Interventions were categorized as persuasive interventions (distribution of educational materials; local consensus process; educational outreach visits; local opinion leaders; reminders provided verbally, on paper, or via the computer; audit and feedback), restrictive interventions (formulary restrictions, prior authorization requirements, therapeutic substations, automatic stop orders and antibiotic policy changes), and structural (changing from paper to computerized records, introduction of quality monitoring mechanisms).	A wide variety of interventions has been shown to be effective in changing antibiotic prescribing for hospitalized patients. Restrictive interventions have a greater immediate impact than persuasive interventions, although their impact on clinical outcomes and long-term effects are uncertain.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Estabrooks 2004[20]	To map research utilization as a field of study in nursing and identify the structure of this scientific community, including the current network of researchers.	Systematic literature review.	Bibliometric analysis to map the development and structure of the field. Outcomes were journal patterns of publication, country patterns of publication, author patterns of publication, references per article, co-occurrence of words, citation patterns, interdisciplinary flow of information, within field diffusion of information.	630 articles (350 opinion articles, 65 conceptual articles, 112 research utilization studies, 103 research articles) published in 194 different journals.	Article location and data abstraction up to 2001/2002.	On the basis of co-citation, scholars at the core of the field are Horsley, Stetler, Fun, Titler, and Goode. The field has attained a critical mass of nurse scholars and scholarly works as demonstrated by more than 60% of the references in articles are to research by nurses. Emergence of interdisciplinary collaborative groups in this field is yet evolving.
Feldman 2005[64] Murtaugh 2005[77]	Tested a basic and an augmented e-mail reminder to improve evidence-based care of individuals with heart failure (HF) in home health care settings.	RCT. Evidence level 2 (Table 3.1)	Prospective randomized trail with 3 groups (control, basic e-mail reminder, augmented e-mail reminder). Outcome measures were nursing practices and patient outcomes. Level 1 outcomes.	Older adults with heart failure (n = 628; $\bar{x}$ age = 72) and nurses (n = 354; $\bar{x}$ age = 43.6; 93% female) caring for those patients. Home health care agency in a large urban setting.	Basic e-mail reminder upon patient admission to the nurses' care that highlighted 6 HF-specific clinical practices for improving patient outcomes. Augmented intervention included basic e-mail reminder plus package of material for care of HF patient (medication management, prompter card for improving communication with physicians, self-care guide for patients) and followup outreach by a clinical nurse specialist (CNS) who served as an expert peer.	Basic and augmented intervention significantly improved delivery of evidence-based care over control group; augmented intervention improved care more than basic intervention.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Foxcroft and Cole 2000[188]	Organizational infrastructures to promote evidence-based nursing practice.	Systematic literature review.	RCT, controlled clinical trial, and interrupted time series (levels 2, 3, 7). Unit of intervention was organizational, comprising nurses or groups of professionals including nurses. Outcomes = objective measures of evidence-based practice (levels 1 and 2).	121 papers were identified as potentially relevant, but no studies met the inclusion criteria. After relaxing the criteria, 7 studies were included and all used a retrospective case study design (15).	Entire or identified component of an organizational infrastructure to promote effective nursing interventions.	No high-quality studies that reported the effectiveness of organizational infrastructure interventions to promote evidence-based nursing practice were identified. Conceptual models that were assessed positively against criteria are briefly included in this review.
Greenhalgh 2005[22]	Diffusion, spread, and sustainability of innovations in the organization and delivery of health services.	Systematic literature review. Evidence level 1 (Table 3.1).	Metanarrative review.	Comprehensive report of factors and strategies to promote use of innovations in health care services.	7 key topic areas addressed: characteristics of the innovation, adoption by individuals, assimilation by organizations, diffusion and dissemination, the inner context, the outer context, implementation and routinization.	Complex process requiring multiple strategies. Excellent resource of scholarly work in knowledge transfer and innovation adoption.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Grilli 2002[120]	Assess the effect of mass media on use of health services.	Systematic literature review. Evidence level 1 (Table 3.1).	RCTs, controlled clinical trials, controlled before-and-after studies, and interrupted time series analysis (levels 2, 3, 4). Outcomes were objective measures of health services (drugs, medical or surgical procedures, diagnostic tests) by professionals, patients, or the public.	26 papers reporting 20 time series and on controlled before-and-after study met the inclusion criteria.	All studies relied on a variety of media, including radio, TV, newspapers, posters, and leaflets. To meet inclusion criteria, studies had to use mass media, be targeted at the population level, and aimed to promote/discourage use of evidence-based health care interventions or change public lifestyle.	Mass media campaigns have a positive influence upon the manner in which health services are used. Mass media have an important role in influencing use of health care interventions. Mass media campaign is one of the tools that may encourage use of effective services and discourage those of unproven effectiveness.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Grimshaw 2004[144] Grimshaw 2006[65]	Assessment of the effectiveness of guideline dissemination and implementation strategies.	Systematic literature review. Evidence level 1 (Table 3.1).	RCTs, controlled clinical trials, controlled before-and-after studies, interrupted time series from 1966 to 1998 (levels 2, 3, 4). Outcomes were objective measures of provider behavior and/or patient outcomes (levels 1, 2).	Studies of guidelines aimed at medically qualified professionals. (Studies on guidelines aimed at multiple professionals were included only if results for medical professionals were reported separately or if medical professionals represented more than 50% of the targeted population.) The review included 110 clustered RCTs, 29 patient RCTs, 7 clustered controlled clinical trials, 10 patient controlled clinical trials, 40 controlled before-and-after studies, and 39 interrupted time series designs. The most common setting was primary care (39%) followed by inpatient settings (19%) and generalist ambulatory settings (19%). Other studies addressed settings across sites of care or were in a variety of other types of settings (e.g., nursing homes).	Interventions were educational materials, educational meetings, educational outreach, consensus, opinion leaders, patient-directed interventions, audit and feedback, reminders, other professional (marketing, mass media), financial interventions, organizational interventions, structural interventions, and regulatory interventions. Studies compared single interventions to no intervention, multifaceted interventions to no intervention, or a control receiving one or more single intervention. This systematic review compared findings from studies with a single intervention against a “no-intervention” control group; single interventions against an “intervention” control group; multifaceted interventions against “no-intervention” control group (7 different types of comparisons); multifaceted interventions against intervention controls (4 different types of comparisons). A total of 309 comparisons were done. This systematic review also includes economic evaluations and cost analysis.	This is a comprehensive review of implementation strategies. The reader is referred to the technology report, as a comprehensive summary of findings is beyond the scope of this chapter. Overall findings include: the overall quality of studies were poor; the majority of comparisons (86.6%) observed improvements in care; reminders are a potentially effective intervention and are likely to result in moderate improvements in care processes; educational outreach may result in modest improvements in processes of care; educational materials and audit and feedback appeared to result in modest improvements in care; multifaceted interventions did not appear to be more effective than single interventions; multifaceted interventions did not appear to increase with the number of

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Grimshaw 2006[124]	Examine the feasibility of identifying opinion leaders using a sociometric instrument (frequency of nomination of an individual as an OL by the responder) and a self-designating instrument (tendency for others to regard them as influential).	Cross-sectional study. Evidence level 5 (Table 3.1).	Survey. Mailed questionnaires of different professional groups. Outcomes = general and condition-specific opinion leader types classified as sociometric OLs and self-designated OLs (level 2 outcomes).	All general practitioners, practice nurses, and practice managers in two regions of Scotland. All physicians and surgeons and medical and surgical nursing staff in two district general hospitals and one teaching hospital in Scotland as well as Scottish obstetric and gynecology, and oncology consultants.	None	The self-designating instrument identified more OLs. OLs appear to be condition specific.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Horbar 2004[66]	To evaluate a coordinated, multifaceted implementation intervention designed to promote evidence-based surfactant therapy.	Clustered randomized trial.	Cluster randomized trial with randomization at the hospital level (level 2). Outcomes were proportion of infants receiving their first dose of surfactant in the delivery room, proportion of infants treated with surfactant who received their fist dose more than 2 hours after birth, and time after birth at which the first dose of surfactant was administered; proportion of all infants who developed a pneumothorax, and proportion of all infants who died prior to discharge (levels 1 and 2).	114 hospitals with membership in the Vermont Oxford Network, not participating in a formal quality improvement collaborative, with the majority of infants born in the hospital rather than transferred in and born in 1998 and 1999; received the first dose of surfactant within 15 minutes after birth. Subjects were high-risk preterm infants 23 to 29 weeks gestational age. The intervention group had 3,313 neonates and 2,726 in the comparison group.	The multifaceted 18-month intervention included quarterly audit and feedback of data, evidence reviews, an interactive 3-day training workshop, and ongoing support to participants via conference calls and e-mail discussion.	The proportion of infants 23 to 29 weeks gestational age receiving surfactant in the delivery room was significantly higher in the intervention than the control group for all infants (OR = 5.38). Those who received surfactant more than 2 hours after birth was significantly lower in the intervention than control group (OR = 0.35). There were no significant differences in rates of mortality or pneumothorax between groups. Infants in the intervention group received their first dose of surfactant significantly sooner after birth with a median time of 21 minutes as compared to 78 minutes in the control group ($p <$ .001).

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Hysong 2006[67]	Exploratory study of how high-performing facilities and low-performing facilities differ in the way they use clinical data for feedback purposes.	Cross-sectional study.	Descriptive, qualitative, cross-sectional study. Subjects were interviewed using a semistructured interview format (level 4). Outcomes were participant responses to questions asking how CPGs were currently implemented at their facility, including strategies, barriers, and facilitators.	Study setting was 6 VA medical settings (from a pool of 15) ranked as high performing (n = 3) and low performing (n = 3) organizations with respect to 20 indicators for 6 chronic conditions treated in outpatient settings. 102 employees across 6 facilities were the subjects. Within each facility, facility leadership (n = 25), middle management (n = 34), and outpatient clinic personnel (n = 33) were interviewed.	No study intervention, but transcripts were analyzed using grounded theory, and passages that specifically addressed feedback of data were included in the analyses.	High-performing institutions provided timely, individualized, nonpunitive feedback to providers, whereas low performers were more variable in their timeliness and nonpunitiveness and relied more on standardized, facility-level reports. The concept of actionable feedback emerged as the core concept around which timeliness, individualization, nonpunitiveness, and customizability are important.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Irwin & Ozer 2004[68] Ozer 2005[189]	To determine if a systems intervention for primary care providers resulted in increased preventive screening and counseling of adolescent patients compared to usual care.	Controlled trial.	2 intervention outpatient pediatric clinics and 2 comparison outpatient pediatric clinics in the same health system were used to test the intervention. Level 3. Outcomes were adolescent reports of whether their provider screened and counseled them for risky behavior (tobacco, alcohol, drugs, sexual behavior, and safety—helmet and seatbelt use). Level 2.	4 outpatient pediatric clinics within Kaiser Permanente, Northern California. 76 clinicians were in the study (37 in each treatment arm). Adolescent reports of provider behavior—across all phases of the study, the intervention sample size was 1,717, and the comparison sample size was 911. Mean age of adolescents was 14.8 years (SD = 1.34). Data were collected from adolescents at baseline, following training, and following forms implementation.	The intervention was 2 phases. First phase was an 8-hour clinician training in adolescent preventative services based on social cognitive theory, including didactic education, discussions, demonstration role plays, and interactive role-plays at each intervention site (4 months). Second phase was implementation of screening and chart forms customized for this study (4 months). All clinicians participated in the training and the tools were implemented on a clinic-wide basis. Local opinion leaders were integrally involved in the intervention.	Average baseline screening rates in the intervention group ranged from 42% for helmet use to 71% for tobacco use. Following training, screening rates increased significantly across all 6 target areas, ranging from 70% for helmet use to 85% for tobacco use, and remained constant during the posttools implementation phase. Counseling rates followed a similar pattern. By comparison, screening and counseling rates in the comparison group tended to remain stable across all 3 data collection points. Screening and counseling rates were significantly higher in the intervention group than the comparison group after the full implementation of the intervention; screening and counseling rates were significantly higher in the intervention than the comparison group after the training component of the intervention; screening and counseling rates

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Jacobson 2005[69]	Assessment of the effectiveness of patient reminder and patient recall systems in improving immunization rates.	Systematic literature review. Evidence level 1 (Table 3.1).	RCTs, controlled before-and-after studies, and interrupted time series (levels 2 and 3). Outcomes were immunization rates or the proportion of the target population up to date on recommended immunizations.	43 studies. Approximately three-fourths of the studies were conducted in the United States. The majority of the studies were RCTs. Studies included children and adults and a variety of settings.	Reminder methods and recall systems included letters to patients, postcards, person-to-person telephone calls, autodialer, postcard and phone combination, and tracking and outreach.	Patients receiving patient reminder and recall interventions were more likely to have been immunized or up to date on immunizations (OR = 1.70). All types of reminders and recall were found to be effective, with increases in immunization rates on the order of 5%–20%. Person-to-person telephone reminders were the most effective single approach (OR = 1.92). Letter reminders were similar to phone reminders in effectiveness (OR = 1.89). Reminder and recall interventions were effective for children and adults in all types of settings.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Jamtvedt 2006[70]	Use of audit and feedback to improve professional practice.	Systematic literature review. Metaregression along with visual and qualitative analyses. Evidence level 1 (Table 3.1).	Randomized trails (level 2). Outcome measures = noncompliance with guideline recommendations (level 2).	85 studies. 53 trials in North America, 16 in Europe, 8 in Australia, 2 in Thailand, 1 in Uganda. In most trials, the professionals were physicians; in 2 studies the providers were nurses, and 5 involved mixed providers.	Audit and feedback defined as any summary of clinical performance of health care over a specified period of time, delivered in written, electronic, or verbal format.	Audit and feedback can be effective in improving professional practice with effects generally moderate. Absolute effects of audit and feedback are more likely to be larger when baseline adherence to recommended practice is low. Audit and feedback should be targeted where it is likely to effect change.
Jones 2004[71]	Improvement of pain practices in nursing homes.	Clustered RCT. Evidence level 2 (Table 3.1).	An intervention study to improve pain practices (RCT). The intervention was implemented in 6 nursing homes (level 2). Outcomes = pain knowledge and attitudes of staff; pain assessment and treatment decisions based on 2 short case studies; barriers to effective pain management. Outcomes measured from questionnaires distributed to nurses and nursing assistants (level 3).	12 long-term care sites in Colorado—6 in urban sites and 6 in rural sites. Nursing homes ranged in size from 65 to 150 beds.	Education for staff; resident educational video; designation of a 3-member internal pain team; pain vital sign; site visits with discussion of feedback reports; pain rounds and consultations. Implementation phase lasted 9 months.	No significant treatment effect for staff knowledge or staff attitudes; staff in the treatment group were 2.5 times more likely to chose an aggressive pain management strategy than those in the control group (p = .002); no significant treatment effect for decreasing barriers to pain management.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Katz 2004[72,98]	Testing an intervention to improve use of EBP smoking cessation guidelines.	RCT with randomization at the clinic level. Evidence level 2 (Table 3.1).	Prospective randomized trial of 8 primary care clinics in southern Wisconsin (level 2). Outcomes included staff performance and patient quit rates (levels 1 and 2).	8 community-based clinics (6 family practice, 2 internal medicine).	Multimodality intervention (5 components—didactic and interactive education of staff, modified vital signs stamp imprinted on each encounter form, offering nicotine patches and telephone counseling, group and confidential individual feedback to providers on whether clinicians had assessed smoking status and provided cessation counseling as needed) to implement AHRQ smoking cessation guideline.	Quit rates higher in experimental (E) sites at 2 and 6 months. Percentage of patients advised to quit smoking higher at E sites than control (C) sites.
Levine 2004[73]	Test a nurse-administered, protocol-driven model for comprehensive preventive services in a low-income outpatient setting. Focus was on preventive services as recommended by the U.S. Preventive Services Task Force (USPSTF).	Controlled trial.	Controlled comparison using a convenience sample of patients within a single practice (n = 987) and a usual care group (n = 666) obtained from a random sample of households from the postal zip codes served by the same practice (level 3). Outcomes were percentage of preventive services initiated in the treatment arm versus the comparison arm (level 1).	Primary care single practice with internal medicine, family medicine, and pediatric clinics. Patients receiving care in this clinic between January and September 2001. Children = 514 (about 170 in each of 3 age groups: 0–2, 3–7, 8–17; 63% African American). Adults = 473 (about 170 in each age group 18–49 and 50–64; 130 in 65 or older; 76% African American).	Offer all identified preventive services that are needed using a nursing model under the guidance of a protocol agreed upon by the medical staff.	Use of a nursing protocol for USPSTF recommendations was associated with a significantly higher percentage of preventive services initiated (99.6%) in the experimental arm as compared to usual care group (18.6%) ($p < .001$).

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Locock 2001[123]	Role of opinion leader in innovation and change.	Systematic literature review.	Case studies using principally qualitative methods. Outcomes = effectiveness of opinion leaders in promoting change/adoption of evidence-based practices (level 2.)	Variety of acute care and primary care settings. Evaluation of PACE project[100] and Welsh Clinical National Demonstration Project.	Local opinion leaders defined as those perceived as having particular influence on the beliefs and actions of their colleagues, either positive or negative.	Both expert and peer opinion leaders have important and distinct roles to play in promoting adoption of EBPs. Opinion leadership is part of a wider process that cannot be understood in isolation of other contextual variables with which it may interact. The value of the expert opinion leader is in the initial stages of getting an idea rolling, endorsing the evidence, and translating it into a form that is acceptable to practitioners and takes account of their local experience. Peer opinion leader influence seems to be important in mainstream implementation, providing a role model for fellow practitioners and building their confidence. The local context may modify or magnify the opinion leader influence.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Loeb 2004[74]	To test the effect of a multifaceted implementation intervention for safely reducing antimicrobial prescriptions for suspected urinary tract infections in nursing home residents.	Cluster RCT.	The study design was randomization of 24 nursing homes to an intervention group or a usual care group (level 2). Main outcome measures were antimicrobials prescribed for urinary infections, total antimicrobials, hospitalizations, and deaths (level 1).	Free standing, community-based nursing homes with 100 or more beds in Hamilton, Ontario, region and Boise, Idaho, region were sites for the study. The numbers of residents were 2,156 in the intervention arm and 2,061 in the comparison arm.	Implementation of algorithms for diagnostic testing and antibiotic prescribing developed from research findings. Implementation strategies included interactive education with nurses, one-on-one meeting with physicians that see more than 80% of the patients, written materials, real-time paper reminders, and quarterly outreach visits targeted to nurses and physicians.	The rate of antimicrobial use for suspected urinary infections was significantly lower in the treatment arm (1.17 courses of antimicrobials per 1,000 resident days) as compared to the comparison arm (1.59 per 1,000 patient days) (*P* = .03). The proportion of antimicrobials prescribed for suspected urinary infections were lower in the intervention arm than the comparison arm (*P* = .02). There was no significant difference for total antimicrobial use, rate of urine cultures obtained, overall hospitalization, or mortality.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Lozano 2004[174]	To test the effectiveness of 2 implementation interventions in reducing asthma symptom days as compared to usual care.	Cluster RCT.	RTC. Outcomes were annualized asthma symptom days, asthma-specific functional health status, and frequency of brief oral steroid bursts (level 1).	42 primary care practices in 3 locales and targeted 3–17-year-old children with mild to moderate persistent asthma enrolled in practices affiliated with man-aged care organizations. Among the 638 patient subjects, the mean age was 9.4 years (SD = 3.5); the majority were white (66%) and boys (60%).	3 treatment arms were usual care, provider (MD, PA, NP) oriented strategy of targeted education through an on-site peer leader, and an organizational approach that combined the provider education with a nurse-run intervention (planned care arm) to better organize chronic asthma care in the primary care practice.	Children in the planned care arm had 13.3 fewer symptoms annually (P = .02) and 39% lower oral steroid burst rate per year relative to usual care (P = .01). Those in the peer leader arm showed a 36% decrease in annualized steroid bursts per year as compared to usual care (P = .008). Improvements in asthma-specific functional status were also found for both the peer leader and planned care arm as compared to usual care.
McDonald 2005[75]	Testing of 2 computer-based reminder interventions designed to promote evidence-based pain management practices among home care nurses.	RCT. Evidence level 2 (Table 3.1).	Nurses were randomly assigned to one of 3 treatment groups (control, basic e-mail reminder, augmented e-mail reminder). Outcomes = pain management practices of nurses and patient's pain (levels 1 and 2).	Home health care. Nurses were mostly female (> 90%) with an average age of 43.3 years.	Basic e-mail reminder that focused on 6 key practices (2 treatment arms) was sent to nurse every time an eligible cancer patient with pain was admitted to his/her care. Nurses in the augmented intervention group also received provider prompts, patient education material, and CNS outreach.	Nursing pain management practices did not differ significantly among the groups (P < .05), but pain levels were lower in the 2 treatment groups as compared to the control group. Patients treated by nurses in the augmented group had a 25% reduction in the probability of hospitalization.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
O'Brien 1997[119]	Assess the effect of outreach visits on improving professional practice or patient outcomes.	Systematic literature review. Evidence level 1 (Table 3.1).	Randomized trials (level 2). Outcomes of provider performance (level 2).	18 trials. Providers were mainly primary care physicians practicing in community settings. In 13 trials the behaviors were prescribing practices. 10 trials in North America, 4 in Europe, 2 in Indonesia, and 2 in Australia.	Outreach visits defined as use of a trained person who meets with providers in their practice settings to provide information with the intent of changing provider's performance. The information may include feedback about performance.	Positive effects on practice were observed in all studies. Only 1 study measured a patient outcome. Educational outreach visits, particularly when combined with social marketing, appear to be a promising approach to modifying health professional behavior, especially prescribing. Further research is needed to identify key characteristics of outreach visits important to success.
O'Brien 1999[116]	Assessment of the use of local opinion leaders on the practice of health professionals or patient outcomes.	Systematic literature review. Evidence level 1 (Table 3.1).	RCTs (level 2). Outcomes were objectively measured provider performance in a health care setting or health outcomes (levels 1 and 2).	Focus was on health care providers responsible for patient care.	Use of providers nominated by their colleagues as educationally influential. 8 studies met inclusion criteria. A variety of patient problems were targeted.	In 3 trials that measured patient outcomes, 1 achieved an impact on practice. Only 2 trials provided strong evidence for improving performance of health care providers. Local opinion leaders may be important change agents for some problems.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
O'Brien 2001[118]	Assess the effects of educational meetings on professional practice and health care outcomes.	Systematic literature review. Evidence level 1 (Table 3.1).	Randomized trials and well-designed quasi-experimental studies (levels 2 and 3). Outcomes were objectively measured health professional practice behaviors or patient outcomes in a setting where health care was provided (levels 1, 2, 3).	32 studies met inclusion criteria with 30 RCTs. 24 studies were in North America, 2 in the United Kingdom, and 1 each in Australia, Brazil, France, Indonesia, Sri Lanka, and Zambia. Most of the study participants were physicians; 4 included nurses, and 3 other health professionals.	The intervention was defined as continuing education: meetings, conferences, lectures, workshops, seminars, symposia, and courses that occurred off-site from the practice setting. Education was defined as didactic (predominately lectures with Q and A), or interactive (sessions that involved some type of interaction in small, moderate, or large groups). 7 studies were didactic and 25 were interactive. Duration and frequency of the intervention varied widely.	The few studies that compared didactic education to no intervention did not show an effect on professional practice. Studies that used interactive education were more likely to be effective in improving practice. Studies did not include information to determine what makes some interactive educational sessions more effective than others. Interactive workshops can result in moderately large changes in professional practice. Didactic education alone is unlikely to change professional practice.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Redfern 2003[79]	Evaluation of the South Thames Evidence-based Practice (STEP) project.	Pretest and posttest.	Each of the 9 projects followed a pretest/posttest design within a clinical audit framework over a period of 27 months (level 6). Outcomes = intermediate outcomes of uptake of change by staff and patient outcomes (levels 1 and 2).	9 projects that focused on improving evidence-based nursing practices. UK sites included acute care wards, community nursing services, and long-term care. Topics were leg ulcer management, breast-feeding, pressure ulcer care, nutrition in stroke patients (n = 2), Use of functional independence measure (FIM) assessment tool, assessment of continence, assessment and transfer of older adults on discharge from hospital, family therapy in schizophrenia.	A 2-week training program followed by 3 monthly seminars, staff training program, active support in the practice setting.	Intermediate outcomes improved in most projects; leaders' ratings of staff adherence were moderate or better in the majority of the projects; patient outcomes improved in most projects. Organizational factors were found to have a major impact on achieving successful change in practice. Having enough staff of the right skill mix, strong leadership, supportive managers and colleagues, and organizational stability are important to successful change. Project leaders and a credible change agent who works with practitioners face-to-face to encourage enthusiastic involvement are also important.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Shaw 2005[185]	Tailored interventions to address specific identified barriers to change in professional performance.	Systematic literature review with metaregression. Evidence level 1 (Table 3.1).	RCTs (level 2). Outcomes = professional performance, patient outcomes, or both (levels 1 and 2).	15 RCTs. 7 in primary care or community settings and health care professionals responsible for patient care. 10 in North America, 2 in the United Kingdom, 2 in Indonesia, and 1 in Norway.	An intervention was defined as tailored if it was chosen after identification of barriers and to overcome those barriers.	Results were mixed with variation in the direction and size of effect. The effectiveness of tailored interventions remains uncertain, and more rigorous trials including process evaluations are needed.
Titler 2006[81]	Testing a TRIP intervention for promoting adoption of evidence-based acute pain management practices for care of older adults hospitalized with hip fracture.	RCT with randomization at the clinic level. Evidence level 2 (Table 3.1).	Prospective randomized trial of 12 acute care hospitals in the Midwest United States (level 2). Outcomes included nurse and physician performance, patient pain levels, and cost effectiveness (levels 1 and 2).	12 large (n = 2), medium (n = 6), and small hospitals (n = 4) in the Midwest.	Multifaceted intervention that addressed the characteristics of the EBP, the users, the social context of care, and communication, based on Rogers' diffusion of innovation framework.	Acute pain management strategies improved more in the experimental than comparison group, and the TRIP intervention saved health care dollars.

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Wensing 2006[82]	Organizational strategies for improving professional performance, patient outcomes, and costs.	Systematic literature review. Evidence level 1.	A review of reviews that included RCTs, interrupted time series, controlled before/after studies, and prospective comparative observational studies (levels 2, 5, 6, 7). Outcomes = professional practice and patient outcomes (levels 1 and 2).	36 reviews were included. A taxonomy of organizational strategies to improve patient care was developed to organize findings.	Revision of professional roles, multidisciplinary teams, integrated care services, knowledge management, quality management.	Revision of professional roles can improve professional performance, while positive effects on patient outcomes remain uncertain. Multidisciplinary teams can improve patient outcomes but have primarily been tested in highly prevalent chronic diseases. Integrated care systems can improve patient outcomes and save costs; they have been extensively tested in highly prevalent chronic conditions. Professional performance and patient outcomes can be improved by implementation of computers in clinical practice settings (knowledge management). Effects of quality management on professional performance and patient outcomes remain uncertain. There is growing evidence of rigorous evaluations of organizational strategies, but the evidence underlying some strategies is limited; for no strategy can

Source	Issue Related to EBP	Design Type*	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Findings
Zwarenstein 2000[117]	Usefulness of interprofessional education (IPE) interventions on professional practice and health care outcomes.	Systematic literature review. Evidence level 1 (Table 3.1).	RCTs, controlled before-and-after studies, and interrupted time series studies (levels 2, 6, 7). Outcomes included health care outcomes (mortality rates, complication rates, readmission rates) and impact on professional practice (teamwork and cooperative practice) (levels 1 and 2).	89 studies were reviewed for possible inclusion, but none met the inclusion criteria.	An educational intervention during which members of more than one health and/or social care profession learn interactively together for the purpose of improving collaborative practice and/or the health of patients.	Despite finding a large body of literature on the evaluation of IPE, studies lacked the methodological rigor needed to understand the impact of IPE.

***Study design type:** Use the following numbers for categories to reference the specific type of evidence ("evidence level"):

1. Meta-analysis
2. Randomized controlled trials
3. Non-randomized trials
4. Cross-sectional studies
5. Case control studies
6. Pretest and post-test (before and after) studies
7. Time series studies
8. Noncomparative studies
9. Retrospective cohort studies
10. Prospective cohort studies
11. Systematic literature reviews
12. Literature reviews, nonsystematic/narrative
13. Quality improvement projects/research
14. Changing practice projects/research
15. Case series
16. Consensus reports
17. Published guidelines
18. Unpublished research, reviews, etc.

Chapter 8. Health Services Research: Scope and Significance

Donald M. Steinwachs, Ronda G. Hughes

Background

The provision of high-quality, affordable, health care services is an increasingly difficult challenge. Due to the complexities of health care services and systems, investigating and interpreting the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services is key to informing government officials, insurers, providers, consumers, and others making decisions about health-related issues. Health services researchers examine the access to care, health care costs and processes, and the outcomes of health services for individuals and populations.

The field of health services research (HSR) is relied on by decisionmakers and the public to be the primary source of information on how well health systems in the United States and other countries are meeting this challenge. The "goal of HSR is to provide information that will eventually lead to improvements in the health of the citizenry."[1] Drawing on theories, knowledge, and methods from a range of disciplines,[2] HSR is a multidisciplinary field that moves beyond basic and applied research, drawing on all the health professions and on many academic disciplines, including biostatistics, epidemiology, health economics, medicine, nursing, operations research, psychology, and sociology.[3]

In 1979, the Institute of Medicine defined HSR as "inquiry to produce knowledge about the structure, processes, or effects of personal health services"[4] (p. 14). This was expanded upon in 2002 by AcademyHealth, the professional organization of the HSR field, with the following definition, which broadly describes the scope of HSR:

> Health services research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being. Its research domains are individuals, families, organizations, institutions, communities, and populations.[5]

More specifically, HSR informs and evaluates innovations in health policy. These include changes in Medicare and Medicaid coverage, disparities in access and utilization of care, innovations in private health insurance (e.g., consumer-directed health plans), and trends among those without health insurance.[6–10] The health care industry continues to change, and HSR examines the impact of organizational changes on access to care, quality, and efficiency (e.g., growth in for-profit hospital systems). As new diagnostic and treatment technologies are introduced, HSR examines their impact on patient outcomes of care and health care costs.

The definition of HSR also highlights the importance of examining the contribution of services to the health of individuals and broader populations. HSR applied at the population level is particularly important in understanding health system performance and the impact of health policy on the public's health. In the United States, the *National Healthcare Quality Report*,[11] *National Healthcare Disparities Report*,[12] and *Healthy People Year 2010*[13] exemplify our

capacity for monitoring quality and assessing change. These reports tell us that the American quality of care is inconsistent and could be substantially improved. The associated cost of health care services is monitored by the Centers for Medicare & Medicaid Services (CMS). CMS reports tell us that American health care is the most expensive in the world, consuming approximately 16 percent of America's gross domestic product.[14]

Beyond health policy, HSR examines the process of care and the interactions of patients and providers. For example, HSR methods have been developed to describe doctor-patient communication patterns and examine their impact on patient adherence, satisfaction, and outcomes of care.[15–17]

Advances in HSR measurement methodologies have made possible policy innovations. Prospective payment of hospitals, nursing homes, and home health care by Medicare became possible with the development of robust case-mix measurement systems.[18] CMS was able to initiate a pay-for-performance demonstration, rewarding hospitals with better quality performance, using valid and robust measures of quality.[14] Innovations in health care policy are frequently made possible by advances in measurement of indicators of health system performance.

History of Health Services Research

The history of HSR is generally considered to have begun in the 1950s and 1960s with the first funding of grants for health services research focused on the impact of hospital organizations.[19, 20] On the contrary, HSR began with Florence Nightingale when she collected and analyzed data as the basis for improving the quality of patient care and outcomes.[21] Also significant in the history of HSR was the concern raised about the distribution, quality, and cost of care in the late 1920s that led to one of the first U.S. efforts to examine the need for medical services and their costs, undertaken in 1927 by the Committee on the Costs of Medical Care.[22] The committee published a series of 28 reports and recommendations that have had a significant impact on how medical care is organized and delivered in the United States.[23] Other key reports of historical importance to HSR were, for example, the national health survey in 1935–1936 by the Public Health Service, the inventory of the nation's hospitals by the American Hospital Association's Commission on Hospital Care in 1944, and studies by the American Hospital Association's Commission on Chronic Illness on the prevalence and prevention of chronic illness in the community.[23]

In 1968, the National Center for Health Services Research and Development was established as part of the U.S. Public Health Services to address concerns with access to health services, quality of care, and costs. The Center funded demonstration projects to measure quality and investigator-initiated research grants. In 1989, Congress created the Agency for Health Care Policy and Research and broadened its mission to focus attention on variations in medical practice, patient outcomes of care, and the dissemination of evidence-based guidelines for the treatment of common disorders. Later Congress reauthorized and renamed the agency, Agency for Healthcare Research and Quality (AHRQ). AHRQ provides Federal leadership for the field, investing in methods for quality measurement, development of patient safety methods, and health information technology (e.g., electronic health records and decision support systems).

The Federal role in HSR has expanded over time, and investments in HSR are made by multiple Federal agencies. In addition to AHRQ, the U.S. Department of Veterans Affairs, Centers for Disease Control and Prevention, the National Institutes of Health, CMS, and other

Federal agencies fund HSR. The diversification of funding comes, in part, from the recognition that HSR is important in managing health care systems, such as the Veterans Health Administration, and provides essential information on the translation of scientific discoveries into clinical practice in American communities, such as those funded by National Institutes of Health. It is estimated that total Federal funding of HSR was $1.5 billion in 2003, of which AHRQ was responsible for approximately 20 percent.[24]

Private funding of HSR has also grown over time. Funding by private foundations has a significant role and complements Federal funding. Among the many foundations funding HSR are the Robert Wood Johnson Foundation, Commonwealth Fund, Kaiser Family Foundation, Kellogg Foundation, and Hartford Foundation. Other private funding sources include the health care industry, for example, pharmaceutical companies, health insurers, and health care systems.

Goals for Health Services and Patient Outcomes

The goal of health services is to protect and improve the health of individuals and populations. In a landmark 2001 report, *Crossing the Quality Chasm: A New Health System for the 21st Century*,[25] the Institute of Medicine (IOM) of the National Academy of Sciences proposed that the goals for health services should include six critical elements:

1. **Patient Safety:** Patients should not be harmed by health care services that are intended to help them. The IOM report, *To Err Is Human*,[26] found that between 46,000 and 98,000 Americans were dying in hospitals each year due to medical errors. Subsequent research has found medical errors common across all health care settings. The problem is not due to the lack of dedication to quality care by health professionals, but due to the lack of systems that prevent errors from occurring and/or prevent medical errors from reaching the patient.
2. **Effectiveness:** Effective care is based on scientific evidence that treatment will increase the likelihood of desired health outcomes. Evidence comes from laboratory experiments, clinical research (usually randomized controlled trials), epidemiological studies, and outcomes research. The availability and strength of evidence varies by disorder and treatment.
3. **Timeliness:** Seeking and receiving health care is frequently associated with delays in obtaining an appointment and waiting in emergency rooms and doctors' offices. Failure to provide timely care can deny people critically needed services or allow health conditions to progress and outcomes to worsen. Health care needs to be organized to meet the needs of patients in a timely manner.
4. **Patient Centered:** Patient-centered care recognizes that listening to the patient's needs, values, and preferences is essential to providing high-quality care. Health care services should be personalized for each patient, care should be coordinated, family and friends on whom the patient relies should be involved, and care should provide physical comfort and emotional support.
5. **Efficiency:** The U.S. health care system is the most expensive in the world, yet there is consistent evidence that the United States does not produce the best health outcomes[27–30] or the highest levels of satisfaction.[31] The goal is to continually identify waste and inefficiency in the provision of health care services and eliminate them.
6. **Equity:** The health care system should benefit all people. The evidence is strong and convincing that the current system fails to accomplish this goal. The IOM report, *Unequal Treatment*,[32] documented pervasive differences in the care received by racial and ethnic minorities. The findings were that racial and ethnic minorities are receiving poorer quality of

care than the majority population, even after accounting for differences in access to health services.

Crossing the Quality Chasm concludes that for the American health care system to attain these goals, transformational changes are needed.[25] The field of HSR provides the measurement tools by which progress toward these goals is assessed, as seen in the *National Healthcare Quality Report.*[11] Equally important, health services researchers are developing and evaluating innovative approaches to improve quality of care, involving innovations in organization, financing, use of technology, and roles of health professionals.

Evaluating the Quality of Health Care

HSR evaluation of quality of care has proven to be an inexact science and complex, even though its definition is relatively simple: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] This definition draws attention to the importance of the application of current professional knowledge in the diagnostic and treatment processes of health care. The goal of quality care is to increase the likelihood of achieving desired health outcomes, as expressed by the patient.

The complexity in measuring quality comes from gaps in our knowledge regarding which services, for which patients, will actually improve the likelihood of desired health outcomes. Also, patients need not have the same desired health outcomes and therefore might not receive the same care for an identical health problem, further complicating the measurement of quality of care. Quality measurement has advanced substantially, but it remains early in its development.

The conceptual framework widely applied in evaluating quality comes from years of research and the insightful analysis of Avedis Donabedian.[33] He formalized the conceptual model for describing, analyzing, and evaluating the quality of care using three dimensions: (1) structure, (2) process, and (3) outcome. This model is applied in the evaluation of health services and the accreditation of health care providers and organizations.

Seminal research about variation in the quality of care patients received brought to focus the need to monitor and improve the quality of health care. Wennberg and Gittelsohn[34, 35] found wide variation in practice patterns among community physicians, surgical procedures, and hospitals. Brook and colleagues[36] found that a small number of physicians were responsible for a large number of improperly administered injections. This was the precursor to research on the appropriateness of procedures and services under specific circumstances[36, 37] as well as the development of practice guidelines and standards for quality care.[38] Yet the challenge of research on variations in care is the implication of the inappropriateness of care. The challenge is determining whether there is a direct relationship between rates of utilization, variations in appropriateness, and quality of care.

One of the challenges in understanding quality, how to measure it, and how to improve it is the influence of physical, socioeconomic, and work environments. Income, race, and gender—as well as individuals within society and organizations—influence health and risks to health.[40] Researchers have found that differences in internal factors, such as collaborative relationships with physicians, decentralized clinical decisionmaking, and positive administrative support, impact nurse and patient outcomes[41, 42] and the quality and safety of care.[43] Differences in external factors, such as insurance and geographic location, can influence access to available health care professionals and resources, what type of care is afforded patients, and the impact of

care on patients. The structure, process, and outcome dimensions of quality are influenced by both internal and external factors.

Structure of Health Care

The structure of health care broadly includes the facilities (e.g., hospitals and clinics), personnel (e.g., number of nurses and physicians), and technology that create the capacity to provide health services. Structural characteristics are expected to influence the quality of health care services. One component in the accreditation of health care facilities (e.g., hospitals, nursing homes) is the review of the adequacy of structural characteristics, including staffing, on-call resources, technology, and support services (laboratory, pharmacy, radiology). The structural resources of health care facilities and organizations are the foundation upon which quality health care services are provided.

Process of Care

The interactions between the health care providers and patients over time comprise the process of health care. The process of care may be examined from multiple perspectives: the sequence of services received over time, the relationship of health services to a specific patient complaint or diagnosis, and the numbers and types of services received over time or for a specific health problem. Examining the time sequence of health care services provides insights into the timeliness of care, organizational responsiveness, and efficiency. Linking services to a specific patient complaint or diagnosis provides insights into the natural history of problem presentation and the subsequent processes of care, including diagnosis, treatment, management, and recovery. Examining the natural history of a presenting health complaint across patients will reveal variations in patterns of care. For example, presenting complaints for some patients never resolve into a specific diagnosis. An initial diagnosis may change as more information is obtained. Patients may suffer complications in the treatment process. Also, the process of care may provide insights into outcomes of care (e.g., return visit for complications). Generally it is not possible to examine the process of care and determine how fully the patient has recovered prior health status by the end of the episode of treatment. For this reason, special investigations are needed to assess outcomes of care.

Evaluation of the process of care can be done by applying the six goals for health care quality.[25] Was the patient's safety protected (i.e., were there adverse events due to medical errors or errors of omission)? Was care timely and not delayed or denied? Were the diagnosis and treatments provided consistent with scientific evidence and best professional practice? Was the care patient centered? Were services provided efficiently? Was the care provided equitable? Answers to these questions can help us understand if the process of care needs improvement and where quality improvement efforts should be directed.

Outcomes of Care

The value of health care services lies in their capacity to improve health outcomes for individuals and populations. Health outcomes are broadly conceptualized to include clinical measures of disease progression, patient-reported health status or functional status, satisfaction with health status or quality of life, satisfaction with services, and the costs of health services.

Historically, quality assessment has emphasized clinical outcomes, for example, disease-specific measures. However, disease-specific measures may not tell us much about how well the patient is able to function and whether or not desired health outcomes have been achieved. To understand the patients' outcomes, it is necessary to ask patients about their outcomes, including health status, quality of life, and satisfaction with services. HSR has developed valid and robust standardized questionnaires to obtain patient-reported information on these dimensions of health outcomes. As these are more widely applied, we are learning about the extent to which health care services are improving health.

Public Health Perspective on Health Services

Another perspective on health care services comes from the field of public health in which preventive health services are conceptualized at three levels: primary, secondary, and tertiary prevention.[44] Primary prevention includes immunizations, healthy lifestyles, and working and living in risk-free environments. Primary prevention seeks to prevent disease or delay its onset. Examples of primary prevention include immunizations against infectious disease; smoking prevention or cessation; and promotion of regular exercise, weight control, and a balanced diet. Secondary prevention includes the range of interventions that can reduce the impact of disease morbidity once it occurs and slow its progression. With the increasing burden of chronic diseases, much of the health care provided is directed at secondary prevention. Tertiary prevention is directed at rehabilitation for disabilities resulting from disease and injury. The goal of tertiary prevention is to return individuals to the highest state of functioning (physical, mental, and social) possible. The public health framework expands the structure, process, and outcome conceptual model by identifying the role and value of health services at three stages: prior to onset of disease, disease management, and disease recovery and rehabilitation.

Methodologies and Data Sources Used in Health Services Research

The interdisciplinary character of HSR draws on methods and data sources common to the many disciplines that form the intellectual underpinnings of the field. This section discusses the measurement of effectiveness and efficacy of health services and some of the methods and data sources used to understand effectiveness. Effectiveness is one of the six goals of health services. Effectiveness is interrelated with the other five goals, and some of these interrelationships are discussed.

Efficacy and Effectiveness

An important distinction is made between efficacy and effectiveness of health services. Efficacy is generally established using randomized controlled trial (RCT) methods to test whether or not clinical interventions make a difference in clinical outcomes. A good example is the series of studies required for Food and Drug Administration approval of a new drug before it is certified as safe and efficacious and allowed to be used in the United States. Efficacy research is generally done with highly select groups of patients where the impact of the drug can be validly measured and results are not confounded by the presence of comorbid conditions and

their treatments. The efficacy question is: What impact does a clinical intervention have under ideal conditions?

In contrast, effectiveness research is undertaken in community settings and generally includes the full range of individuals who would be prescribed the clinical intervention. Many of these individuals will have multiple health problems and be taking multiple medications, unlike those who were recruited to the RCT. Effectiveness research is seeking to answer the question: Who will benefit from the clinical intervention among all those people in the community who have a specific health problem(s)?

Both efficacy and effectiveness questions are important. Logically, effectiveness research would be conducted after finding the clinical intervention to be efficacious. However, there are many treatments for which no efficacy information exists; the treatments are accepted as common practice, and it would not be ethical to withhold treatments from a control group in an RCT. As a result, effectiveness research may not have the benefit of efficacy findings.

The routine use of an RCT to evaluate efficacy began in the 1960s and is the accepted procedure for evaluating new medications. However, this standard is not applied across all health care services and treatments. Most surgical procedures are not evaluated using an RCT. Intensive care units have never been evaluated using an RCT, nor are nurse staffing decisions in hospitals or the evaluation of many medical devices. We currently accept different standards of evidence depending on the treatment technology. As a result, the level of evidence guiding clinical and public health decisionmaking varies.

Methods for Effectiveness Research

A variety of methods are used to examine effectiveness of health services. RCT methods are not usually applied in effectiveness research because the intervention being studied has demonstrated efficacy or is acknowledged as accepted clinical practice. When this is true, it would be unethical to randomly assign individuals who would be expected to benefit from the intervention to a control group not receiving an efficacious treatment. We will discuss when RCT methods can be used to test effectiveness and provide several examples. More commonly, effectiveness research uses statistical methods for comparing treatments across nonequivalent groups.

RCT and Policy Research

RCT study methods can be used to compare the effectiveness and costs of services across randomly assigned representative population groups. In an RCT, study participants are randomly assigned to two or more groups to ensure comparability and avoid any selection bias. At least one group receives an intervention (clinical, organizational, and/or financial), and usually one group serves as a control group, receiving a current standard of care, sometimes referred to as "usual care." Two examples of effectiveness research using an RCT methodology to answer policy questions are described.

Health insurance experiment. Probably the first application of RCT methods in effectiveness research was undertaken in the 1970s as a health insurance experiment. The experiment was designed to test the impact on cost and health outcomes of different levels of insurance deductibles and copayment rates. A total of 3,958 people, ages 14–61, were randomized to a set of insurance plans and followed over 3 to 5 years.[45]

The economic impact of receiving free care in one plan versus being in a plan requiring payment out-of-pocket of deductibles and co-insurance had the expected impact on utilization. Those paying a share of their medical bills utilized approximately one-third fewer doctor visits and were hospitalized one-third less frequently.

The impact on 10 health measures of free health insurance versus paying a portion of medical care costs out of pocket was evaluated. The findings were that there was largely no effect on health as measured by physical functioning, role functioning, mental health, social contacts, health perceptions, smoking, weight, serum cholesterol, diastolic blood pressure, vision, and risk of dying.[46] The exceptions were that individuals with poor vision improved under free care, as did low-income persons with high blood pressure.

Medicare preventive services experiment. A more recent example of RCT methods applied in HSR is the Baltimore Medicare Preventive Services Demonstration. The study evaluated the impact on cost and outcomes of offering a defined preventive services package to Medicare beneficiaries. This was compared to usual Medicare coverage, which paid for few preventive services. The preventive services coverage being evaluated included an annual preventive visit with screening tests and health counseling. The physician could request a preventive followup visit during the year, which would also be covered. Medicare beneficiaries (n = 4,195) were randomized to preventive services (the intervention group) or usual care (the control group). Sixty-three percent of those in the intervention group had at least one preventive visit. Significant differences were found in health outcomes between intervention and control groups. Among the 45 percent with declining health status, as measured by the Quality of Well-Being scale,[47] the decline was significantly less in the group offered preventive services. Mortality was also significantly lower in the intervention group. There was no significant impact of preventive services on utilization and cost.[48]

Comparative Clinical Effectiveness and RCTs

The passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included provisions for the funding of comparative effectiveness studies. AHRQs' Effective Health Care Program (authorized under MMA Section 1013) informs comparative clinical effectiveness efforts by conducting and supporting research and evidence syntheses on priority topics to CMS.

Comparative effectiveness studies ask the question: Which of the alternative treatments available is best and for whom? Interest in this question reflects how advances in science have provided multiple treatment options for many conditions. Currently, there is no systematic process by which treatment options are compared and matched to the needs of different types of patients. Frequently, patients are started on one treatment and then may be prescribed alternative treatments if they cannot tolerate the treatment or if it is not as effective as expected. RCT methods can be used to evaluate comparative effectiveness of an intervention in treatment and control populations. This is ethical to do when there is no evidence that the treatments are not equivalent.

An example of a comparative effectiveness study using RCT methods is the CATIE study, testing alternative antipsychotic medications in the treatment of schizophrenia. A study of 1,493 persons with schizophrenia compared five of the newer antipsychotic medications (second generation) and also compared them against one of the first-generation antipsychotic medications.[49, 50] The findings were surprising to many. The second-generation antipsychotics

were no more effective in controlling psychotic symptoms than the first-generation drug. There was one exception, the drug Clozapine.[51] Furthermore, second-generation medications showed significant side effects that can affect health outcomes. These included weight gain, metabolic changes, extrapyramidal symptoms, and sedation effects. Each medication showed a somewhat different side-effect risk profile. From a positive perspective, the findings indicated that the clinician and patient can choose any of these medications as first-line treatment except Clozapine, which is generally used for treatment-resistant cases due to more intensive clinical monitoring requirements. The ultimate choice of treatment will depend on the patient's ability to tolerate side effects that vary by drug.

The conduct of any RCT is resource intensive, requiring the recruitment of participants, and participants must give informed consent to be randomized. The rationale for making this investment may depend on the importance of the policy or practice issue. As shown, RCT methods can be applied to address policy and clinical care concerns with effectiveness. To the extent that the RCT includes a broad cross-section of people who would be affected by a policy or receive a clinical treatment, this methodology provides robust effectiveness findings.

Comparing Effectiveness and Costs Across Nonequivalent Groups

A range of statistical methods can be used to compare nonequivalent groups (i.e., groups receiving different treatments or exposures when there has been no random assignment to ensure comparability of group membership). It is not practical to review all the specific statistical approaches that can be applied. In general, the statistical methods seek to adjust for nonequivalent characteristics between groups that are expected to influence the outcome of interest (i.e., make the comparisons fair). Statistical adjustment for nonequivalent characteristics is referred to as "risk adjustment." The foundations for risk adjustment come from multiple disciplines. Epidemiologic methods are routinely used to identify and estimate disease and outcomes risk factors. These methods are applicable in comparative effectiveness evaluations.[52]

Operations research uses methods for creating homogeneous groups predictive of cost or disease outcomes. These methods are used to make fair comparisons across provider practices and health plans and to control the cost of health care. They also have been used in designing payment systems, including diagnostically related groups used in Medicare's Prospective Payment System to reimburse hospitals for care rendered to Medicare beneficiaries, and resource-based relative value scales used in Medicare's physician payment system. Diagnostically related groups are used to standardize and rationalize patient care in hospitals—provided largely by nurses and other health professionals—and resource-based relative value scales are used to standardize and rationalize patient care in outpatient settings—care provided largely by physicians and nurse practitioners. Other disciplines also contribute to our understanding of risk factors for the range of health outcomes, including mortality, health and functional status, quality of life, and rehabilitation and return to work

The basic form of a nonequivalent group comparison includes adjusting the outcomes of each group for the risk factors that are known to affect the occurrence and/or severity of the outcomes being evaluated.[53] For many disease outcomes, risk factors include demographic characteristics (age, gender), disease-specific risk factors (e.g., health behaviors, environmental exposures, and clinical indicators of risk), and indicators of health status (e.g., presence of comorbid conditions). After adjustment for risks factors, variations in access to care and quality of care (e.g., choice of treatment and adherence to treatment) would be expected to explain the remaining observed

variation in outcomes. Ideally, the nonequivalent group comparison makes it possible to compare the effectiveness of alternative treatments and assess the impact of poor access to care. One limitation of this methodology is the limit of current knowledge regarding all relevant disease risk factors. Even when risk factors are known, limits on data availability and accuracy of risk factor measurement have to be considered.

Risk adjustment methods are also used to make cost comparisons across health care providers to determine which providers are more efficient. Instead of adjusting for disease risk factors, adjustments are made for the costliness of the patient mix (case mix) and differences in costs of labor, space, and services in the local area. Comparisons may be made to assess efficiency of providing specific services (e.g., hospitalization, office visit, or laboratory test). These comparisons would use case-mix measures that adjust for the costliness of different mixes of hospital episodes.[18] Comparisons of the total cost of care for insured populations would apply case-mix measures that adjust for disease and health factors that affect total cost of care.[54]

Data Sources for Effectiveness Research

A range of data sources is used in effectiveness research, including administrative and billing data, chart reviews and electronic health records, and survey questionnaires. The following discussion identifies major attributes of each category of data source.

Medical records. Medical records document the patient's presenting problem or condition, tests and physical exam findings, treatment, and followup care. The medical record is generally the most complete source of clinical information on the patient's care. However, medical records are generally not structured to ensure the physician or other provider records all relevant information. The completeness of medical record information can vary considerably. If the patient does not return for followup care, the medical record may provide no information on outcomes of care. If a patient sees multiple providers during the course of treatment, each with its own separate medical record, complete information on treatment requires access to all the records. Lack of standardization of medical records also can make abstracting records for research very resource intensive.

Administrative and billing data. Health care providers generally have administrative and billing data systems that capture a limited and consistent set of data on every patient and service provided. These systems uniquely identify the patient and link information on insurance coverage and billing. Each service received by the patient is linked to the patient using a unique patient identifier. Services are identified using accepted codes (e.g., ICD9-CM, CPT), together with date of service, provider identifier, and other relevant information for billing or management reporting. Administrative data make it possible to identify all individual patients seen by a provider and produce a profile of all services received by each patient over any defined time period. Administrative data are comprehensive and the data are generally complete (i.e., no problems with missing data). The primary limitation is the data set collected by administrative systems is very limited and lacks the detail of the medical record.

Administrative data systems can provide some insights into quality and outcomes of care. AHRQ has developed software that provides quality indicators and patient safety measures using one administrative data set, hospital discharge abstracts.[55, 56] Utilization-based indicators of outcome include rehospitalization, return to surgery during a hospitalization, and incidence of complications; some systems include information on death. Administrative data can efficiently provide quality and outcomes indicators for defined populations and for health systems. Other

applications of administrative data include assessing efficiency, timeliness, and equity. The limitation is that there are many health conditions and health outcomes that cannot currently be measured using administrative data.

Survey questionnaires. Neither the medical record nor the administrative data capture information on the patient's experience in health or patient-reported outcomes of care. Survey questionnaires are routinely used to obtain information on patient satisfaction in health plans. A widely used example is the Consumer Assessment of Healthcare Providers and Systems or CAHPS.[57]

Information on the impact of health conditions on health and functional status has to come from the patient. This may be obtained at the time of a visit or hospitalization. However, to assess patient outcomes of care, systematic followup of patients after the completion of treatment is generally required. This can be done using mail questionnaires, telephone interviews, or in-person interviews. The HSR field has developed health-status and quality-of-life measures that can be used no matter what health conditions the patient has.[47, 58–60] Numerous condition-specific measures of outcome are also used.[53]

Effectiveness research relies on a range of data sources. Some are routinely collected in the process of medical care and patient billing. Others may require special data collection, including medical record abstracts to obtain detailed clinical data and survey questionnaires to gain information on the patient's perspective on treatment and outcomes. Efficient strategies for examining effectiveness may use administrative data to examine a limited set of data on all patients, and a statistically representative sample of patients for in-depth analysis using data from chart abstracts and survey questionnaires.

Using HSR Methods To Improve Clinical Practice

HSR research tools can be applied in clinical settings to improve clinical practice and patient outcomes. These tools are used as part of quality improvement programs in hospitals, clinics, and health plans. Two examples illustrate applications to improve quality-of-care performance.

Evidence-based treatment. For many chronic medical conditions, clinical research has evaluated the efficacy of diagnostic methods and treatment interventions. As a result, evidence-based reviews of research literature can provide a basis for establishing quality-of-care criteria against which to judge current practice. In a national study of quality of medical care, it was found that only 55 percent of patients received evidence-based treatments for common disorders and preventive care.[61] The researchers examined treatment for a range of health conditions, using a national sample of medical records abstracts. For each quality criterion, a classification was applied to determine if the quality-of-care deficiency was one of underuse, overuse, or misuse. Greater problems were found with underuse (46 percent) than with overuse (11 percent). Quality of care varied by condition: senile cataracts scored highest, 78 percent of recommended care received, and alcohol dependence scored lowest, 10 percent of recommended care received. Overall, only about half of recommended care was received, frequently due to underuse of services.

Researchers have sought to identify why rates of conformance with evidence-based treatments are low. Frequently cited barriers to evidence-based practice include physician disagreement with the evidence, perception that patients will not accept treatment, low ratings of self-efficacy as a provider of the treatment, and difficulty of integrating the evidence-based

treatment into existing practice.[62] More needs to be learned how to assist health care providers to overcome barriers to the adoption of evidence-based practices.

The described data sources and methods can be applied in clinical settings to assess conformance to evidence-based quality criteria and provide feedback to clinicians. If electronic health records are available, the feedback and reminders may be directly incorporated into the medical record and seen by the clinician at the time of a visit. Intermountain Health Care utilizes its electronic health records to monitor adherence to evidence-based quality standards and to provide decision support to clinicians when seeing patients. This strategy has contributed to substantial improvements in their quality performance.[63]

Outcomes management system. In 1988, Paul Ellwood proposed the adoption of outcomes management system (OMS) as a method to build clinical intelligence on "what treatments work, for whom, and under what circumstances."[64] OMS would require linking information on the patient's experience with outcomes of care and information on diagnosis and treatment that would usually come from the medical record.

In 1991, the Managed Health Care Association, an employer organization, brought together a group of employers and their health plan partners who were interested in testing the OMS concept in health plans.[65] To do so would require a set of methods that could be widely applied across health plans with differing information systems. The methodology chosen was for each of 16 health plans to identify all adult enrollees with at least two diagnoses of asthma over the previous 2 years. A stratified sample was chosen with half of the enrollees having more severe asthma (e.g., hospitalization or emergency room visit in the past 2 years) and the other enrollees having less severe asthma (outpatient visits only). Each adult received a questionnaire asking about their asthma treatment and health status. Followup surveys were done in each of 2 successive years to track changes over time.

The findings were compared to national treatment recommendations for adult asthma.[66] Across the health plans, 26 percent of severe asthmatics did not have a corticosteroid inhaler, and 42 percent used it daily, as recommended.[67] Only 5 percent of patients reported monitoring their asthma using a home peak flow meter. Approximately half of adults with asthma reported having the information they needed to avoid asthma attacks, to take appropriate actions when an asthma flare-up occurs, and to adjust medications when their asthma gets worse. Health plans used the baseline findings to develop quality-improvement interventions, which varied across health plans. Followup surveys of the patient cohort provided feedback to health plans on their success in improving asthma treatment and outcomes over time.

Conclusion

This chapter has provided a definition and history of the field of health services research and discussed how this field is examining quality-of-care issues and seeking to improve quality of care. Comparisons of current practice to evidence-based standards with feedback to clinicians and the integration of patient-reported outcomes are two examples of how HSR tools can be used to provide quality-improvement information for health care organizations. These examples utilize multiple data sources, including medical records, patient surveys, and administrative data. The opportunities for nurse researchers to provide invaluable contributions to the growing field of health services research are innumerable.

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Chapter 9. Synergistic Opportunity to Connect Quality Improvement and Emergency Preparedness

Sally Phillips, Ronda G. Hughes, and Lucy A. Savitz

Background

A critical element in the mission of health care organizations is high quality health care. Organizationally, the hospital enterprise is a hierarchical structure that has separate functional charges, lines of authority, and personnel resources for quality improvement and emergency management. The overall umbrella of safety and health care delivery can be viewed to encompass quality improvement and emergency preparedness, and nursing plays an integral role in ensuring continuous quality improvement. The interaction of quality improvement and emergency preparedness resources in hospital settings promises to yield a combined effect that is greater than the sum of their individual efforts to ensure patient safety and enhanced health care quality. By strengthening communication channels and fostering opportunities for collaborative project implementation across quality improvement, emergency preparedness and organizational functions can be highly synergistic.

Engaging People in Place

According to the current working knowledge of quality improvement and emergency management in hospitals, it is suggested that the bioterrorism/emergency response function resides in the facilities management area, while quality improvement is incorporated into clinical operations. Job enlargement of selected nursing staff can serve to bridge the quality improvement–emergency preparedness gap. Quality improvement and patient safety initiatives are led by executives who report directly to the chief medical officer and/or vice president for quality/safety. Emergency management typically has a less direct reporting route through the chain of command; however, there are exceptions. Exceptions are likely to appear in hospitals and health systems that have experience with natural disasters (e.g., University of North Carolina Hospitals' experience with hurricanes), known manmade threats (e.g., Intermountain Healthcare's experience with chemical stockpiles and manufacturing research facilities), and/or specialized facets of bioterrorism threats (e.g., University of Pittsburgh Medical Center Health System). The boards of directors of such health systems are beginning to request methodologically rigorous research and comparative preparedness data for benchmarking and quality improvement of emergency management—the customary practice over the past decade for health care quality and, more recently, patient safety.

The Agency for Healthcare Research and Quality (AHRQ) sponsored the Integrated Delivery System Research Network (IDSRN),[*] a network of five health systems with nearly 70 hospitals in seven States across the United States committed to applied research representing a cross-section of the hospital industry. In-depth knowledge of these health care systems—and more

[*] RTI Master Task Order Contract No. 290-00-0018, L.A. Savitz, Director; 2004.

general knowledge of the hospital industry—was obtained, affording the opportunity to identify several common practices. The leadership of the administrative emergency management function in health care organizations was often former military personnel with security experience or individuals who had worked their way up through increasing responsibility in facility/environmental services. Only those organizations with the most visible commitment to emergency preparedness also had clinical champions who partnered with the administrative emergency management function. Conversely, quality management typically had clinical leaders (i.e., physicians and/or nurses) with some training or on-the-job experience in health care administration. These individuals were repeatedly trained through continuing education and professional society meetings, used a journal specifically dedicated to implementation science (visit http://www.implementationscience.com), and reinforced change management principles using the Institute for Healthcare Improvement collaborative model (visit http://www.ihi.org). A corollary for support of similar change management efforts does not exist for emergency management. However, fostering transfunctional collaboration of emergency preparedness and quality improvement is promising; both the Joint Commission (see the Joint Commission–issued, revised emergency management standards that were effective January 1, 2008 – visit http://www.jcrinc.com/28380) and the American Hospital Association are working toward increasing opportunities for such dialogues.

Recent experience with Hurricane Katrina has highlighted the "soft underbelly" of hospital preparedness and emphasized the inseparable role that emergency management plays in the overall quality and safety of health care delivery. The emergency preparedness of this country is based on a robust health care delivery system. The public expects and is entitled to receive the highest quality evidence-based care within the most efficient delivery system possible. At times of crisis be it a disaster, natural or man made, or a major infectious disease, SARS or Pandemic, the already stressed health care system operating at the margins will be challenged to deliver this level of care without concerted planning and cooperation. Nurse executives must lead a cultural shift towards using evidence-based management and clinical practices (Williams 2006) in both quality improvement and emergency preparedness. Principal team players must include nurses, who are the essential back-bone of successful change efforts in hospitals (Savitz & Kaluzny, 2000). The extent to which nursing leaders, including middle managers, can be engaged in change management activities (Dopson & Fitzgerald, 2006) for emergency preparedness will be an important investment in successful design and implementation of targeted interventions. There is not good visibility for emergency preparedness commitment on the part of clinical staff in operational areas demonstrated, for example by most staff avoiding required drills failing to see the priority from their leaders. Health system leadership can change this by appropriately acknowledging and rewarding such efforts and modeling the commitment.

Opportunity for Learning Exchange

Development of meaningful working relationships and opportunities for learning exchanges between quality improvement and emergency preparedness initiatives could fundamentally enhance change management efforts within these separate functional areas in hospitals. There are differences in the degree to which initiatives in emergency preparedness are germane to quality improvement with respect to knowledge utilization (e.g., community collaboratives, data sharing, information technology solutions, measurement and feedback reporting to involved staff). This is because nurses can be involved in both quality improvement and emergency response in their

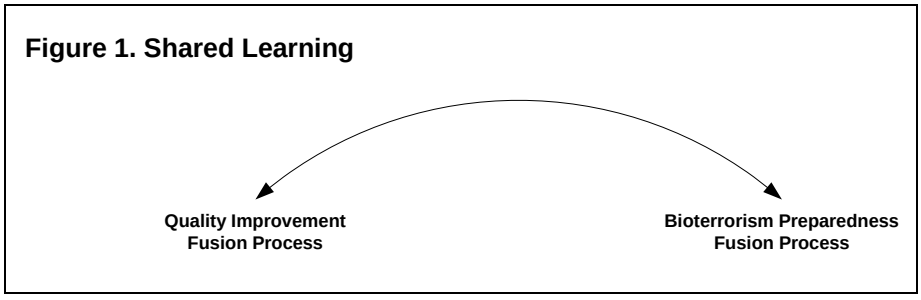
role as caregivers and clinical managers. Consequently, it would be possible to link knowledge-based learning about how interventions are implemented (a.k.a., implementation science) so that advancements in our understanding are not confined to any single aspect of quality health care delivery, but are opportunities for cross-fertilization and synergy.

As stated by Mittman,[4] implementation science focuses on a second level of research translation where one takes evidence-established benchmarks from limited settings (i.e., level 1 translation) to practice innovations, and more broadly to disseminate that knowledge. Implementation science (or second-level research translation) is an evolving, multidisciplinary area, and the terminology has not yet been consistently established. For example, Chapter 7 ("The Evidence for Evidence-Based Practice Implementation") in this *Handbook* discusses "translation science" to describe the same concept. Despite the inconsistent terminology, researchers and practitioners are committed to implementing and disseminating promising practices.

Disseminating and Implementing Promising Practices

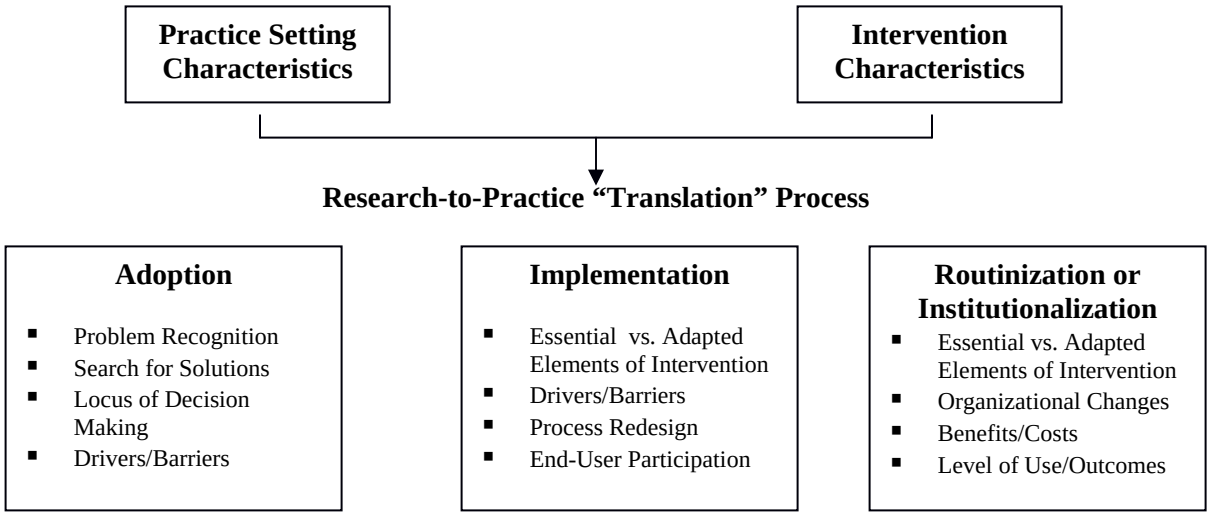
The difficulty of disseminating innovations is a persistent conundrum across settings and situations. There is limited ability to spread successful interventions across a single health care organization, let alone to unaffiliated organizations. The real challenge for health care implementation science is figuring out how to "flatten our world."[5] Opportunities for shared learning (Figure 1) could serve to accelerate the diffusion of innovation processes.[6] By directly engaging nursing leadership, current organizational barriers that inhibit application and shared approaches that promote quality improvement[3] and readiness for emergency response could be ameliorated, but integrating both tacit (i.e., personal experience) and explicit knowledge (e.g., evidence) can be difficult to achieve.[7] The challenge to nursing will be translating quality improvement research into practice to address both functional roles—quality and preparedness.

Figure 1. Shared Learning



The notion of an implementation deficit between what is planned versus achieved and the challenge of effectively translating research into practice has a long-standing literature base, primarily in organizational studies and public policy analysis.[6, 8, 9] In terms of nursing, the research has been inconclusive even about the evidence for specific interventions.[10] A generalized conceptual model of translational implementation, based on Rogers's seminal work,[6] has been incorporated into numerous change management efforts such as the RE-AIM[11, 12] (Figure 2).

Figure 2. Conceptual Model



What we know from reported studies and have been learning in subsequent research is that change will be a nonlinear process stymied by individual and organizational barriers.[2, 13–16] Attempts to advance implementation science in health care have focused on the factors that affect adoption and sorting out different strategies to accelerate that second level of translating of research into practice.[2, 17, 18] A recent report by Hamel[19] described the conditions necessary for management innovation that produced bold breakthroughs in how business was done, including commitment to a big problem (e.g., bioterrorism preparedness), new approaches (e.g., application of information technology such as electronic medical records), deconstruction of management orthodoxies (via exchanged resources and knowledge between the quality improvement and emergency management silos), and shared stories from diverse organizations that redefined what is possible. Early adopters lead the way.

Over the past decade, targeted research related to understanding how clinical process innovations are adopted has been funded by the AHRQ. Building on that base effort, the AHRQ funded the Partnership for Advancing Quality Together (PAQT) grant[*] (part of the AHRQ's Partnerships for Quality initiative) to achieve the following specific aims: strengthen an existing research network that promotes sharing of local innovations, explore factors that impede and facilitate inter- and intra-organizational sharing of knowledge, provide a mechanism to test the transportability of clinical process innovations, influence the breadth and depth of the evidence base for quality improvement, and accelerate the rate at which knowledge utilization occurs. Underlying these aims was a directive to explore the potential synergies between quality improvement and emergency preparedness.

Collaborative efforts to address these issues was done in a focused manner through 17 applied research projects, which led to several important findings and strategies for supporting knowledge transfer and implementation science that are relevant to both quality improvement and emergency preparedness. The three main findings are:

[*] AHRQ 5 U18 HS13706.

- Organizational modeling by credible organizations can accelerate knowledge transfer.
- The primary evidence base (the peer-reviewed literature) is limited to the extent that many innovations are not reported and there is a bias toward reporting only successful efforts, when we can often learn as much from failed attempts.
- Innovations in health care delivery are often complex interventions with multiple elements that are not fully reported, and essential versus adaptable elements of these complex interventions are not clearly delineated.

The bedrock propositions, common to all innovation packages, are that (1) how we deliver preventive or therapeutic services and how we organize those efforts within health care systems and facilities should, whenever possible, be based on knowledge of what works; and (2) effectively sharing such knowledge is a common feature of successful efforts generalized beyond a single program or facility.[20, 21] Understanding how knowledge (i.e., research information and data together with developed tools) can be used to drive high-quality and safe care delivery is critical. This understanding will allow for necessary and innovative changes in practice and processes at both the organizational level and at the point of service.[16]

Health care organizations typically view information and analysis in the context of local data derived from the experiences of patients served in their own organizational settings. Efforts to drive change innovations have expanded this notion of information to include both health services research conducted locally and studies reported in the peer-reviewed literature. Such research reports offer tested models for improvement; however, various barriers such as publication bias,[22] reporting time lags,[23] journal prestige,[24] and the overwhelming volume of a dispersed body of literature diminish the accessibility of such needed evidence. The problem of nontransportability of potential advances in health care information technology efforts is just the newest illustration of a much larger dilemma of generalizability beyond single institutions or systems. The challenge is to build an evidence base and place such evidence in the hands of those who are charged to operationalize knowledge transfer.

Evidence-Based Quality and Safety

Health services researchers and organizational leaders have more recently advocated evidence-based health care or EBHC.[8, 15, 20, 25–27] Sackett[28] defined EBHC as a "bottom-up approach based on good clinical management and supported by the best available evidence and taking into account patient priorities." The "enthusiasts of EBHC naively assumed that the case for implementation would be self-evident and that it would spread automatically and quickly"[8] (p. 29). Further, the authors contend, "There should be a strategy of creating evidence in priority areas, with concomitant systematic efforts to accumulate evidence in the form of robust bodies of knowledge" (p. 30). AHRQ has led the way for the synthesis of evidence through its Evidence-Based Practice Centers or EPCs (visit http://www.ahrq.gov/clinic/epc). Such evidence should be actively disseminated to where it is most needed and made available for the widest possible use.[8]

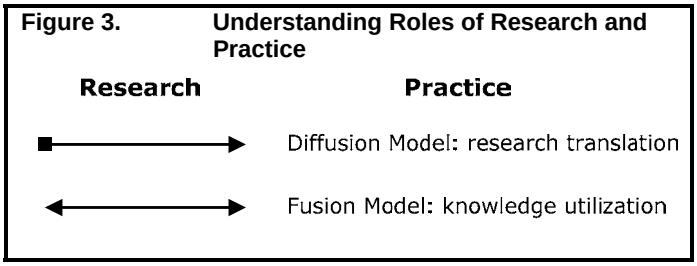
Health care organizations characterized by different levels of experience with clinical process innovation and staff tolerance for change set the "evidence bar" quite differently.[2] Mature organizations with extensive experience and local pilot projects require independent research by affiliated researchers whose results were published in the peer-reviewed literature. Less experienced organizations are comfortable simply modeling clinical process innovations based on evidence in the peer-reviewed literature, but without local development and testing. Further,

we have learned[29] that there is a life cycle associated with organizational learning, and where an organization or unit sits on that life cycle is influenced by staff tolerance for change and experience with innovation implementation over time. Whether the evidence is self-generated or modeled from reports in the literature, a primary issue is how to appropriately target intended end users. Novel approaches and use of preexisting dissemination channels will be needed to accelerate the rate at which such knowledge is put into practice.

Implementation Science in Practice

A great deal of attention has been paid to understanding the process of implementing science into practice.[30–33] Recent work conducted by Helfrich and colleagues[34] in studies funded by the Centers for Disease Control and Prevention and AHRQ suggest that it is more meaningful to examine how knowledge is used to influence changes in organizations and the microsystems of care by viewing this as a "fusion versus diffusion" process. Level 2 translation of research into practice (Figure 3) traditionally presumes a unidirectional flow or diffusion of information from research to practice; this presumption may act as a barrier to uptake quite apart from the limitations of the evidence base noted above. In contrast, a fusion perspective acknowledges shared learning between research and practice (i.e., knowledge utilization) whereby each informs the other to advance understanding.[35, 36] Concomitantly, the source of evidence and how that evidence is packaged and communicated greatly influences its use. Active engagement of organizational leaders and clinical investigators in the research process, as we propose herein, has proven critical to effective fusion/knowledge transfer.[13, 15, 37–39] Chapter 7 in this *Handbook* discusses steps for evidence-based practice in greater detail, drawing on Rogers's[6] work and the AHRQ model (Figure 3).

Figure 3. Understanding Roles of Research and Practice



Our review of literature reporting on health care innovations suggests that there are three overarching problems to the dissemination of evidence-based innovations: (1) incomplete reporting of interventions being implemented, (2) biased literature, and (3) the fact that interventions evolve over time as an effort moves through various stages from adoption to implementation through institutionalization/routinization.

Implementation efforts are not fully reported, limiting dissemination and uptake in other places. With this limitation in mind, we demonstrated our ability to fully capture all elements of complex interventions in a recent study of diabetes management in 15 community-based sites: *Evaluation of the Robert Wood Johnson Foundation Diabetes Initiative* (2003–2005), L.A. Savitz, Qualitative Research Director. A key finding from the formative evaluation was the breadth and complexity of interventions that evolved as the programs were implemented. Indeed, without probing, none of the sites visited had fully reported the breadth of intervention elements (ranging from 9 to 37) they developed and were using.

We have observed that interventions are adapted as they are implemented in varying clinical settings and/or for different patient populations. In addition to our understanding of the extent to which innovations are underreported and bias in the literature (limiting knowledge transfer), our observation that interventions evolve during implementation through institutionalization/

routinization is important; and we have the tools to monitor such evolution in comparing and contrasting a single intervention across multiple clinical sites.

Generalized Approach for Implementing Quality and Safety Interventions

Basic tenets of quality improvement in health care organizations include the necessity to embed and routinize an intervention into the normal work process. From an emergency preparedness perspective, this same issue is addressed through the design of dual-use tools and technologies. The shared intent is to ensure that an intervention is practiced and available when needed (e.g., resuscitation procedures on medical units, personal protective equipment and isolation precautions hospital-wide). The construction of such interventions follows a knowledge management and decision support model whereby

- A problem is identified and has visibility with executive management.
- A clinical champion is identified and a team is formed.
- The process is flow charted before and after implementation of the intervention so that changes in responsibility and resource needs are transparent.
- Necessary tools to support the change are developed and used (outcomes tracking, built into decision support information systems, and education/training materials).
- Monitoring with feedback is provided to involved staff on a periodic basis for review.
- Continual detailing of the intervention is recorded for ongoing improvement and maintenance.

While quality improvement in health care has built on the existing evidence base around how to manage and guide change, similar evidence is virtually nonexistent in the emergency/bioterrorism preparedness literature. Nevertheless, similar strategies for improved functioning are observed (e.g., systematically conducting drill exercises with evaluation measures for monitoring, feedback, and improvement), and these initiatives would likely benefit from the growing implementation science evidence base.

Specific examples of similar, yet separate, strategic interventions for enhanced functioning used in hospital settings include the following:

- **Drilling:** Scenario-based event drills are used in both functional areas; for example, emergency preparedness drills[40–42] and maternity ward eclampsia drills[43] have been used to train and refresh staff knowledge of key processes and protocols in the event of an infrequent yet crisis situation.
- **Training and simulation technology:** Skill-based training is deeply rooted in both areas with tools developed to support such efforts.[44–46] For example, simulation as a training and assessment tool has been used at Cornell-Weill, UPMC Wiser Center, and in the United Kingdom for intubation training.
- **Triage:** This is a common concept used in providing quality health care and in emergency response.[47, 48] However, a major departure from clinical training for triage activities occurs when a health care facility has scarce resources and is overwhelmed by the victim load, requiring battlefield triage in which the most likely survivors are treated first (i.e., frail elderly and small children may not be the highest priority given their vulnerability to succumb).[49]
- **Surveillance:** Quality improvement and infection control have long-standing experience in conducting surveillance for nosocomial infections, and a growing area in patient safety

is targeted injury detection systems. Surveillance systems for bioterrorism have been deployed at the health system (e.g., Intermountain Healthcare during the Winter Olympics) and regional levels for monitoring select illness and disease patterns to mitigate potential events.

- **Performance measurement:** Performance measurement in quality improvement is currently getting a great deal of attention[50] due to the early mantra of leading thinkers like Juran—*you can't manage what you can't measure*. Boards are now asking for emergency preparedness measures to ascertain comparative readiness.[*]

As illustrated by these examples, both areas—quality improvement and emergency preparedness—are focused on preparedness, and both face the challenge of how to implement targeted interventions. As one seeks to implement new programs and interventions in complex health care settings, one faces the same challenges associated with adoption, implementation, and maintenance of the intervention. Teams in both domains should consistently report both successes and failures within their settings and in publications that reach those most likely to use such information and be open to understanding how such reports can advance their respective work. Further, taking successful quality improvement or emergency preparedness interventions and disseminating such promising practices across a health system, a community, and/or to the industry is a hurdle at best.

Generalized Approach to Dissemination and Implementation

As part of the PAQT work, a committed group of organizational liaison staff was established that has worked successfully together on 17 projects in both bioterrorism preparedness and quality improvement. This PAQT grant has allowed the investigators to bring staff from partner health systems together for in-person meetings to discuss key organizational and care process issues, create a community for shared issue identification and learning, and explore the diffusion of knowledge within and across integrated delivery systems. In particular, the focus has been to study successful bioterrorism preparedness and quality improvement interventions, their adoption, and diffusion across the research network, together with identifying synergies across quality/safety and emergency preparedness. From the assessment of required implementation in the PAQT grant, a six-step strategy to promote cross-system diffusion of learning has been identified (Table 1).

Table 1. Generalized Strategy for Dissemination and Implementation

	"Implementation Science" Learning from Partnership in Advancing Quality Together
Step 1	Pilot innovation in credible place by a credible clinical champion with an engaged team that is empowered with resources.
Step 2	Create a toolkit or manual that serves as a conduit with audit tool for performance monitoring and feedback to involved staff.
Step 3	Review by adopting organization/unit facilitated by linking agent/clinical champion and his/her team.
Step 4	Adaptation by adopting organization/unit.
Step 5	Phased implementation: seeding the innovation on a small scale to support minimal adaptation and demonstrate value.
Step 6	Spread; organization-wide diffusion as appropriate.

[*] The American Hospital Association is currently fielding a survey that is intended to generate data that will yield comparative results on hospital preparedness.

Visibility with facility leadership and a six-step approach have been developed from observed implementation efforts over the past 2 years. This generalized approach to dissemination and implementation is both evidence- and experience-based, having been used successfully in leading partner health systems for both bioterrorism preparedness and quality improvement interventions.

Key among these six steps is the preparation of the training manual (the *conduit*) and the site-specific clinical champions (*linking agents*), which are believed to be essential in accelerating innovation diffusion and institutionalization.[*] The constructs of conduits and linking agents were recently conceptualized by Rogers[6] within his diffusion of innovation framework and related literature. Conduits are those tools or dissemination vehicles developed to facilitate uptake of research into practice (i.e., a DVD and companion training manual). Using conduits has been a major focus of our applied research and dissemination efforts to date. Linking agents have been described both in terms of agencies within a system (e.g., community hospital policies) and individuals (e.g., staff nurses implementing guideline recommendations); linking agents are the same as opinion leaders/champions or change agents. While the importance of conduits and linking agents are separately acknowledged in the change management and quality improvement literature, integration of the conduit and linking agent constructs into formal implementation planning processes has not been done.

Practice Implications

As a hospital addresses quality improvement throughout its operating structure, it should be examining all aspects of performance relating to delivering safe and high-quality services to its patients in all situations. These quality improvement efforts not only address the day-to-day services and functions, but also address the ability to meet those challenges presented during an emergency. Institutions should be incorporating evidence-based quality improvement measures that build on efforts already in place and begin to build the evidence and experience for emergency preparedness that complement these efforts. Maintaining separate structures for these activities is not only inefficient, but counterproductive.

As health care systems institute change management efforts, they should be incorporating emergency preparedness initiatives. Health care organizations should address a series of emergency preparedness activities and should initiate them within their quality improvement framework. For example, if an exercise is conducted to test the emergency preparedness plan, meeting one of the performance standards of the Joint Commission accreditation, it should be set up within a quality improvement framework. The institutional or unit performance should be measured for emergency preparedness using evidence-based tools like the one developed by AHRQ.[51] This quality improvement strategy—deployed throughout the system to address efficiency, effectiveness, and safety/quality—is no different or separate from this one dimension of emergency preparedness. As the metric of preparedness performance is measured, focused quality improvements can be initiated.

There is an impressive body of quality improvement literature that can be brought to bear on emergency preparedness. However, the literature on the metrics for preparedness and quality

[*] The research evidence for this approach is reviewed in depth in Chapter 7 of this *Handbook*.

improvement is scant and inconclusive.[52] Health care organizations on the cutting edge of this field are encouraged to report the use of evidence-based tools and piloted quality improvement measures in the literature and share their experience with colleagues. It was mentioned earlier in this paper that there are few forums that address institutional emergency preparedness measures that are initiated within a quality improvement framework. Hospitals and health systems should create opportunities for dialogue and shared learning; they should support the development of leaders within their organizations who bridge the chasm between the two activities. Nurses are well positioned to provide such leadership. The astute manager of these organizations should address vital strategies for reorganization that merge these activities and consider the career path for clinical leaders within the organization who can participate and provide leadership in the planning and evaluation strategies for these innovations. To achieve organizational awareness and commitment, the merged mission activities need to be supported though open dialogues and structured committee discussions at all levels of the organization affected by emergency preparedness.

The emergency preparedness activities thrust on an organization can either be presented as an annoying add-on function that distracts the organization from its primary mission, or they can be incorporated into the fabric of the mission and staff roles. The unique exercises and training activities required for emergency preparedness could be expanded to incorporate testing and evaluating new quality improvement measures. For example, resuscitation competency training in the emergency department could easily be incorporated into a drill testing the emergency department's response to an explosive or mass-casualty attack—thereby testing a day-to-day activity that can be measured for improvement and instituting remedial training alongside other skills and competencies for an effective emergency response. Also, essential in emergency preparedness planning are critical functions and strategies that require activities to protect the staff and the facility (e.g., avoiding contact with an infectious agent or a contaminant). Strategies such as fit testing masks, decontamination procedure, mass prophylaxis of staff and their families, and enhanced infection control measures are not unique to emergency preparedness and, therefore, are easily accommodated in day-to day-quality improvement, education, and training requirements of any health care institution. A good clinical champion from the infectious disease department (usually a nurse) can easily translate the interrelatedness of the two functions and readily get on board with an integrated approach.

Research Implications

This is an exciting and dynamic area in which little is currently known. Nurse leaders, nurse researchers and other nurses should and can have a critical role in taking these aforementioned concepts and design strategies, building on quality improvement and emergency preparedness methods, and demonstrating their effectiveness and impact. High priority should be given to developing and testing models that can be generalizable and actionable for clinicians that clearly define the roles and impact of nursing leadership. In so doing, the actual process of integrating quality improvement and emergency preparedness needs to be clearly delineated so that the successes of demonstration projects can be understood and replicated, particularly in preparation for unanticipated catastrophic events.

Conclusions

Nursing leadership has the opportunity to use new emergency preparedness evidence- and experienced-based measures that are or can be developed and disseminated. To realize this integrated approach locally, it is essential to embed interventions into the fabric of work and make these efforts visibly present so that staff are perpetually readied for the day-to-day issues of improving quality and safety, and the extraordinary issues of an unanticipated catastrophic event. With strong mission leadership to merge the two areas structurally and functionally, acceptance of valid measures and cross-integration can be achieved. In conclusion, hospital leadership should

1. Recognize the synergies between quality improvement and emergency preparedness, providing support, visibility, and performance feedback for these shared functions;
2. Empower clinical leaders to formally bridge the gap and share knowledge across these functional areas; and
3. Support the evidence base by providing resources to contribute to the literature on implementation science that can foster modeling in other facilities and communities.

Building the evidence base and recognizing the synergies between quality improvement and emergency preparedness is vital for the safety of patients in the resource-constrained environment in which we provide hospital care. Executive management is challenged to think prospectively to connect the dots and take advantage of these synergies to efficiently provide the highest quality health care possible to their patients.

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Chapter 10. Fall and Injury Prevention

Leanne Currie

Background

Fall and injury prevention continues to be a considerable challenge across the care continuum. In the United States, unintentional falls are the most common cause of nonfatal injuries for people older than 65 years. Up to 32 percent of community-dwelling individuals over the age of 65 fall each year, and females fall more frequently than males in this age group.[1, 2] Fall-related injuries are the most common cause of accidental death in those over the age of 65, resulting in approximately 41 fall-related deaths per 100,000 people per year. In general, injury and mortality rates rise dramatically for both males and females across the races after the age of 85, but males older than 85 are more likely to die from a fall than females.[2-6] Unfortunately, fall-related death rates in the United States increased between 1999 and 2004, from 29 to 41 per 100,000 population.[2, 7] Sadly, these rates are moving away from the Healthy People 2010 fall-prevention goal, which specifically seeks to reduce the number of deaths resulting from falls among those age 65 or older from the 2003 baseline of 38 per 100,000 population to no more than 34 per 100,000.[8] Thus, falls are a growing public health problem that needs to be addressed.

The sequelae from falls are costly. Fall-related injuries account for up to 15 percent of rehospitalizations in the first month after discharge from hospital.[9] Based on data from 2000, total annual estimated costs were between $16 billion and $19 billion for nonfatal, fall-related injuries and approximately $170 million dollars for fall-related deaths across care settings in the community.[10, 11] Several factors have been implicated as causes of falls and injuries; to date, however, no definitive predictor profile has been identified. Although the underlying status of the individual who sustains a fall may contribute to the fall and subsequent injury, the trauma resulting from the fall itself is most often the cause of morbidity and mortality.

Over the past 20 years gerontology researchers, spearheaded by Mary Tinnetti from Yale University, have carried out a significant amount of research to address the problem of falls and injuries in the community. However, ubiquitous use of successful interventions is not yet in place in the community. As health care moves toward patient-centered care, and as a growing body of research provides guidance for widespread fall-prevention programs, fall- and fall-related-injury prevention now has the potential to be addressed across the care continuum.

Inpatient fall prevention has been an individual area of concern for nursing for almost 50 years.[12, 13] Traditional hospital-based incident reports deem all inpatient falls to be avoidable, and therefore falls are classified as adverse events. Indeed, falls are the most frequently reported adverse events in the adult inpatient setting. But underreporting of fall events is possible, so injury reporting is likely a more consistent quality measure over time and organizations should consider judging the effects of interventions based on injury rates, not only fall rates. Inpatient fall rates range from 1.7 to 25 falls per 1,000 patient days, depending on the care area, with geropsychiatric patients having the highest risk.[14-18] Extrapolated hospital fall statistics indicate that the overall risk of a patient falling in the acute care setting is approximately 1.9 to 3 percent of all hospitalizations.[16-18] In the United States, there are approximately 37 million hospitalizations each year;[19] therefore, the resultant number of falls in hospitals could reach more than 1 million per year.

Injuries are reported to occur in approximately 6 to 44 percent of acute inpatient falls.[5, 20-23] Serious injuries from falls, such as head injuries or fractures, occur less frequently, 2 to 8 percent, but result in approximately 90,000 serious injuries across the United States each year.[20] Fall-related deaths in the inpatient environment are a relatively rare occurrence. Although less than 1 percent of inpatient falls result in death, this translates to approximately 11,000 *fatal falls* in the hospital environment per year nationwide. Since falls are considered preventable, fatal fall-related injuries should *never* occur while a patient is under hospital care.

In the long-term care setting, 29 percent to 55 percent of residents are reported to fall during their stay.[24, 25] In this group, injury rates are reported to be up to 20 percent, twice that of community-dwelling elderly. The increase in injury rates is likely because long-term care residents are more vulnerable than those who can function in the community.[26] Rubenstein[27] reported 1,800 long-term care fatal falls in the United States during1988. The current number of long-term care fatal falls has not been estimated; however, there are 16,000 nursing homes in the United States caring for 1.5 million residents in 2004.[28] This population will likely grow in the coming years, thus fall and injury prevention remains of utmost concern.

Fall and Fall-Related Injury Reporting

Falls and related injuries have consistently been associated with the quality of nursing care in the acute care setting. They are included as a nursing-quality indicator monitored by the American Nurses Association, National Database of Nursing Quality Indicators (ANA–NDNQI) and by the National Quality Forum.[29, 30] Participation in the ANA–NDNQI provides hospitals with the ability to view their fall and injury rates in relation to other hospitals of similar type and size. However, participation in ANA–NDNQI is voluntary; despite a rapidly growing participation rate, it is not yet ubiquitous (1,089 hospitals as of June 2007, approximately 15 percent of U.S. hospitals). The National Quality Forum also advocates for voluntary reporting of quality indicators for acute care (falls prevalence and fall-related injuries) and ambulatory care (fall-risk screening for geriatrics).[31, 32]

The Maryland Quality Indicator Project is a second voluntary national repository that provides fall and fall-related injury benchmarks for the behavioral health, long-term care, and home care settings.[33] Unfortunately, this project has a participation level of approximately 1,000 hospitals (approximately 14 percent), making national benchmarking difficult. In the home care setting, the Centers for Medicare & Medicaid Service's Outcome and Assessment Information Set (CMS–OASIS) provides the reporting basis for the patients' physical functioning.[34] Growing efforts to expand patient safety initiatives to the home care setting seek to include falls as a quality indicator for patients who are cared for at home, but who are not completely bed bound.[35, 36] Collection of these data has the potential for organizations to track fall rates of vulnerable patients and to identify patients at risk for falls and injuries. However, further research is required to validate such screening and to examine which interventions are effective based on risk status.

In the nursing home setting, the long-term care minimum dataset (LTCMDS) is used for reporting all aspects of care. The LTCMDS captures fall and injury histories via assessments that are performed on admission and at regular intervals during a resident's stay.[37] In addition, residents are evaluated for balance and for the ability to perform activities of daily living (ADLs), with the goal to apply fall-prevention measures should the patient be deficient in these areas. Recent research by Hill-Westmoreland and Gruber-Baldini[38] indicated only a 75 percent

concordance between chart abstraction and minimum dataset reporting for a group of long-term care facilities. A more recent development in the long-term care setting, the Nursing Home Quality Initiative, promotes the collection of a list of enhanced quality indicators, including those that track declines in functional and cognitive status.[34, 37] The Agency for Healthcare Research and Quality (AHRQ) has elected to monitor only postoperative hip fracture as their fall-related preventive quality indicator, which is consistent with thinking that monitoring fall-related injuries is a more dependable measure of quality.[39, 40] However, tracking of all fractures would be of benefit. The Health Plan Employer Data and Information Set has recently added Fall Risk Assessment to its dataset, which will provide a method to benchmark the evaluation of fall risk between health insurance providers.[41] However, application of fall- and injury-prevention programs is not included as an indicator, which will make it difficult to benchmark these important measures. Increased and more accurate monitoring of these elements has the potential to reduce falls among nursing home residents; however, the effect of these efforts has yet to be established.

Definitions of Falls and Fall-Related Injuries

Falls and related injuries have had varying definitions.[42, 43] Falls may be precipitated by intrinsic or extrinsic factors. Intrinsic factors are those that have a physiologic origin, and extrinsic factors are those precipitating from environmental or other hazards. Distinguishing between intrinsic or extrinsic risk factors can facilitate identification of preventive strategies. According to Tinetti, Speechley, and Ginter,[44] a fall in the nonhospitalized geriatric population is defined as "an event which results in a person coming to rest unintentionally on the ground or lower level, not as a result of a major intrinsic event (such as a stroke) or overwhelming hazard." Agostini, Baker, and Bogardus[45] adapted this definition for the inpatient, acute, and long-term care areas to define a fall as "unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of syncope or overwhelming external force."

Other definitions are broader and include falls related to intrinsic events such as syncope or stroke. For example, Nevitt's[46] definition of a fall is "falling all the way down to the floor or ground, or falling and hitting an object like a chair or stair." The ANA–NDNQI provides an all-inclusive definition[47] (p. 26):

> An unplanned descent to the floor (or extension of the floor, e.g., trash can or other equipment) with or without injury. All types of falls are included, whether they result from physiological reasons or environmental reasons.

The International Classification of Diseases 9 Clinical Modifications (ICD-9-CM) uses several codes to categorize falls, all of which have broad descriptions: Accidentally bumping against moving object caused by crowd with subsequent fall (E917.6); Fall on or from ladders or scaffolding (E881); Fall from or out of building or other structure (E882); Other fall from one level to another (E884); Fall on same level from slipping, tripping, or stumbling (E885); Fall on same level from collision, pushing, or shoving by or with another person (E886); and Other and unspecified fall (E888).[48] In the inpatient care setting, E888 is the code that is typically used to record a fall in a medical record. However, this ICD-9-CM code is not consistently used for reporting; therefore, institutions generally rely on incident reports as the method of counting fall events.[48]

Fall-related injuries in the community, home care, and long-term care areas are generally characterized by ICD-9-CM diagnoses for the related injured body part. In contrast, incident reports in the acute care setting use the following ANA–NDNQI fall-related injuries categories:

(1) *None* indicates that the patient did not sustain an injury secondary to the fall.
(2) *Minor* indicates those injuries requiring a simple intervention.
(3) *Moderate* indicates injuries requiring sutures or splints.
(4) *Major* injuries are those that require surgery, casting, further examination (e.g., for a neurological injury).
(5) *Deaths* refers to those that result from injuries sustained from the fall.[29]

According to Morse,[21] inpatient falls can be classified into three categories: accidental falls (derived from extrinsic factors, such as environmental considerations), anticipated physiologic falls (derived from intrinsic physiologic factors, such as confusion), and unanticipated physiologic falls (derived from unexpected intrinsic events, such as a new onset syncopal event or a major intrinsic event such as stroke). Morse asserts that using this classification, approximately 78 percent of the falls related to anticipated physiologic events can be identified early, and safety measures can be applied to prevent the fall. Research to identify precursors to unexpected intrinsic events, such as screening for predictors of syncopal events, might increase the early identification of anticipated physiologic falls, which could ultimately prevent more falls.[49-51]

Falls and Fall-Related Injuries as Medical Errors

The definition of a fall is consistent with that of a medical error: "the failure of a planned action to be completed as intended" (i.e., error of execution) or "the use of a wrong plan to achieve an aim" (i.e., error of planning).[52, 53] For example, an error of execution might be the failure to perform the planned action of placing a call light within the patient's reach, and an error in planning might be to provide aggressive physical therapy before a patient's balance has been established. An error of commission is "an error that occurs as a result of an action taken," for example, a fall that occurs subsequent to a behavioral health patient's electroconvulsive therapy. An error of omission, "an error which occurs as a result of an action not taken," might occur if the patient is not assessed for fall and injury risk, which prevents appropriate interventions from being applied. Latent errors related to fall and injury prevention are those in which an agency does not apply appropriate standards, training, or support for the practice-based fall- and injury-prevention processes. Recent efforts by the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) in its National Patient Safety Goals advocate for institution-wide risk assessment for falls and documentation of a fall-prevention program.[54] These efforts have the potential to eliminate latent errors related to falls and injuries. Monitoring errors might occur if the patient is not monitored to identify fall risk, or if the patient is not monitored to identify a post-fall injury such as a subdural hematoma.

This review summarizes the current research related to fall and injury prevention. The chapter is organized to present research from two perspectives: (1) community setting, and (2) acute and long-term settings. For each setting, the research that addresses risk factors, risk assessment instruments, and fall- and injury-prevention interventions are reviewed. Reports on the outcomes of fall- and injury-prevention research using experimental or quasi-experimental research design is summarized in tables at the end of the chapter.

Research Evidence

Falls and Related Injuries in the Community

In the following section, research about falls and related injuries in the community were identified and categorized as follows: risk factor identification, risk assessment instruments, and prevention strategies.

Risk factors in the community. The pivotal research of Tinetti, Speechly and Ginter[44] related to fall and injury prevention in community-dwelling individuals older than 65 years identified the following risk factors for falling: (1) postural hypotension, (2) use of any benzodiazepine or sedative-hypnotics, (3) use of four or more prescription medications, (4) environmental hazards, and (5) muscular strength or range of motion impairments. Other researchers have identified additional patient or treatment risk factors: (1) comorbidities, including diabetes, diabetic foot ulcer,[55] stroke,[56] syncope,[57] anemia,[58, 59] Alzheimer's disease,[60] Parkinson's disease,[61] vitamin D deficiency,[62, 63] and vitamin D deficiency in combination with low creatinine clearance;[64] (2) patient characteristics, including fallophobia (also known as "fear of falling"),[65, 66] gait problems (e.g., weakness and impaired sensation),[67] postural hypotension, inability to get out of chair, impaired ability to perform ADLs, frailty,[68-70] inability to follow instructions,[71] and inability to adapt to changing environment;[72] and (3) other characteristics, including recent hospitalization,[9] nonsupportive footwear (e.g., slippers),[73] reckless wheelchair use,[74] environmental hazards, and use of psychotropic medication.[75, 76] Age and gender are also associated with falls and fall-related morbidity and mortality. Fall rates increase with age,[77] and in community-dwellers between 65 and 85 years of age, females are more likely to fall, but males are more likely to die from fall-related injuries than females in this group.[1, 2]

The roles of ethnicity and race in relation to falls and injury have also been studied. Reyes-Ortiz and colleagues[78] examined risk factors for Mexican-Americans and found that in the community, the risk factors are the same as for their White counterparts. Hanlon and colleagues[79] examined predictors of falls between Caucasians and African Americans and found that African Americans were 23 percent less likely to fall than Whites (odds ratio = 0.77). Faulkner and colleagues[80] explored this difference in women and found that Caucasian women were 50 percent more likely to fall than African American women, although this was not statistically significant (relative risk = 1.50, 95% confidence interval [95% CI] = 0.90–2.49). The researchers further examined situations leading to falls and found that circumstances differed by ethnicity: Caucasian women were more likely to fall outdoors versus indoors (odds ratio = 1.6, 95% CI = 1.0–2.7) and laterally versus forward (odds ratio = 2.0, 95% CI = 1.1–3.4), but less likely to fall on the hand or wrist (odds ratio = 0.6, 95% CI = 0.3–1.0). This research suggests that activities differ between older African American women and their Caucasian counterparts and should be considered when making fall- and injury-prevention plans.

Risk factors for injury in the community. Risk factors for injury in the community are increasingly well characterized. Porthouse and her research team[81] performed a comprehensive cohort study of almost 4,300 women older than 70 years and confirmed the following risk factors for various types of fall-related fractures: (1) fall in the past 12 months, (2) increasing age, (3) previous fracture, and (4) low body weight. This work also identified that smoking was not associated with fracture risk. A growing body of research is examining vitamin D deficiency as a risk factor for fracture; however, results are conflicting to date, but bear further research.[81, 82]

Colon-Emeric and colleagues[83] used data from a large community epidemiologic study to identify whether historical and functional information could help to predict fracture risk. The researchers identified nine characteristics that were predictors of fracture: (1) female sex, (2) age greater than 75 years, (3) White race, (4) body mass index (BMI) of less than 22.8 kg/m^2, (5) history of stroke, (6) cognitive impairment, (7) one or more ADL impairments, (8) one or more Rosow-Breslau impairments (e.g., perform heavy work, walk a mile, climb stairs), and (9) antiepileptic drug use. Ohm and colleagues[84] recently identified that elderly community-dwelling individuals with traumatic head injuries were more likely to die based on the use of antiplatelet therapy (relative risk = 2.5 for those taking antiplatelet therapies; $P = 0.016$). A similar body of research related to chronic subdural hematomas has identified that patients on anticoagulant or antiplatelet therapy are at higher risk for chronic subdural hematoma and that many of these are first identified when a patient is evaluated after a fall.[85] Many injury risk factors are consistent with fall risk factors, accentuating the need for effective screening of elderly community-dwelling individuals. However, factors that make people more susceptible to injury, such as antiplatelet therapy, establish the need for additional safety measures for individuals at risk for injury. Table 1 lists the intrinsic and extrinsic risk factors for falls, injuries, and fall-related deaths in the community.

Table 1. Risk Factors for Falls, Injuries, and Fall-Related Deaths in the Community

Intrinsic Risk Factors	Fall Risk	Injury Risk	Mortality Risk
Demographics			
• Age: Older Age (especially >70yrs)	Yes	Yes	Yes
• Gender	Female	Female	Male >85
• Race	Caucasian	Caucasian	Caucasian
Cognitive Function			
• Cognitive impairment	Yes	No data	No data
• Fallophobia (fear of falling)	Yes	Yes	No data
• Inability to follow instructions	Yes	No data	No data
• Inability to adapt to changing environment	Yes	No data	No data
Physical Function			
• Gait problems	Yes	No data	No data
• Impaired ability to perform ADLs	Yes	Yes	No data
• Impaired muscle strength or range of motion	Yes	Yes	No data
• Poor/fair self-reported health	Yes	Yes	No data
• Rosow-Breslau impairment	No data	Yes	No data
• Vision problems	Yes	No data	No data
Physical Status			
• BMI less than 22.8 kg/m^2	No data	Yes	Yes
• Frailty	No data	Yes	Yes
• Low body weight (<58 kg=BMI 23 if height 5'3")	Yes	Yes	No data
Comorbidities			
• Alzheimer disease	Yes	No data	No data
• Anemia (including mild anemia)	Yes	No data	No data
• Diabetes	Yes	No data	No data
• Diabetic foot ulcer	Yes	No data	No data
• Fall in the past 12 months	Yes	Yes	No data

Intrinsic Risk Factors	Fall Risk	Injury Risk	Mortality Risk
• Parkinson disease	Yes	No data	No data
• Postural hypotension	Yes	No data	No data
• Previous fracture	No data	Yes	No data
• Stroke	Yes	Yes	No data
• Subdural hematoma (chronic)	Yes	Yes	No data
• Syncope	Yes	No data	No data
• Vitamin D deficiency	Yes	Yes	No data
• Vitamin D deficient w/ low creatinine clearance	Yes	No data	No data
Medications			
• Use of 4 or more medications	Yes	No data	No data
• Anti-epileptics	No data	Yes	No data
• Antihypertensives	Yes	No data	No data
• Antiplatelet therapy	No data	No data	Yes
• Psychotropics	Yes	No data	No data
• Sedatives and hypnotics	Yes	No data	No data
Extrinsic Risk Factors	**Fall Risk**	**Injury Risk**	**Mortality Risk**
• Environmental hazards	Yes	No data	No data
• Footwear, non-supportive (e.g., slippers)	Yes	No data	No data
• Hospitalization, recent	Yes	No data	No data
• Wheelchair use, reckless wheelchair use	Yes	No data	No data

Risk assessment instruments for community dwellers. Tinetti[86] developed a fall risk assessment index based on the following nine risk factors: mobility, morale, mental status, distance vision, hearing, postural blood pressure, back examination, medications, and ability to perform ADLs. This instrument has been the most widely used and tested, with a reported sensitivity of 80 percent and specificity of 74 percent.[87] Other instruments used in the community include the following (with reported sensitivities and specificities in parentheses): (1) Berg Balance Test (sensitivity = 77 percent; specificity = 86 percent), (2) Elderly Fall Screening Test (sensitivity = 93 percent; specificity = 78 percent), (3) Dynamic Gait Index (sensitivity = 85 percent; specificity = 38 percent), and (4) Timed Get Up and Go test (sensitivity = 87 percent; specificity = 87 percent).[87] Aside from the Timed Get Up and Go test, which takes less than a minute for a health care provider to administer, these instruments generally take 15 to 20 minutes to complete.[87]

Lord and colleagues[88] recently evaluated the effect of an exercise-related fall-prevention program, but found that the intervention was not useful in community dwellers who were not screened for risk. The researchers concluded that screening to identify individuals at high risk for falls would be necessary for a successful fall-prevention program. Further research to identify the most accurate, yet easy-to-use risk assessment instrument would be necessary to move these efforts forward.

A recent systematic review by Scott and colleagues[89] examined fall risk assessment instruments in the community. The authors concluded that, in general, risk assessment instruments are available; however, most have been tested in only one setting. Therefore, further validation studies should be conducted on fall risk assessment instruments before any specific instrument can be recommended.

A potential time point for risk assessment is in the emergency department (ED). Several researchers have examined the effect of fall- and injury-prevention interventions applied to patients who are discharged from the ED after a noninjury or nonserious-injury fall. The overarching goal of these studies is to evaluate the ability of comprehensive risk assessment followed by targeted interventions to prevent future falls and fall-related injuries. Several studies have successfully shown that screening followed by tailored management can decrease repeat falls.[42, 90-94] Close and colleagues[42] found that fall rates were reduced by 61 percent and recurrent falls were reduced by 67 percent for patients who had comprehensive risk assessment after a fall, compared to individuals who received standard treatment. Davison and colleagues[90] found a 36 percent decrease in fall rates after 1 year for patients who received a multimodal intervention for fall prevention after being identified as a faller on admission to the ED. In addition, these researchers noted an increase in falls self-efficacy, which is a measure of an individual's perception of their ability to manage situations where they are at high risk for falling – the higher self-efficacy, the more able a person is able to manage high risk situations. In a related study, Lee, Hurley, and colleagues[91] conducted a randomized controlled trial to examine the impact of a personal emergency response system and found that there was no difference between treatment and control groups for self-efficacy or patient anxiety. The Lee and colleagues study is informative in that emergency contact alone was not sufficient to improve a patient's belief in their ability to manage fall risk situations. Although no standardized instrument has yet been developed for use in the ED environment, the potential for the prevention of falls and related injuries in the community would be increased with the accurate identification of patients at risk for falls while they are in the ED.

Automated risk assessment in the community setting. To date, a limited number of computer-based, community-based fall assessment instruments have been described. By far the most complex and integrated is the Fall Risk Assessment and Management System, which was developed by the Australia Family Practice Group for use in the community by family practice physicians.[95] Fall Risk Assessment and Management System includes automated recommendations after the clinician executes a thorough patient assessment. Although this system appears promising, its efficacy has not yet been reported.

Lord, Menz, and Tiedemann[96] describe an electronic fall risk assessment instrument that provides a method to measure several risk factors, including vision, peripheral sensation, muscle force, reaction time, and postural sway. Although this instrument is thorough, it is meant for use by a physical therapist or a physician, nurse practitioner, or physician assistant for a focused fall risk assessment, rather than as a triage or screening tool. The novel aspect of this instrument is the comparison of the individual's score to the normative scores for each of the assessments, which provides the clinician with an anchor and may facilitate improved screening over time. However, the predictive validity of this instrument has not been reported, and its use may be limited to a fall-prevention clinic.

Another electronic fall risk assessment instrument, described by Dyer and colleagues,[97] is an electronic checklist in a fall-prevention clinic. Unfortunately, the researchers concluded that the clinic itself was more successful than the instrument in identifying risk factors for falling, underscoring the reality that the implementation of an instrument without associated policy and procedure changes may have limited effect.

The presence of these automated systems indicates that there is movement toward computerized fall risk assessment. Indeed, many clinical information systems have adapted paper-based assessment instruments for use in the acute care setting. However, the efficacy of

these systems has not been reported, and their effectiveness is likely to be constrained by the limits of the original instrument, the system in which they are placed, and the design team in ensuring that the automated instrument accurately reflects the original instrument.

Prevention strategies in the community. To date, several reviews conducted to examine the evidence available to support practice in this area have identified the need for multimodal, interdisciplinary prevention programs; the need for more accurate risk assessment instruments; and the need for more research related to this complex and costly problem.[11, 98-107]

Cumming[100] reviewed 21 trials and concluded that exercise programs were the most promising, and reduction of antipsychotic medications should be considered. However, Cumming also concluded that none of the reviewed research studies provided a definitive prevention strategy. Chang and collaborators[99] conducted a similar review targeted at examining interventions for older adults in the community and found that multimodal assessments with targeted intervention reduced risk of falls by 37 percent, and that exercise interventions reduced fall risk by 14 percent. Hill-Westmoreland, Soeken, and Spellbring[38] conducted a recent meta-analysis, including a sensitivity analysis, which identified an improved effect on fall prevention in the community when individualized management was added to exercise interventions. They concluded that exercise interventions were not sufficient in and of themselves, and interventions needed to be tailored to address individual risk factors.

Researchers have explored several other individual prevention strategies, including fall prevention clinics, exercise interventions with leg strengthening (e.g., Tai Chi), vitamin D supplements, home visits for safety evaluations, cataract surgery, and cardiac pacing. Falls and balance clinics present a promising community-based solution to the problem of falls.[108] Perell and colleagues[109] found a 50 percent reduction in fall rates for patients who were screened at a clinic and who had tailored interventions applied; however, this study had no control group and the researchers did not report injury rates, so the results are tentative. Clinics such as these provide focused intervention planning for patients identified at risk for falling, but the success of such clinics is contingent upon accurate identification of high-risk patients.

Identification of recurrent fallers via comprehensive screening followed by tailored interventions has been successful at reducing recurrent falls. Screening and intervention done in the ED reduced recurrent falls by 36 percent in one study,[90] and a nurse-led intervention that provided home assessment and tailored interventions reduced recurrent falls by 38 percent in another study.[110] Hogan and colleagues[111] also evaluated tailored interventions for patients who had had a fall within the past 3 months. They found no significant differences between the intervention and control groups in fall rates or time to first fall; however, the intervention group had a longer time between falls ($P = 0.001$). However, the Hogan and colleagues study limited inclusion criteria to patients older than 65 years of age who had fallen in the past 3 months, and these two factors alone are likely insufficient to determine risk. These recent studies add to early work in the PROFET study, which found a 61 percent decrease in falls for patients who were identified in the ED and who had subsequent detailed risk assessment and tailored interventions.[42]

Exercise-related interventions are by far the most commonly studied individual community prevention strategy. Most of this research indicates that exercise is beneficial for patients, and some research demonstrates that exercise regimes that involve leg strengthening and balance training, such as Tai Chi, are most effective.[112-122] Robertson and colleagues[123] performed a meta-analysis of four studies that examined effects of home exercise programs. They found in the pooled effect analysis that both fall and injury rates decreased by 35 percent. Exercise in

conjunction with cognitive behavioral therapy, where patients are taught how to increase self-awareness about risky situations, has demonstrated promising results, including a longer time to first fall and decreased injuries.[124] Unfortunately, this work did not demonstrate an effect on falls efficacy, fear of falling, or actual fall rates. More recently, balance training has been compared to general exercise, and results show that balance training can prevent falls in the nonfrail elderly, but not in the frail elderly.[125] Lin and colleagues[126] found that deployment of large scale Tai Chi training to the general community had mixed results. Luukinen and colleagues[127] found a decrease in fall and injury rates with a targeted exercise program when compared to usual care, but the results were statistically significant only in a group that was not homebound—suggesting that early intervention may be more effective. Further research to explore interventions for homebound community dwellers, particularly for the very old and frail, will be important.

Laboratory studies indicate that calcium and vitamin D reduce bone loss,[128] and a growing body of work is examining the ability for vitamin D supplementation to prevent fractures in individuals who are vitamin D deficient. A meta-analysis performed by Bischoff-Ferrari and team[129] revealed that larger doses of vitamin D supplementation (700–800 IU/deciliter) reduced the risk of fracture by up to 26 percent, whereas smaller doses of vitamin D (400 IU/deciliter) did not reduce fracture risk. However, research to date has been inconclusive, and larger, more recent studies have indicated that the use of vitamin D does not reduce fracture risk in the general community.[130] On the other hand, vitamin D supplementation may be integral in preventing falls themselves:[131] Recently, Latham and colleagues[132, 133] demonstrated that vitamin D intake is an individual predictor for fall reduction, primarily by improving muscle strength. Bischoff-Ferrari and colleagues[134] have also identified a reduction in fall risk for women, but not for men, using vitamin D supplementation. Although these results are promising, more research is required to identify best practice recommendations related to vitamin D deficiency screening and vitamin D supplementation or other bone-supporting medication regimes.

Other researchers are exploring the ability for osteoporosis-prevention medications to reduce fracture risk.[135] Sato and colleagues[136, 137] reported that risedronate, an oral bisphosphonate for osteoporosis prevention, was effective at preventing fracture in older females, older males who have had a stroke, and older females with Alzheimer's disease. A recent large study by McCloskey and colleagues[138] (N = 5579) demonstrated a 20–29 percent decrease in clinical fractures in community-dwelling females older than 75 years with and without osteoporosis who were prescribed clodronate 800 mg daily. However, this study did not find a decrease in hip fractures. Recent reports of adverse side effects of large doses of bisphosphonates, including osteonecrosis of the jaw, indicate that further research is warranted and that patients should be monitored for side effects of these drugs. Other related fall prevention efforts include home assessment for risk factors with the implementation of safety devices such as handrails, nonslip surfaces on stairs, and removal of throw rugs.[139-143] Researchers who conducted a recent randomized controlled trial found that thin-soled shoes were found to be the best type of shoe for patients, rather than running shoes, which have sticky soles.[144] Research addressing syncope-related falls indicate that cardiac pacing may be appropriate for individuals with syncope.[145]

Summary of community-based research on falls and related injuries. In summary, authors of several reviews have examined the efficacy of community-based fall- and injury-prevention programs. These reviewers have indicated that individualized multimodal interventions are effective at reducing falls and related injuries in the community setting.[105] However, multimodal interventions are not in place across primary care areas, which hinders their potential efficacy, and the aging community would likely benefit from large-scale

implementation of these proven preventive interventions. (See Evidence Tables 1 through 9 for individual study results.)

Falls and Related Injuries in the Acute and Long-Term Care Settings

Fall and related injury prevention is a major focus for both acute and long-term health care organizations. In 2005, the Joint Commission added the requirement for fall risk assessment and periodic reassessment as a National Patient Safety Goal in the acute care setting.[54] The goal of this requirement is to ensure that all patients are screened for falls and thus seeks to reduce harm from falls. However, the outcome is unpredictable because fall and injury risk assessment instruments have shown inconsistent reliability and validity A more promising extension of this goal starting in 2006 and continuing forward is the additional requisite of implementing and evaluating a fall-prevention program.[146] National compliance with these goals has the potential to significantly impact the problem of falls in the acute care setting. Efforts to enhance quality of care in the long-term care environment via improved reporting have the potential to reduce falls and related injuries in these particularly vulnerable patients; however, the successful implementation of fall-prevention programs will be necessary to improve the problem.

Falls in the acute and long-term care settings have several possible consequences. Recurrent falls have been identified as contributing to increases in the length of stay (LOS) in elderly psychiatric patients.[147] However, some research has suggested that LOS itself may be a predictor. A fall may also lead to a poorer quality of life because of fallophobia, a fear of future falls, which may itself contribute to fall risk.[148] Injuries occur in between 6 and 44 percent of falls in the acute care setting.[20, 21, 23] In the long-term care population, between 9 and 15 percent of falls result in injury, with approximately 4 percent of these falls resulting in fractures.[149] Additionally, patients who have underlying disease states are more susceptible to injuries; for example, osteoporosis can increase the risk for fracture, and bleeding disorders can increase the risk for subdural hematomas.[150] Moreover, fall-related injuries increase resource utilization: injuries from falls lead to increased LOS and an increased chance of unplanned readmission or of discharge to residential or nursing home care.[151] Furthermore, inpatients who have incurred an injury due to a fall have approximately 60 percent higher total charges than those who did not fall or those who fell and did not sustain an injury.[152]

Evans and colleagues,[153] via the Joanna Briggs Institute, performed a systematic review of the evidence up to 1997 for fall and injury prevention in the acute care setting. They examined 200 studies related to identification of predictors, risk assessment instrument development and testing, and fall- and injury-prevention interventions. Of these studies, only two were randomized controlled trials (RCTs). The trial by Tideiksaar and colleagues[154] examined the use of bed alarms to notify staff when patients at high risk for falls got out of bed; however, this study had a sample size that was too small to identify an effect from using bed alarms. The other RCT examined the use of colored bracelets to identify patients at high risk for falls. Again, the study results were inconclusive.[155] Evans and colleagues concluded that the fall risk assessment instruments available were not generalizable. However, they did not adequately compare the psychometric properties of the instruments in question; rather they evaluated research related to the implementation of such instruments, which was relatively weak up to that time. In addition, Evans and colleagues concluded that individual interventions were not more useful that any of the fall-prevention programs that might be developed at a particular institution for a specific subset of patients. However, recent research has seen a growing number of RCTs, which will

facilitate the ability to make stronger practice recommendations for this complex and challenging problem.

For this review, research related to falls and related injuries in the acute and long-term care settings were identified and categorized as follows: risk factor identification, risk assessment instruments, and prevention strategies. Each category of research is discussed below.

Acute care and long-term care risk factors. Factors associated with patients at risk of falling in the acute care setting have been explored extensively, particularly over the past two decades.[17, 87, 156-160] Evans and colleagues[161] conducted a systematic review of research and identified 28 risk factors for falling, including impaired mental status, special toileting needs, impaired physical status, and to some extent age and medications. Oliver and colleagues[159] reviewed risk factor and risk assessment literature and identified five risk factors consistent across studies: unsteady gait, increased toileting needs, confusion, sedative-hypnotics, and history of falling. In the long-term care environment, risk factors are largely the same, with the addition of inability to transfer effectively[162] and short-term memory loss.[163] Although ability to transfer and short-term memory function might be characterized by unsteady gait and confusion, these items are expressly captured via the LTCMDS.

Research has consistently demonstrated that multiple factors are associated with falling in elderly and hospitalized patients and that fall risk increases as the number of factors increases.[98, 153, 156-159, 164-166] Although increased age is a strong predictor of falling in the community, increased age has not always been identified as a predictor in the acute care setting. Some studies have found increased age to be a risk factor,[17, 165] but others have found that increased age is not a factor in acute care.[157, 167, 168] Comorbidities and impaired functional status may be more important predictors of falls and subsequent injury in this setting.[150, 157] Recent work by Hendrich[169] did not support the association between increasing age (older than 65 years) and increasing risk of falling in the inpatient environment. Instead, Hendrich and colleagues[169] found that confusion was the most important risk factor associated with the risk of falling. Nevertheless, age must be considered when discussing injury associated with falls because often with age comes frailty. Several researchers have identified gender as a risk factor, with female gender being a stronger risk factor in the older population[170] and male gender a stronger factor in the younger population.[167, 169, 171] A recent retrospective analysis by Krauss and colleagues[170] found that altered mental status was not a factor in falls, but that patients in academic medical centers were more likely to fall. This research was limited because it did not control for patient acuity or staffing levels.

Harwood and colleagues[172, 173] reviewed the literature related to visual problems and falls and found that uncorrected visual impairment nearly doubled the risk of falling. Cardiovascular causes of falls derive predominantly from neurally mediated disorders (e.g., vasovagal syncope) and cardiac abnormalities (e.g., arrhythmias, infarction, valvular stenosis).[174, 175] Time of day has also been implicated; Tutuarimia and colleagues[176] identified a higher rate of falls on the night shift, but this is inconsistent with other research and may in fact be explained by staffing patterns. Association of falls to the lunar cycle has also been explored, but no association was found.[177]

Vitamin D deficiency has been implicated as a risk factor for falls and fracture in the long-term care setting.[178] In addition, elevated alkaline phosphatase and low serum parathyroid hormone have been identified as predictors for falls,[179, 180] and anemia has also been implicated.[181]

A number of researchers are exploring the relationship between nurse-to-patient staffing ratios and an increase in the incidence of falls.[20, 176, 182-184] Some of this work has identified an

inverse association between licensed nurse staffing ratios and fall rates (i.e., a higher proportion of nurses is associated with lower fall rates);[176, 182, 184, 185] however, the overall the results are inconclusive.[186] In addition, a growing body of research related to failure to rescue, defined as being "based on the premise that although deaths in hospitals are sometimes unavoidable, many can be prevented,"[187-189] supports the inclusion of unanticipated physiologic events in the definition of falls since the patient's safety issues should be addressed at all times. Other researchers examining nurse staffing ratios and fall rates suggest that fall rates are reduced by increasing the number of nurse aids rather than licensed nursing staff.[190] This is potentially supported by recent work by Krauss and colleagues;[191] of the fallers in their case-control study, 85 percent of those in need of assistance or supervision with ambulation fell while not being supervised.

Certain subgroups of patients have been identified at higher risk because of the inherent characteristics of their disease process or treatment modalities. These groups include geriatric, behavioral health, oncology, rehabilitation, stroke, and multiple sclerosis patients. In the behavioral health setting, fall rates range from 4.5 to 25 falls per 1,000 patient days.[192, 193] Researchers have identified the typical faller in the behavioral health setting as a female with a history of falls; who was younger than 65 years of age; who was experiencing anxiety and agitation; and who was receiving a sedative, a tranquilizer, or a laxative.[194] Irvin[195] explored risk factors in the psychiatric setting and found that gait or balance problems and history of falls were the primary predictors. Although many of these characteristics are consistent with patients in the acute care setting, younger age and comorbidities such as depression and psychosis are often predictors in the behavioral health population.[196-199] In addition, treatments specific to behavioral health patients are different than those in the acute care setting. For example, patients being treated for late-life depression are at risk for falling in the first weeks of using a tricyclic antidepressant and should be monitored closely while they are adjusting to the new medication.[75] De Carle and Kohn[200, 201] have described risk factors in behavioral health patients and have identified electroconvulsive therapy as a predictor.

Patients in rehabilitation units are also at higher risk, likely because they have suffered neurological injuries such as stroke or head injury, which precipitate muscle weakness, impaired cognition, and impulsivity.[202-205] In addition, these patients are being physically challenged, which places them in higher-risk situations and thus at greater risk for falling.[206]

In the pediatric inpatient setting, fall rates range from 0 to 0.8 per 1,000 patient days.[207] These rates are very low compared to adult inpatient and long-term care rates. The factors that limit the number of falls in this population are unclear, but may be related to increased supervision of pediatric patients via higher nurse-to-patient staffing ratios and the common practice of parents staying with pediatric inpatients.

Injury risk factors in the acute and long-term care setting. In general, injury risk factors are similar across care areas. Vassallo and colleagues[208] examined the risk factors associated with injury in a group of inpatient fallers and found that three factors were associated with injuries related to falls: (1) history of falls, (2) confusion, and (3) unsafe gait. In addition to these, Rothschild and colleagues[134] identified physiological processes, such as increased bleeding tendencies and osteoporosis, as factors that increased risk for bleeding or fracture. The risk for medications or physiologic factors to precipitate injuries related to bleeding have been explored on a limited basis in the inpatient population. Contrary to results in the community,[84] Stein and team[209] found that hospitalized stroke patients who are anticoagulated are not at higher risk for injury than nonanticoagulated patients; however, this study was small and the issue warrants

further research. Bond and colleagues[210] examined over a 4-year period the risk for bleeding injury among 1,600 patients who fell while hospitalized. These researchers found that half of the patients were on thrombotic therapy and that the incidence of fall-related intracranial hemorrhage was low, even in persons taking warfarin. The authors suggested that selection bias may be a factor because physicians might withhold anticoagulant therapy for patients who have a higher fall risk. More recently, Spector and colleagues[211] performed a large study of nursing homes and found that 85 percent of fractures were caused by falls, and that those with epilepsy, those with agitation, and those taking anticonvulsants had the highest risk of sustaining a fracture if they fell.

Table 2. Risk Factors for Falls and Injuries in Acute and Long-Term Care

Intrinsic Risk Factors	Fall Risk	Injury Risk
Demographics		
• Age	Across ages	Older
• Gender	Male	Female
Cognitive Function		
• Agitation	Yes	Yes
• Anxiety	Yes	No data
• Cognitive impairment	Yes	No data
• Impulsivity	Yes	No data
• Inability to follow instructions	Yes	No data
• Short-term memory loss	Yes	No data
Physical Function		
• Fall history	Yes	Yes
• Fatigue	Yes	No data
• Gait problems	Yes	No data
• Impaired muscle strength	Yes	No data
• Impaired physical functioning	Yes	No data
• Toileting needs increased	Yes	No data
• Postural hypotension	Yes	No data
• Visual impairment	Yes	No data
Physiologic Status		
• Alkaline phosphatase level elevated	Yes	No data
• Anemia	Yes	No data
• Parathyroid hormone deficiency	Yes	Yes
• Prolonged bleeding time	No data	Yes
• Vitamin D deficiency	Yes	Yes
Comorbidities		
• Alzheimer's disease	Yes	No data
• Depression	Yes	No data
• Diabetes	Yes	No data
• Comorbidities in general	Yes	No data
• Multiple sclerosis	Yes	No data
• Parkinson disease	Yes	No data
• Stroke	Yes	No data
• Syncope	Yes	No data
Medications		
• Anticoagulants	No data	Yes
• Antiepileptics	Yes	No data
• Chemotherapeutics	Yes	No data

Intrinsic Risk Factors	Fall Risk	Injury Risk
• Laxatives	Yes	No data
• Psychotropics	Yes	No data
• Sedatives and hypnotics	Yes	No data
Extrinsic Risk Factors	**Fall Risk**	**Injury Risk**
Other Factors		
• Staffing	Yes	No data
• Time of day	Yes	No data
• Electroconvulsive therapy (in behavioral health)	Yes	No data
• Being physically challenged (in rehab)	Yes	No data

Acute care risk assessment instruments. Many tools have been developed to identify patients at highest risk for falling in the acute care setting.[21, 159, 167, 169, 212-215] Perell and colleagues[87] reviewed risk assessment tools and identified 6 functional assessment instruments and 15 fall risk assessment instruments developed by nursing. Vassallo and colleagues[216] concurrently examined the predictive validity in the acute care setting of four commonly used risk assessment instruments (STRATIFY, Downton, Tullamore, and Tinetti) and found that the STRATIFY instrument was the easiest to use, was most effective of the four at predicting falls in the first week of inpatient admission (total predictive accuracy of 66.6 percent), but had the poorest sensitivity (68.2 percent).

The most commonly reported risk assessment instrument is the Morse Falls Risk Assessment Tool.[217] In 2002, O'Connell and Myers[218] conducted psychometric testing with this tool on 1,059 patients admitted to an Australian hospital. In this study, the Morse Falls Risk tool had a sensitivity of 83 percent and a specificity of 29 percent, but a positive predictive value of only 18 percent. This resulted in a very high false-positive rate, with the tool identifying more than 70 percent of patients who did not fall at high risk for falling. This research was confounded by the fact that the interventions were applied based on the instrument's predictions; therefore, the predictive validity cannot be conclusively stated. The STRATIFY Falls Prediction tool also had a low positive predictive value (30 percent) and relatively low sensitivity (66 percent) and specificity (47 percent).[212]

The Heinrich Falls Risk Model I is reported to be more robust (sensitivity, 77 percent; specificity, 72 percent) than either of the others, and the Hendrich Falls Risk Model II demonstrated even more improvement (sensitivity, 74.9 percent; specificity 73.9, percent; positive predictive value, 75 percent).[169] The inclusion of a Get Up and Go test in the Heinrich II tool was the major change between version I and version II. The Get Up and Go test evaluates a person's ability to rise from a chair in a single movement, which is an assessment method that has been explored in earlier fall-prediction research. It is surprising that the sensitivity and specificity of the tool increases only slightly with the addition of this factor, underscoring the complexity of predicting patient falls. In addition, prospective evaluation of the use of the Hendrich II instrument has yet to be reported.

Several studies have tested the predictive validity of fall risk assessment instruments in relation to the judgment of nurses. Myers and Nikoletti[219] concluded that neither the fall risk assessment instrument nor nurses' clinical judgment acted as a reliable predictor. Eagle and colleagues[220] compared the Functional Reach test, the Morse Falls Scale, and nurses' clinical judgment in the rehabilitation and geriatric environment. This study also concluded that the two standardized assessment processes were no better at predicting falls than the clinical judgment of nurses. A limitation in both of these studies was that the evaluation occurred only at one time

point close to admission, which does not account for the variability of patient status throughout a patient's hospital stay.

In the domain of rehabilitation medicine, Ruchinskas[221] compared structured assessments—including the Mini-Mental State Exam, the Geriatric Depression Scale, the Functional Intervention Model, and the clinical judgment of physical and occupational therapists—on admission and discharge. This study concluded that the clinical judgment of therapists had a positive predictive power of 33 percent and a negative predictive power of 82 percent. However, the more accurate predictors of falling for the patients in their sample were a history of falls and presence of a neurological diagnosis. In the residential care environment, Lundin-Olson and colleagues[222] found that clinical judgment can contribute to the accurate prediction of fall risk, but is not sufficient on its own as a valid predictor.

Although fall-prediction research has been performed for two decades, it is clear that fall prevention is a complex problem that cannot be solved by risk assessment alone, hence the dissatisfaction with available risk assessment instruments.

Long-term care assessment instruments. Lundin-Olson and colleagues[223] developed the Mobility Interaction Fall Chart (MIF chart), which is an instrument based on a patients' ability to walk and talk at the same time, the ability to maintain pace while carrying a glass of water, visual impairment, and difficulty concentrating. When the predictive validity of the MIF chart was evaluated, the researchers found that the chart was helpful only when used in conjunction with clinical judgment and knowledge of a patient's history of falls, thus making the use of this instrument on its own limited.[222]

The Downton instrument, originally developed in the community setting, characterizes risk by five factors: (1) increased dependency, (2) cognitive impairment, (3) increased number of physical symptoms, (4) presence of anxiety, and (5) presence of depression.[224] This instrument has recently been prospectively evaluated in the long-term care setting with a reported sensitivity ranging from 81 to 95 percent and specificity ranging from 35 to 40 percent.[225] Although the specificity is low, this instrument might provide a standardized measure to identify those at risk in the long-term care environment.

Becker and colleagues[162] have recently described an algorithm to assess fall risk in the long-term care setting, categorizing long-term care residents into three subgroups: (1) residents requiring assistance to transfer, (2) residents able to transfer with history of falls and requiring the use of restraints, and (3) residents able to transfer and with no history of falls but with urinary incontinence and visual impairment. The researchers found that the residents with the history of falls were at highest risk for falls, which is consistent with other research in this domain, but might be useful to tailor interventions and would warrant prospective evaluation.

Acute care pediatric risk assessment instruments. Falls in the acute care pediatric setting are relatively rare; however, standardized assessment may be beneficial to reduce falls and injuries in this population. Graf[207] has recently developed an instrument for acute care pediatric risk assessment. According to Graf, factors associated with pediatric falls include (1) seizure medication (odds ratio 4.9), (2) orthopedic diagnosis, (3) not using an IV (odds ratio 3.6), (4) physical/occupational therapy ordered, and (5) LOS (odds ratio 1.84 for every 5 days). This model has a sensitivity and specificity of 69 percent and 84 percent, respectively, and is being prospectively evaluated by the investigator with the hope that standardized assessment will facilitate reduction in these already-low rates.

Automated risk assessment in the acute and long-term care settings. Recent national patient safety efforts highlight the promise of using informatics processes to manage patient

safety issues such as the management of patient falls. However, to date, most automated risk assessment techniques in the acute care setting are electronic versions of existing fall risk assessment instruments, with limited use of computerized decision support.[167, 226, 227] Promising new work in data mining for fall prediction has demonstrated that use of the LTCMDS has the potential to use existing data to generate risk models for patients in this setting. Volrathongchai[228] has recently explored the ability to use computerized data mining techniques to identify elderly residents of long-term care facilities who were at risk for falls. Although this work has not been prospectively evaluated, the research found that the use of these data mining techniques, in conjunction with nursing knowledge, had the potential to identify fallers.

Acute and long-term care prevention strategies. The goal of any fall- and injury-prevention effort is to decrease adverse outcomes for the patients who are most vulnerable to falling. A beneficial consequence of fall- and related-injury-prevention programs is the potential to streamline resource use, with the added potential for decreased costs associated with this problem.[229-231] To date, however, a ubiquitous fall- and injury-prevention strategy has not been identified for hospitalized patients, and implementation of multifaceted strategies is often difficult to introduce in the complex clinical environment.[232]

Several reviews have examined fall-prevention strategies in the acute and long-term care settings.[98, 99, 153, 159, 233] Oliver, Hopper, and Seed[234] examined 10 studies, including 3 RCTs and 7 prospective studies with historical controls. Oliver and colleagues found that the pooled effects ratio was 1.0 (95% CI = 0.60–1.68), indicating that overall the interventions were not able to prevent falls. More recently, Oliver and colleagues[235] have performed a meta-analysis of fall- and injury-prevention strategies and found a decrease in fall rates with multimodal intervention and a decrease in hip fractures with hip protectors in the long-term care setting. Agostini, Baker, and Bogardus[98] conducted a review of the literature related to fall prevention for hospitalized and institutionalized older adults. This review did not pool the results, but examined the literature related to the use of armbands, bed alarms, and restraints for fall prevention, all of which will be discussed individually below.

The use of physical restraints to prevent falls has been refuted because restraints limit mobility, contribute to injuries, and don't prevent falls.[236, 237] Agostini and colleagues[98] examined literature related to fall prevention via restraint and side rail use, as well as fall rates when restraints were removed. Six studies found that restraints were associated with increased injuries, and restraint and side rail removal did not increase fall rates. Evans, Wood, and Lambert[238] also examined the literature and found 16 studies that examined restraint minimization, concluding that restraint-minimization programs involving effective staff education can reduce injuries and do not increase fall rates.

Several individual fall-prevention interventions have been examined, including the use of armband identification bracelets, exercise regimen, postfall assessment, bed alarms, toileting regimen, and vitamin D supplementation. Mayo and colleagues[155] conducted a randomized controlled trial to examine if armbands would help identify high-risk patients in a rehabilitation unit and prevent falls in the high-risk group. The researchers, however, found that high-risk patients with a blue armband had higher fall rates than those without the armband. Despite widespread use, only one study from 1993 has examined bed alarms. Tideiksaar and colleagues[154] found that bed alarms were an effective method for fall prevention (relative risk = 0.32), but the intervention warrants further research. An associated intervention, a movement detector, has recently been developed. Kwok and colleagues[239] studied movement detectors and found no difference between intervention and control groups. However, a pilot study examined

the use of a movement detection patch attached to the thigh, which alerts clinicians when elderly long-term care residents are moving about.[240] Kelly and colleagues found a 91 percent decrease in falls during the 1-week testing period. Although this study quality was poor, the intervention might be suitable for select patients and bears further testing. Rask and colleagues[224] and Taylor and colleagues[225] evaluated the use of a fall-prevention program with a fall coordinator in the long-term care setting; they found that the control nursing homes had increases in fall rates over 4 years, whereas the intervention nursing homes had stable fall rates during the same time period.

Mulrow and colleagues[241] examined the effects of a physical therapy exercise intervention for frail long-term care residents and found that fall rates increased in the intervention group. However, the intervention group in this study also showed an increase in general strength and a decrease in the use of assistive devices, making one wonder if the physical therapy intervention sought to decrease the use of assistive devices in inappropriate situations. Rubenstein and colleagues[242] examined the ability for post-fall assessment to identify underlying factors that could be remedied to prevent further falls. Choi and colleagues[243] examined the effect of Tai Chi in the long-term care setting and found a 38 percent decrease in falls in the Tai Chi group, but this was not statistically significant (relative risk = 0.62; 95% CI = 0.32–1.19). A larger study may demonstrate statistical significance. A more recent study by Nowalk[244] reported no difference between groups who received strength training. The authors concluded that long term care residents may require individualized training, rather than group training.

Bakarich, McMillan, and Prosser[245] examined the impact of a toileting regimen for elderly confused patients with mobility problems in the acute care units of a large metropolitan teaching hospital. The researchers found that there were 53 percent fewer falls during shifts in which the risk assessment and toileting intervention was used, but that compliance with the assessment and intervention was difficult to maintain. More recently, Klay and Marfyak[246] found that a continence specialist in the long-term care environment reduced falls by 58 percent. Vitamin D has also reduced falls in elderly females in the long-term care setting by up to 49 percent, and in both males and females by 25 percent.[129, 134, 178, 247, 248] Further investigation of the use of vitamin D in the acute care and rehabilitation setting for fall and injury prevention is warranted. Jensen and colleagues[249] examined the effect of exercise training on elderly residential care patients and found an increase in strength and balance, and a nonstatistically significant decrease in falls. This study was limited by its small sample size and unequal distribution of important risk factors such as Mini-Mental State Exam scores across groups.

As with community interventions, tailored, multipronged prevention strategies are being shown to be more effective in acute and long-term care settings than individual interventions alone. Hofmann and colleagues[250] used three concurrent interventions—staff education, an exercise program, and environmental modifications—for a frail elderly population. The concurrent use of these interventions decreased the fall rate by 38 percent and decreased the fracture rate by 50 percent. Haines and colleagues[251] also examined a multipronged intervention involving staff and patient education, an exercise program, and the use of hip protectors. Researchers found a 22 percent decrease in falls and a 28 percent decrease in injuries in the intervention group.

One of the most promising studies by Jensen and her research team[252] investigated the effects of a comprehensive fall risk assessment and tailored intervention program in the long-term care setting. The intervention included assessment via the Mobility Interaction Fall Chart, visual evaluation, medication evaluation, and delirium screening by all members of the care team—physicians, nurses, and physical and occupational therapists. This research demonstrated that the

comprehensive assessment and tailored interventions reduced falls by 51 percent and injuries by 77 percent over a 34-week period. Healy and colleagues[253] also found a statistically significant reduction in falls (RR = 0.71) by applying a tailored plan of care to adult inpatients who were deemed at high risk for a fall based on having had a previous fall. In effect, this research used history of fall as a method to triage high-risk patients, who then received a comprehensive risk assessment with targeted interventions. This research did not demonstrate a decrease in injuries; however, further research using this technique will be useful. McMurdo, Millar, and Daly[254] found up to a 55-percent reduction in fall rates in a group of 133 nursing home residents with comprehensive risk assessment and balance training, but these results were not statistically significant. A larger sample size would provide a better understanding of the effect of the intervention.

Other research examining multimodal interventions have had mixed outcomes. A recent study by Vassallo and colleagues[255] in long-term care facilities found a decrease in falls was nullified when the results were controlled for LOS. However, controlling for LOS removes the ability for LOS to be identified as a predictor, which may be the case for patients who stay longer in a hospital setting. Kerse and colleagues[256] found that in a group of nursing homes, long-term care residents who were randomized to risk assessment followed by tailored interventions showed an increase in falls (incident rate ratio = 1.34; $P = 0.018$). Semin-Goossens, van der Helm, and Bossuyt[257] evaluated the effect of a guideline with semistructured interventions and found that fall rates in high-risk neurology and medical patients were not reduced. The researchers attributed the failure of the program to resistance by nurses to changing attitudes toward falls with the statement that nurses did not find falls troublesome enough. However, the failure was more likely due to system issues, such as ability to implement and agreement with the guideline, and training issues, which are common with guideline implementation failures.[258, 259] In addition, the Semin-Goossens guideline did not use a standardized risk assessment instrument, which might have made it difficult to identify patients at risk. Fonda and colleagues[260] studied a multimodal process-improvement plan and found that after 3 years, fall rates were decreased by 19 percent and injuries were decreased by 77 percent. Furthermore, this effect was sustained with continued use of the multimodal intervention. Schwendimann and others[261] found a moderate, but not statistically significant decrease in fall rates, and no change in injury rates after implementing an interdisciplinary fall-prevention program. Lane[262] found no decrease in patient fall rates before and after implementation of a fall-prevention program. Although the results of multimodal studies are conflicting, it is important to note that none of the studies of multimodal interventions—whether effective or ineffective results—controlled for staffing ratios or skill mix.

An increasing number of studies are examining the prevention of injury in the acute and long-term care settings. Hip protectors have been evaluated in the long-term care environment since the early 1990s. Although early work found that hip protectors were effective in reducing hip fractures in the frail or osteoporitic elderly,[263] more recent work indicates that compliance with using hip protectors is difficult to maintain, making recommendation for hip protector use conditional.[264, 265] Ray and colleagues[266] examined the ability of a 2-day staff safety education plan to reduce serious fall-related injuries and found that this intervention was not effective, but the result may have been confounded by lack of staff compliance with the safety plan. (See Evidence Tables 1 to 9 for individual study results.)

Summary of acute and long-term care falls and related injuries. In summary, fall prevention in the acute and long-term care settings is a complex and demanding problem with

multiple patient types and risk factors to manage. Standardized risk assessment with multimodal tailored interventions appears to be the most successful method of prevention; however, implementation of comprehensive interventions across care settings can be challenging. Further research toward overcoming barriers to implementation, guideline adherence, staffing ratios, and tailored interventions for newly identified risk factors such as vitamin D deficiency and anemia are warranted. Furthermore, research must be conducted on a larger scale to demonstrate generalizability and to be able to translate evidence into practice.

Evidence-Based Practice Implications

Screening for fall and injury risk should be performed across settings. In the community, all patients older than 65 years should be screened, and in the home care, acute care, and long-term care settings, patients of all ages should be screened. Screening needs to include injury risk, not just fall risk. The most effective interventions are multimodal ones that address specific areas of risk and work with interdisciplinary fall-prevention teams.

In the community, screening can take place with a general annual physical exam or other routine health care visit. A standardized risk assessment tool should be used, such as the Tinnetti screening tool, which has the highest sensitivity and specificity for use in the community, but screening for injury risk must be included. If a patient is seen in an emergency room because of a fall, evidence suggests that focused fall and injury risk evaluation is warranted, especially if the patient is to be discharged home, i.e., the discharge prescription should include a focused fall risk assessment by the primary care provider or by a fall-prevention clinic. Tailored interventions for elderly community dwellers can decrease fall rates. Interventions that have had the most success in the community include exercise interventions with leg strengthening and balance training (e.g., Tai Chi), medication adjustment, management of cardiac-related syncope, effective diabetes management, management of vitamin D deficiency, and home safety modifications. Interventions to prevent injury in the community include calcium with vitamin D for fracture prevention, and additional fall precautions and increased screening for patients on anticoagulant therapy.

In the acute and long-term care settings, screening should be carried out using a standardized assessment tool for all patients. The Morse tool is the most commonly used in the acute care setting, but it does not screen for injury risk. In the long-term care setting, the LTCMDS may be an effective screening tool. In both acute and long-term care, effective interventions are multimodal and include medication adjustment, environmental adjustment, alarm devices, staff safety education, calcium and vitamin D, exercise interventions, and treatment of other underlying disorders. Interventions to prevent injury in the acute and long-term care settings include limiting restraint use, lowering bedrails, using hip protectors in long-term care, calcium with vitamin D, and possibly bisphosphonates in long-term care. Across the health care continuum, effective interventions have been identified, but their use is not ubiquitous.

Research Implications

In the community setting, identification of the best timing for screening and reassessment is needed. Identification of methods to build fall- and injury-prevention programs in the community is needed to guide policymakers. In the acute and long-term care settings, large multisite intervention studies that use multimodal interventions tailored for individual risk factors and that control for comorbidities, acuity, staffing, and other environmental factors are needed. Cost-

effectiveness studies to characterize the impact of fall- and injury-prevention programs are needed in the acute and long-term care settings.

Recommendations From Evidence-Based Practice and Research Implications

1. Recommendations for screening and assessment

- Fall and injury risk screening should be performed in all settings.
- All patients who fall should receive a comprehensive postfall assessment.
- Methods for computerized screening and followup should be explored.

Table 3. Recommendations for Screening and Assessment

Evidence-Based Practice Recommendations	Research Implications
Community:	
• Screen all patients over 65 during routine or other visit.	• Examine risk factors related to race and gender.
• For patients who screen positive, refer to fall-injury prevention clinic for focused fall-injury risk assessment, if available.	• Identify barriers to widespread screening. • Examine barriers to establishment of fall-injury prevention clinics.
• Use a standardized risk assessment tool, such as Tinetti's 9-item screening tool for (1) mobility, (2) morale, (3) mental status, (4) distance vision, (5) hearing, (6) postural blood pressure, (7) back examination, (8) medications, and (9) ability to perform activities of daily living (ADLs). (*Note:* This tool does not overtly assess for injury risk.)	• Validate risk assessment instruments across culture, race, and language. • Examine predictive validity of injury risk factors such as antiplatelet therapy, bleeding disorders, vitamin D deficiency, and chronic subdural hematomas. • Develop instruments for patient self-assessment for fall and injury risk.
• For patients > 65 years who present to the emergency department (ED) with a fall, refer to primary care provider for focused fall-injury risk assessment.	• Examine the effect of identification in the ED using large, multicenter randomized controlled trials. • Identify barriers to widespread adoption.
Evidence-Based Practice Recommendations	**Research Implications**
Home Care and Long-Term Care:	
• Screen patients of all ages.	• Validate home care assessment instruments.
• Use a standardized risk assessment tool, such as Tinetti's 9-item screening tool.	• Examine predictive validity of Long Term Care Minimum Data Set.
• Reassess at regular intervals.	• Examine best timing for reassessment in home care and long-term care.
Evidence-Based Practice Recommendations	**Research Implications**
Acute Care Setting:	
• Screen patients of all ages.	• Develop and validate instruments for subgroups.
• Use a standardized risk assessment instrument such as the Morse, Hendrich II, or STRATIFY tools. (*Note:* These tools do not assess for injury risk.)	• Validate instruments in multiple settings. • Explore predictive validity of physiologic factors such as low creatinine clearance, vitamin D deficiency, and anemia.
• Assess for injury risk for patients with injury risk factors such as low BMI, frailty, osteoporosis, vitamin D deficiency, and antiplatelet therapy.	• Validate instruments that assess for injury risk.
• Reassess patients at regular intervals.	• Examine the best timing for reassessment.

2. Recommendations for interventions in the community setting

- Apply multimodal interventions as identified by risk assessment.
- Participate in national reporting activities such as ANA–NDNQI.
- Examine the use of computer-based guidelines in all settings.

Table 4. Recommendations for Community Setting

Evidence-Based Practice Recommendations	Research Implications
Fall Prevention:	
• Provide balance training with leg strengthening, such as Tai Chi.	• Examine effect of starting balance training at younger age (i.e., 50 years). • Examine barriers to establishment and use of balance training centers.
• Monitor medication side effects for patients older than 65.	• Identify medications with minimal side effect profiles for patients older than 65.
• Limit medications to fewer than four, if possible.	• Examine medication dosing for groups of medications.
• Monitor and treat calcium and vitamin D deficiency.	• Examine factors related to calcium and vitamin D metabolism in relation to muscle function.
• Manage underlying disorders such as cardiac-related syncope, diabetes, and vision problems (e.g., cataracts).	• Explore factors to manage groups of disorders. • Explore other diseases that may predict falls.
• Provide home safety modifications.	• Explore barriers to home safety modification.
• Educate about use of thin-soled shoes (not running shoes).	• Further explore shoe type for specific patient groups.
• Provide education about how to manage risky situations.	• Explore fall prevention self-management strategies.
Injury Prevention:	
• Monitor for calcium and vitamin D deficiency; provide supplements for fracture prevention.	• Conduct large studies that control for comorbidities, age, and other factors to explore efficacy of hip protectors in the community.
• Increase screening for patients on anticoagulant therapy, those with bleeding disorders, and for the frail and very old.	• Identify safety measures for bleeding-injury prevention. • Explore interventions for the very old and frail.
• Use bisphosphonates for patients with documented osteoporosis.	• Explore safety of long-term use of bisphosphonates.

3. Recommendations for interventions in the acute and long-term care settings

- Apply multimodal interventions as identified by risk assessment.
- Participate in national reporting activities such as ANA–NDNQI.
- Examine the use of computer-based guidelines in all settings.
- Large, multi-site randomized controlled trials that evaluate tailored interventions while controlling for organizational culture, staffing, comorbidities, acuity, and other factors are needed. Injury rates should be the primary outcome of interest, since fall-rate reporting may be an imprecise measure.
- Characterize the cost effectiveness of bundles of tailored interventions.

Table 5. Recommendations for Acute and Long-Term Care

Evidence-Based Practice Recommendations	Research Implications
Fall Prevention	
• Educate staff about safety care. • Train medical team, including students and residents, for fall-injury risk assessment and postfall assessment.	• Examine impact of safety education across interdisciplinary team.
• Use alarm devices.	• Examine impact of alarms on caregiver satisfaction.
• Monitor medication side effects and adjust as needed.	• Examine effect of computerized decision support for medication management.
• Adjust environment (e.g., design rooms to promote safe patient movement).	• Examine cost effectiveness of environmental adjustments.
• Provide exercise interventions (e.g., Tai Chi) for long-term care patients.	• Examine usefulness of exercise interventions for acute care patients.
• Provide toileting regimen for confused patients (e.g., check patients every 2 hours).	• Study barriers to maintaining and sustaining monitoring activities.
• Monitor and treat calcium and vitamin D levels for long-term care patients.	• Examine effects of calcium and vitamin D management for acute care patients.
• Treat underlying disorders such as syncope, diabetes, and anemia.	• Examine constellations of disorders that might precipitate falls.
Injury Prevention	
• Limit restraints use.	• Identify methods to overcome barriers to restraints reduction.
• Lower bedrails.	• Study efficacy of environmental changes.
• In addition to fall rates, monitor injury rates.	• Establish fatal fall rates across settings.
• Use hip protectors for geriatrics and long-term care.	• Identify methods to overcome barriers to use of hip protectors.
• Use floor mats.	• Examine effect of safety flooring.
• Monitor prothrombin time, international normalized ration (PT/INR) for patients at risk for falling.	• Identify safety measures for bleeding-injury prevention.
• Ensure postfall assessment.	• Examine barriers to postfall assessment.
• Use bisphosphonates for patients with documented osteoporosis.	• Explore safety of long-term use of bisphosphonates.

Conclusion

Falls and related injuries are an important issue across the care continuum. National efforts in the community via Healthy People 2010, in the acute care setting via the Joint Commission's National Patient Safety Goals, and in the long-term care setting via the Nursing Home Quality Initiative project have the potential to significantly reduce falls and related injuries. The growing number of randomized controlled trials related to fall-prevention efforts is promising. However, most of these studies have been carried out in the community and long-term care environments, with few randomized controlled trials evaluating fall- and injury-prevention measures in the acute care setting. As with other nursing-sensitive quality indicators, recent research demonstrating an association between fall rates and nurse staffing ratios needs to be more fully explored. In addition, further research needs to explore automated methods of assessing and communicating fall risk, better methods for risk identification, and the identification of

prevention measures. Indeed, with coordinated efforts to apply the evidence to practice, the problem of falls might be managed more effectively.

Search Strategy

MEDLINE,® the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), and Cochrane databases from inception to March 2007 were searched for medical subject heading terms, both individual terms and combinations of the following: accidental falls, patient safety, medical errors, nursing-sensitive quality indicators, and fall prevention. In addition, references from relevant articles were searched using the snowball technique, as were archives of select nursing research and gerontology journals. The Related Links function in MEDLINE was also used to maximize the search strategy. Google, Google Scholar, and citations from identified articles were also searched for additional possible references. Articles related to occupational falls, sports-related falls, alcohol-related falls, and physical abuse-related falls were excluded. Articles that reported physiologic characteristics that are suspected to preclude falls but that did not examine falls or fall-related injuries as outcomes were also excluded because the causative effect on falls and fall-related injuries is, to date, inconclusive. Further, articles that were published in a foreign language were excluded. Two hundred and twenty seven articles were reviewed. Sixty-one of these were intervention research studies related to fall and injury prevention (32 from the community setting; 33 from the acute and long-term care setting).

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Evidence Table 1. Reviews Examining Fall-Prevention Interventions in the Community

Source	Safety Issue Related to Clinical Practice	Design Type*	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weigand 2001[93]	Fall and injury prevention in the community	Literature Review	**Design:** Review **Outcomes:** Fall rates	**Setting:** Community **Population:** Emergency patients	Assessment of fallers & targeted interventions	*Falls:* No definitive evidence to support ED assessment followed by targeted interventions is effective for preventing falls. More research required.
Cumming 2002[100]	Fall and injury prevention in the community	Literature Review	**Design:** Review **Outcomes:** Fall rates	**Setting:** Community **Population:** Older adults	Multiple interventions; 21 trials reviewed	*Falls:* • Exercise programs most promising. • Reduction of antipsychotic medications should be considered. • No definitive prevention strategy.
Gillespie 2003[104]	Fall and injury prevention in the community	Meta-analysis	**Design:** Systematic Review **Outcomes:** Fall rates	**Setting:** Community **Population:** 21,668 people	Multiple interventions; 62 trials reviewed	*Falls:* Multimodal, interdisciplinary prevention programs are most successful. *Risk Assessment:* Need more accurate risk assessment instruments.
Chang 2004[99]	Fall and injury prevention in the community	Meta-analysis	**Design:** Review **Outcomes:** Fall rates	**Setting:** Community **Population:** Older adults	Multiple interventions; 40 trials reviewed	*Falls:* Multimodal assessments with targeted intervention reduced risk of falls by 37 percent, and exercise interventions reduced fall risk by 14 percent.
Hill-Westmore-land 2005[38]	Fall and injury prevention in the community	Meta-analysis	**Design:** Meta-analysis **Outcomes:** Fall rates	**Setting:** Community **Population:** Older adults in long-term care setting	Multiple interventions; 12 studies reviewed	*Falls:* Decrease in fall rates when individualized management added to exercise interventions.
Stevenson 2005[135]	Fall and injury prevention in the community	Systematic Review	**Design:** Systematic review **Outcomes:** Fracture, vertebral and nonvertebral	**Setting:** Community **Population:** Older women at risk for fracture	Review of calcium, vitamin D, and bisphosphonates	*Fractures:* • Calcium, with or without vitamin D, reduces fractures in patients with high risk for fracture. • Calcium with vitamin D can prevent fractures in women not at risk for fractures.

* Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Source	Safety Issue Related to Clinical Practice	Design Type*	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Shekele 2003[11]	Fall and injury prevention in the community	Meta-analysis	**Design:** Meta-analysis **Outcomes:** Fall and injury rates	**Setting:** Community **Population:** Medicare recipients	Mulriple interventions	*Falls:* Multifactorial fall prevention programs decrease fall rates

Evidence Table 2. Studies on Community-Based Fall-Prevention Screening with Tailored Interventions (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type†	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Close 1999[42]	Tailored interventions for falls in the community	RCT	**Design:** RCT **Outcomes:** Fall rates, repeat fall rates, hospital admissions, Barthel Score (Max 100; higher score = higher functioning)	**Setting:** Community **Population:** 397 patients ≥ 65 years who presented to an accident and emergency department with a fall	Detailed medical and occupational-therapy assessment with referral to relevant services if indicated with 1 year followup.	*Falls:* Decreased by 61 percent for patients who were identified in the emergency department and who had subsequent detailed risk assessment and tailored interventions (odds ratio = 0.39, 95% CI = 0.23–0.66; *P* = 0.0002). *Recurrent falls:* Decreased by 67 percent (odds ratio = 0.33, 95% CI = 0.16–0.68). *Hospital admissions*: Decreased by 39 percent (odds ratio = 0.61, 95% CI = 0.35–1.05). *Barthel score:* Decline in score with time greater in the control group (*P* < 0.00001).
Hogan 2001[111]	Tailored interventions for falls in the community	RCT	**Design:** Randomized controlled trial **Outcomes:** Fall rates, repeat fall rates, time between falls, emergency department visits, hospital admissions	**Setting:** Community **Population:** 152 patients ≥ 65 years who had fallen within the previous 3 months	In-home assessment in conjunction with the development of an individualized treatment plan, including an exercise program for those deemed likely to benefit.	*Cumulative number falls:* No significant differences (311 v. 241, *P* = 0.34) *One or more falls*: No significant difference (79.2 percent v. 72.0 percent, *P* = 0.30) *Mean number of falls:* 4.0 v. 3.2, *P* = 0.43. *Repeat fall rates*: No significant difference *Time between falls*: Longer time between falls in intervention group (*P* < 0.001) *For multiple fallers at baseline:* • Intervention group less likely to fall (*P* = 0.046) • Time between falls longer for intervention group (*P* < 0.001) *Emergency department visits:* No significant difference *Hospital admissions:* No significant difference

† Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Source	Safety Issue Related to Clinical Practice	Design Type†	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lightbody 2002[110]	Tailored interventions for falls in the community	RCT	**Design:** RCT **Outcomes:** Falls, functional ability, emergency department visits, admission to hospital	**Setting:** Community **Population:** 348 consecutive patients ≥ 65 years who were discharged from emergency room after sustaining a fall	Home assessment for medication, ECG, blood pressure, cognition, visual acuity, hearing, vestibular dysfunction, balance, mobility, feet and footwear	*Recurrent Falls:* Reduced by 38 percent *Falls:* Decreased falls in intervention group, but not statistically significant. *Admissions and bed days:* Fewer fall-related admissions and bed days in intervention group (8 and 69, respectively) than the control group (10 and 233, respectively).
Nikolaus 2003[141]	Tailored interventions for falls in the community	RCT	**Design:** RCT **Outcomes:** Number of falls, compliance with recommendations	**Setting:** Patients identified in university-affiliated geriatric hospital; intervention carried out in patients' homes **Population:** 360 patients showing functional decline, especially in mobility, admitted to a geriatric hospital (mean age 81.5 years)	Comprehensive geriatric assessment followed by diagnostic home visit and home intervention or a comprehensive geriatric assessment with recommendations	*Falls:* Intervention group had 31 percent fewer falls than control group (incidence rate ratio = 0.69, 95% CI = 0.51–0.97). *Falls:* For subgroup with ≥2 falls during previous year, there was a 37 percent decrease in falls (incident rate ratio = 0.63, 95% CI = 0.43–0.94).
Nitz 2004[108]	Tailored interventions for falls in the community	RCT	**Design:** pilot RCT **Outcomes:** Fall rates, balance measures	**Setting:** Australia; academic medical center **Population:** 73 adults (92 percent female) ≥ 65 yrs	Balance training sessions once a week for 10 weeks	*Falls:* Intervention and control groups both showed reduction in fall rates, but no differences between groups. *Balance measures:* Improved for intervention group.

Source	Safety Issue Related to Clinical Practice	Design Type†	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Davison 2005[90]	Tailored interventions for falls in the community	RCT	**Design:** RCT **Outcomes:** Fall rates, number of fall-related admissions, LOS, balance	**Setting:** Accident & emergency departments in a teaching hospital and associated general hospital in the United Kingdom **Population:** 313 cognitively intact patients ≥ 65 years with fall or fall-related injury and at least one additional fall in preceding year	Multimodal postfall assessment, including medical, physiotherapy, and occupational therapy evaluation	*Falls:* 36 percent fewer falls in the intervention group (relative risk = 0.64, 95% CI = 0.46–0.90). *Proportion of fallers:* 65 percent of subjects in the intervention group continued to fall compared with 68 percent in the control group (relative risk = 0.95, 95% CI = 0.81–1.12). *Hospital admissions*: Number of fall-related visits and hospital admissions was not different between groups. *Hospitalization:* Duration of hospital admission was reduced (mean difference admission 3.6 days, 95% CI = 0.1–7.6). *Activities-specific balance confidence score:* Improved in the intervention group.
Perell 2006[109]	Tailored interventions for falls in the community	Pretest post-test design	**Design:** Pretest, post-test **Outcomes:** Falls, repeat falls	**Setting:** Urban Los Angeles – Veterans Affairs System **Population:** 120 elders referred to the clinic. Gender not reported.	Screening following by tailored interventions at falls clinic	*Falls:* Reduction of total falls (pre = 297; post = 141; *P* = 0.0002). Increase in falls reported by 12.5 percent patients. *Mean fall rates:* Reduction in mean falls (pre = 4.1;post = 2.0). *Repeat falls:* Reduction in repeat falls (pre = 86 percent; post = 51 percent).

EvidenceTable 3. Studies Examining Exercise-Related Interventions in the Community (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Reinsch 1992[124]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** Four-arm RCT **Outcomes:** Fall rates, time to first fall, injury rates	**Setting:** 16 senior centers in Orange County, California **Population:** 230 older adults who were participants at senior centers	Exercise in conjunction with cognitive behavioral therapy for safety self-awareness	*Falls:* No effect on fall rates, falls efficacy, or fear of falling. *Time to first fall:* Longer time to first fall. *Injuries:* Decreased injuries. Even though a relatively high percentage (38.6 percent) suffered at least one fall, only 7.8 percent of these community-residing elderly required medical attention.
Province 1995[115]	Exercise-related interventions for fall prevention in the community	Meta-analysis	**Design:** Preplanned meta-analysis of 7 RCTs **Outcomes:** Time to each fall (fall-related injury) by self-report and/or medical records	**Setting:** Two nursing homes and five community sites **Population:** Patients ages 60–75, ambulatory, cognitively intact	Exercise training one area or more of endurance, flexibility, balance platform, Tai Chi (dynamic balance), and resistance	*Falls:* • Fall rates decreased in group with general exercise (odds ratio = 0.90, 95% CI = 0.81–0.99). • Fall rates decreased for those with exercise plus balance training (odds ratio = 0.83, 95% CI = 0.70–0.98). *Injuries:* Patients who did not exercise had an increase in injurious falls, but power was low to detect this outcome.
Wolf 1997[120]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Frailty indicators, occurrence of falls	**Setting:** Community **Population:** 200 men and women ≥ 70 years	Tai Chi, computerized balance training, or education	*Multiple falls:* Risk of multiple falls decreased by 47.5 percent

‡ Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Source	Safety Issue Related to Clinical Practice	Design Type‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Steinberg 2000[143]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT with four arms **Outcomes:** Self-reported slips, trips, or falls	**Setting:** Community, Australia **Population:** 252 active, community-dwelling Australians ≥ 50 yrs.	Education re: fall risk factors, strength/balance exercises, home safety advice, medical evaluation	*Falls:* 30 percent reduction in falls; hazard ratio 0.70 (95% CI = 0.48–1.01). *Slips:* 58 percent reduction in slips; hazard ratio 0.42 (95% CI = 0.29–0.69). *Trips:* 64 percent reduction in trips; hazard ratio 0.36 (95% CI = 0.26–0.66).
Rubenstein 2000[116]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Muscle strength, endurance, mobility, balance, fall rates	**Setting:** Community-living men **Population:** 59 men ≥ 65 years with specific fall risk factors	90 min. exercise sessions 3x/week Focus on increased strength and endurance, improving mobility and balance	*Falls:* • Exercise group had lower fall rates than nonexercisers when adjusted for baseline activity level (6 falls/1,000 hours of activity vs 16.2 falls/1,000 hours, $P < 0.05$). • Total number of falls not decreased. *Strength:* Exercise achieved no significant effect on hip or ankle strength, balance, self-reported physical functioning.
Robertson 2002[123]	Exercise-related interventions for fall prevention in the community	Meta-analysis	**Design:** Meta-analysis of four studies **Outcomes:** Fall rates, injury rates	**Setting:** Community setting: nine cities and towns in New Zealand **Population:** 1,016 women and men ages 65 to 97	Muscle strengthening and balance retraining exercises designed specifically to prevent falls	*Falls and injuries:* Fall and injury rates decreased by 35 percent; no difference between genders. • Fall rate incidence rate ratio (IRR) = 0.65, 95% CI = 0.57–0.75 • Participants reporting a fall in the previous year had a higher fall rate (IRR = 2.34, 95% CI = 1.64–3.34). • Injury rate IRR = 0.65, 95% CI = 0.53–0.81.
Barnett 2003 [113]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Fall rates, balance, muscle strength, fear of falling	**Setting:** Community, South Western Sydney, Australia. **Population:** 163 subjects ≥ 65 years identified as at risk of falling using a standardized assessment screen by general practitioner or physical therapist	Weekly group exercise program with ancillary home exercises over 1 year	*Falls:* Fall rates decreased by 40 percent in the exercise group (IRR = 0.60, 95% CI = 0.36–0.99). *Balance measures*: Improved in exercise group. *Other measures:* No difference between groups in strength, reaction time, and walking speed or on Short-Form 36, Physical Activity Scale for the Elderly or fear of falling.

Source	Safety Issue Related to Clinical Practice	Design Type‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wolf 2003[122]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Time to first fall, fall rates, balance	**Setting:** 20 congregate living facilities in the greater Atlanta area **Population:** 291 women and 20 men ages 70 to 97 who were transitioning to frailty	Intense Tai Chi exercise program or wellness education program	*Falls:* Fall rates decreased in Tai Chi group, but no statistical difference between groups (relative risk = 0.75, 95% CI = 0.52–1.08).
Clemson 2004 [114]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Fall rates	**Setting:** Community **Population:** 310 men and women ≥ 70 years who had had a fall in the previous 12 months or were concerned about falling	Occupational therapy home visits, lower-limb balance and strength training, environmental safety education	*Falls:* • 31 percent reduction in falls for both genders (relative risk = 0.69, 95% CI = 0.50–0.96; *P* = 0.025). • For men alone, 68 percent reduction in falls (relative risk = 0.32, 95% CI = 0.17–0.59).
Morgan 2004[140]	Exercise-related interventions for fall prevention in the community	RCT	**Design**: RCT **Outcomes:** Falls	**Setting:** Community **Population:** 294 men and women ≥ 60 years who had either a hospital admission or bed rest for 2 days or more within the previous month	Exercise sessions lasting 45 minutes, including warm-up and cool-down, 3 times a week for 8 weeks (24 sessions)	*Falls:* • 49 percent reduction in falls for patients with low baseline physical functioning. • 3.5 times increase in falls for patients with high baseline physical functioning.
Suzuki 2004[118]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Fall rates	**Setting:** Community, Japan **Population:** 52 elderly Japanese women	Exercise intervention—home and community center	*Falls:* Fall rates decreased in intervention group (13.6 percent v. 54.5 percent; *P* = 0.0097).

Source	Safety Issue Related to Clinical Practice	Design Type‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Li 2005[112]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcome:** Fall rates, functional balance, physical performance, fear of falling	**Setting:** Community in Portland, Oregon **Population:** 256 physically inactive elders ages 70 to 92	Tai Chi or stretching 3x/week for 6 months	*Falls:* 55 percent reduction in falls in Tai Chi group (relative risk = 0.45, 95% CI = 0.30–0.70). Fewer falls in the Tai Chi group (Tai Chi = 38 vs. stretch = 73; *P* = 0.007), (Tai Chi = 28 percent vs. stretching = 46 percent; *P* = 0.01). *Injuries:* Fewer injurious falls (Tai chi = 7 percent vs. stretching = 18 percent; *P* = 0.03).
Lord 2005[88]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcome:** Fall rates	**Setting:** Community in Australia **Population:** 620 people ≥ 75 years	Interventions to maximize vision and sensation or brief advice or usual care	*Falls:* The rate of falls during the trial period were similar in the three groups. *Injuries:* The rate of injurious falls during the trial period were similar in the three groups.
Faber 2006[125]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Falls, mobility, physical performance, and self-reported disability	**Setting**: 15 homes for the elderly in Amsterdam, The Netherlands **Population:** 287 elderly men and women (mean age +/- standard deviation, 85+/-6yrs)	20-week exercise program of balance training inspired by Tai Chi or daily mobility activities or control	*Falls:* Fall incidence rate lower in balance training group (2.4 falls/yr) compared to the mobility activities group (3.3 falls/yr) and control (2.5 falls/yr), but not statistically significant. *For frail subjects:* Risk of becoming a faller in the exercise groups increased almost 3 times (hazard ratio = 2.95; 95% CI = 1.64-5.32). *For pre-frail subjects:* Risk of becoming a faller decreased by 61 percent (hazard ratio = 0.39; 95% CI = 0.18–0.88).
Lin 2006[126]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Falls, fall-related injuries, related functional outcomes	**Setting:** 6 rural villages in Taiwan: 2 villages received intervention, 4 villages acted as controls **Population:** 1,200 men and women ≥ 65 years screened; 88 participants	Tai Chi training plus fall-prevention education or fall-prevention education alone	*Falls:* 50 percent greater decrease in fall rates among the Tai Chi practitioners (relative risk = 0.5; 95% CI = 0.11–2.17), but not statistically significant. *Tinetti Balance Scale*: Tai Chi practitioners increased by 1.8 points (95% CI = 0.2–3.4). *Tinetti Gait Scale:* Tai Chi practitioners increased by 0.9 point (95% CI = 0.1–1.8). *Fear of Falling:* No significant changes in the fear of falling.

Source	Safety Issue Related to Clinical Practice	Design Type‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Luukinen 2007[127]	Exercise-related interventions for fall prevention in the community	RCT	**Design:** RCT **Outcomes:** Fall rates, time to first fall	**Setting:** Community, home-dwelling Finnish **Population:** 555 older men and women (67 percent ≥ 85 years), most with history of recurrent falls or at least one mobility risk factor	Suggestions for a program consisting of home exercise, walking exercise, group activities, self-care exercise, or routine care	**For all subjects:** *Falls:* • 12 percent decrease in falls from baseline for intervention group (hazard ratio = 0.88, 95% CI = 0.74–1.04). • 7 percent decrease in all falls, but not statistically significantly (hazard ratio = 0.93, 95% CI = 0.80–1.09). **For subjects not homebound:** *Falls:* • 22 percent decrease in falls (hazard ratio = 0.78, 95% CI = 0.64–0.94). • 12 percent decrease in first four falls (hazard ratio = 0.88, 95% CI = 0.74–1.05).

Evidence Table 4. Studies examining physiologic interventions in the community (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type[§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Latham 2003[132]	Physiologic interventions to prevent falls in patients discharged from acute care to the community	RCT	**Design:** RCT **Outcomes:** Falls over 6 months	**Setting:** Five hospitals in Auckland, New Zealand, and Sydney, Australia **Population:** 243 frail older people (53 percent female)	One dose vitamin D 300,000 IU versus placebo OR 10 weeks of high-intensity home-based exercise versus attention lessons	*Falls:* • Increase in falls for patients receiving vitamin D as compared to placebo, but not statistically significant (relative risk = 1.12, 95% CI = 0.79–1.59). • Decrease in falls for patients in exercise group compared to attention group, but not statistically significant (relative risk = 0.96, 95% CI = 0.67–1.36). *Injury:* Patients in the exercise group were at increased risk of musculoskeletal injury (risk ratio = 3.6, 95% CI = 1.5–8.0).
Bischoff-Ferrari 2004[178]	Physiologic interventions to prevent falls and fall-related injuries in the community	Meta-analysis	**Design:** Meta-analysis of five RCTs **Outcomes:** Fracture	**Setting:** Community **Population:** 1,237 participant in the five studies	Vitamin D: Large dose = 700–800IU/d Small dose = 400 IU/d	*Falls:* Compared with patients receiving calcium or placebo, vitamin D reduced risk of falling by 22 percent (corrected odds ratio = 0.78, 95% CI = 0.64–0.92). *Fracture:* • Vitamin D 700–800IU/d reduced the risk of fracture by up to 26 percent. • Vitamin D 400 IU/d did not reduce fracture risk. *Numbers needed to treat:* 15 patients would need to be treated with vitamin D to prevent 1 person from falling. *Sensitivity analysis of 5 additional studies:* Total sample 10,001 – smaller effect size (corrected relative risk = 0.87, 95% CI = 0.80–0.96).

[§] Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Source	Safety Issue Related to Clinical Practice	Design Type[§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Avenell 2005[107]		Meta-analysis	**Design:** Metanalysis of RCTs or quasi-randomized trials **Outcomes:** Fractures	**Setting:** Community **Poplulation:** 7 trials; 18,668 participants	Vitamin D or an analogue alone, or vitamin D with calcium, or Placebo, no intervention, or calcium	**Vitamin D or analogue alone:** • No effect on hip fracture (relative risk = 1.17; 95% CI = 0.98–1.41). • No effect on vertebral fracture (relative risk = 1.13; 95% CI = 0.50–2.55). • Any new fracture (relative risk = 0.99; 95% CI = 0.91–1.09). **Vitamin D or analogue with calcium:** • Marginal reduction in hip fractures (relative risk = 0.81; 95% CI = 0.68–0.96). • Marginal reduction in nonvertebral fractures (relative risk = 0.87; 95% CI = 0.78–0.97). • No effect on vertebral fractures. • Calcitriol may be associated with an increased incidence of adverse effects.
Grant 2005[130]	Physiologic interventions to prevent falls and fall-related injuries in the community	RCT	**Design:** Factorial-design trial **Outcomes:** New low-energy fractures	**Setting:** Patients identified in 21 UK hospitals then treated at home after discharge **Population:** 5,292 people ≥ 70 years (85 percent female) with new low-trauma fracture, and who were mobile before that fracture	800 IU vitamin D daily or 1,000 mg calcium daily or 800 IU vitamin D plus 1,000mg calcium daily or placebo	*Falls:* No differences between groups (hazard ratio = 0.94; 95% CI = 0.81–1.09). *Fractures:* • No difference between vitamin D and placebo (hazard ratio = 1.02; 95% CI = 0.88–1.19). • No difference between combination treatment and placebo.
Sato 2005[137]	Physiologic interventions to prevent fall-related injuries in acute care	RCT	**Design:** RCT **Outcomes:** Vertebral factures, hip fractures	**Setting:** Community in Japan **Population:** 500 women ≥ 70 years with Alzheimer's disease, vitamin D deficiency, and hyperparathyroidism	Risedronate 2.5 with 1,000 IU vitamin D plus 1,200 mg calcium or placebo with 1,000 IU vitamin D plus 1,200 mg calcium	*Fractures:* 72 percent decrease in fractures in the risedronate group (relative risk = 0.28; 95% CI = 0.13–0.59).

Source	Safety Issue Related to Clinical Practice	Design Type[§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bischoff-Ferrari 2006[134]	Physiologic interventions to prevent falls and fall-related injuries in the community	RCT	**Design:** RCT **Outcomes:** Fall rates	**Setting:** Community **Population:** 199 men and 246 women ≥ 65 years living at home	700 IU of vitamin D plus 500 mg of calcium citrate malate per day or placebo	*Falls:* • Vitamin D plus calcium reduced the odds of falling in women by 46 percent (odds ratio = 0.54, 95% CI = 0.30–0.97). • Vitamin D plus calcium reduced the odds of falling in women by 65 percent in less active women (odds ratio = 0.35; 95% CI = 0.15–0.81). • Vitamin D plus calcium did not significantly reduced the odds of falling in men (odds ratio = 0.93, 95 percent CI, 0.50-1.72)
McCloskey 2007[138]	Physiologic interventions to prevent falls and fall-related injuries in the community	RCT	**Design: RCT** (double-blind) **Outcomes:** Hip and any clinical fracture	**Setting:** General community in South Yorkshire and North Derbyshire **Population:** 5,579 women ≥ 75 years	800 mg oral clodronate (Bonefos) or placebo	*Hip fracture:* Slight increase in risk for hip fracture in placebo group (hazard ratio = 1.02, 95% CI = 0.71–1.47). *Any fracture:* 20 percent decrease in risk for any clinical fracture for patients in clodronate group (hazard ratio = 0.80, 95% CI = 0.68–0.94). *Osteoporosis-associated nonhip fractures:* 29 percent decrease in clodronate group (hazard ratio = 0.71; 95% CI = 0.57–0.87).

Evidence Table 5. Reviews Examining Fall Prevention Interventions in Acute and Long-Term Care (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type**	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Evans 1998[153]	Fall and injury prevention in the acute care setting	Literature Review	**Design:** Review **Outcomes:** Fall rates	**Setting:** Acute care **Population:** Patients in acute care setting	Multiple interventions; 200 studies reviewed	*Falls:* Across settings, individual interventions are not more useful than fall-prevention programs for a specific subset of patients.
Oliver 2000[234]	Fall and injury prevention in the acute care setting	Meta-analysis	**Design:** Systematic review **Outcomes:** Fall rates	**Setting:** Acute care **Population:** Patients in acute care setting	Multiple interventions; 10 studies reviewed	*Falls:* Overall the interventions studied did not prevent falls (pooled effects ratio = 1.0; 95% CI = 0.60–1.68).
Agostini 2001[98]	Fall and injury prevention in the acute care setting	Review	**Design:** Review **Outcomes:** Fall rates	**Setting:** Acute care **Population:** Patients in acute care setting	Multiple interventions; two studies and one systematic review reviewed	*Falls:* Interventions with potential to decrease falls include identification bracelets, bed alarms, special flooring, and hip protectors.
Oliver 2007[235]	Fall and injury prevention in the acute care setting	Meta-analysis	**Design:** Systematic review **Outcomes:** Fall rates, fall-related fracture rate	**Setting:** Acute care **Population:** Patients in acute and long-term care setting	Multiple interventions; 43 studies included in meta-analysis	*Falls:* • Multimodal interventions in hospitals showed 18 percent decrease in fall rates (rate ratio = 0.82; 95% CI = 0.68–0.997). • Multimodal interventions in hospitals showed no significant effect on the number of fallers. *Injuries:* • Hip protectors in long-term care homes showed a 33 percent decrease in hip fractures (rate ratio = 0.67; 95% CI = 0.46–0.98). • Multimodal interventions in hospitals showed no significant effect on the number of fractures. *Other interventions:* Insufficient evidence to recommend other interventions.

** Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Evidence Table 6. Studies Examining Environmental Interventions in Acute and Long-Term Care (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type††	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Tideiksaar 1993[154]	Environmental interventions for fall prevention in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Bed falls, staff attitudes toward the use of the system	**Setting:** Geriatric evaluation and treatment unit **Population:** 70 patients (86 percent female), avg. age 84 years, at risk for falls	Bed alarm system	*Falls:* Bed alarms reduced falls by 68 percent, but this was not statistically significant (odds ratio = 0.32; 95% CI = 0.10–1.03). The bed alarm system was well accepted by patients, families, and nurses.
Mayo 1994[155]	Environmental interventions for fall prevention in acute and long-term care	RCT	**Design:** Blinded RCT **Outcomes:** Fall rates	**Setting:** Geriatric care unit at university hospital **Population:** 70 patients at risk for falls	Identification bracelet for patients at high risk for falls	*Falls:* Identification bracelets increase fall risk in high-risk patients (hazard ratio = 1.3, 95% CI = 0.8–2.4), but this was not statistically significant.
Kelly 2002[240]	Environmental interventions for fall prevention in acute and long-term care	Pretest and post-test study	**Design:** Crossover design for 1 week **Outcomes:** Fall rates	**Setting:** Medicare unit of a skilled nursing facility **Population:** 47 patients at high risk for falls	Movement detection patch attached to the thigh	*Falls:* Fall rates decreased from 4.0 falls per 100 patient days to 3.4 falls per 100 days for patients with movement detection patches.
Kwok 2006[222]	Environmental interventions for fall prevention in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Physical restraints use, fall rates	**Setting:** Two geriatric stroke rehabilitation wards in a convalescent hospital in Hong Kong **Population:** 180 geriatric patients perceived by nurses to be at risk of falls	Bed-chair pressure sensor or control	*Falls:* No difference in fall rates between chair alarm group and control group. *Restraints:* No difference in physical restraint use between chair alarm group and control group.

†† Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Evidence Table 7. Studies Examining Physical Activity Interventions in Acute and Long-Term Care (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type‡‡	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mulrow 1994[241]	Physical activity interventions for fall prevention in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Fall rates	**Setting:** 1academic nursing home and 8 community nursing homes **Population:** 194 frail long-term care residents	Individually tailored one-on-one physical therapy sessions or Friendly visits	*Falls:* Fall rates increased in the intervention group (79 versus 60; *P* = 0.11).
Nowalk 2001[244]	Physical activity interventions for fall prevention in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Fall rates	**Setting:** 2 long-term care facilities **Population:** 110 elderly men and women (avg. age 84), capable of ambulating and able to follow simple directions	Resistance-endurance with enhanced exercise or Tai Chi with enhanced exercise or enhanced exercise	*Falls and other outcomes:* Time to first fall, time to death, number of days hospitalized, and incidence of falls did not differ among the treatment and control groups (*P* > 0.05).
Choi 2005[243]	Physical activity interventions for fall prevention in acute and long-term care	Non-randomized trial	**Design:** A quasi-experimental design with a nonequivalent control group **Outcomes:** Fall rates	**Setting:** Residential care facilities **Population:** 68 fall-prone older adults, avg. age 77.8 years	12-week Sun-style Tai Chi exercise program	*Falls:* 38 percent decrease in falls in the Tai Chi group, but not statistically significant (relative risk = 0.62; 95% CI = 0.32–1.19).

‡‡ Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Evidence Table 8. Studies Examining Multimodal Interventions in Acute and Long-Term Care (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type[§§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rubenstein 1990[242]	Multimodal interventions in acute and long-term care	RCT	**Design:** RCT with 2-year followup **Outcomes:** Fall rates	**Setting:** Long-term residential care facility **Population:** 160 ambulatory subjects (avg. age, 87 years)	Tailored interventions based on fall risk factors	*Falls:* Patients in the intervention group had 9 percent fewer falls. *Fall-related deaths:* 17 percent fewer deaths than controls by 2 years, but these trends were not statistically significant.
Bakarich 1997[245]	Multimodal interventions in acute and long-term care	Pretest, post-test	**Design:** Pretest, post-test **Outcomes:** Fall rates	**Setting:** 450-bed metropolitan teaching hospital **Population:** 2,023 patients ≥ 70 years	Toileting regimen for at-risk patients (confused and having mobility problems)	*Falls:* 53 percent less falls during shifts in which the risk assessment and toileting intervention was used.
Lane 1999[262]	Multimodal interventions in acute and long-term care	Pretest, post-test	**Design:** Pre-post and comparative, descriptive design **Outcomes:** Fall rates	**Setting:** Medical-surgical/critical care unit; large community hospital system **Population:** 292 older patients	Fall-prevention program	*Falls:* No decrease in patient fall rate was found between patients who fell before and after implementation of the program.
McMurdo 2000[254]	Multimodal interventions in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Falls and fractures	**Setting:** Nursing home residents **Population:** 133 residents ≥ 84 years	Assessment/ modification and seated balance exercise training program or reminiscence therapy	*Falls:* 55 percent reduction in fall rates for group with exercise training, but not statistically significant (odds ratio = 0.45; 95% CI = 0.19–1.14).

[§§] Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Source	Safety Issue Related to Clinical Practice	Design Type[§§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Jensen 2002[249]	Multimodal interventions in acute and long-term care	RCT	**Design:** cluster RCT **Outcomes:** Fall rates, time to first fall, fall-related injuries	**Setting:** 9 residential care facilities located in northern Sweden **Population:** 439 residential care residents ≥ 65 years	Comprehensive fall risk assessment and tailored interventions	*Falls:* 51 percent reduction in falls (adjusted odds ratio = 0.49; 95% CI = 0.37–0.65). *Injuries:* 77 percent reduction in fall-related injuries (adjusted odds ratio = 0.23; 95% CI = 0.06–0.94).
Bischoff 2003[247]	Multimodal interventions in acute and long-term care	RCT	**Design:** Double-blind RCT **Outcomes:** Fall rates	**Setting:** Long-stay geriatric care **Population:** 122 elderly women (mean age, 85.3 years; range, 63–99 years)	1,200 mg calcium plus 800 IU vitamin D daily or 1,200 mg calcium daily	*Falls:* 49 percent reduction of falls in the group that received calcium plus vitamin D (95% CI = 14–71; $P < 0.01$).
Hofmann 2003[250]	Multimodal interventions in acute and long-term care	Pretest, post-test	**Design:** Pretest, post-test **Outcomes:** Falls, fall-related fractures	**Setting:** 120-bed nursing home **Population:** Frail elderly population	Concurrent: Staff education, exercise, and environmental modifications	*Falls:* 38 percent reduction in fall rates ($P = 0.0003$). *Injuries:* 50 percent reduction in injury rates ($P > 0.05$).
Semin-Goossens 2003[257]	Multimodal interventions in acute and long-term care	Pretest, post-test	**Design:** Pretest, post-test pilot study **Outcomes:** Fall rates	**Setting:** Academic medical center, 2 medical-surgical units **Population:** 2,670 patients	Fall prevention guideline with semistructured interventions	*Falls:* Fall rates in high-risk neurology and medical patients were not reduced.
Haines 2004[251]	Multimodal interventions in acute and long-term care	RCT	**Design:** RCT **Outcomes:** Fall rates, fall-related injury rates, repeat fallers	**Setting:** 3 subacute wards in rehabilitation and elder care hospital **Population:** 626 men and women ages 38 to 99 years (avg. 80 years)	Falls risk alert card, exercise, education program, and hip protectors or usual care	*Falls:* 22 percent decrease in falls (relative risk = 0.78; 95% CI = 0.56–1.06). *Injuries:* 28 percent decrease in injuries in the intervention group, but not statistically significant ($P = 0.20$).

Source	Safety Issue Related to Clinical Practice	Design Type[§§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Healey 2004[253]	Multimodal interventions in acute and long-term care	RCT	**Design:** Cluster randomized trial **Outcomes:** Fall rates	**Setting:** Elder care units and associated community units of a district general hospital in England **Population:** Patients deemed at high risk for falls received intervention	Preprinted care plan for patients identified as at risk of falling and introduced appropriate remedial measures	*Falls:* 29 percent decrease in falls in the intervention group (relative risk = 0.71; 95% CI = 0.55–0.90, *P* = 0.006). *Injuries:* No reduction in injuries.
Jensen 2004[249]	Multimodal interventions in acute and long-term care	RCT	**Design:** Cluster-randomized trial **Outcomes:** Fall rates	**Setting:** 9 residential care facilities in Sweden **Population:** 187 residents at high risk for falling ≥ 65 years	Education, environment, exercise, drug review, postfall assessments, hip protectors	*Falls:* Intervention had no effect on fall rates.
Kerse 2004[256]	Multimodal interventions in acute and long-term care	RCT	**Design:** Cluster RCT **Outcomes:** Fall rates	**Setting:** Residential care homes **Population:** 628 residents	Risk assessment followed by tailored interventions	*Falls:* 34 percent increase in falls (incident rate ratio = 1.34; 95% CI = 1.06–1.72).
Vassallo 2004[208]	Multimodal interventions in acute and long-term care	Non-randomized trial	**Design:** Quasi-experimental **Outcomes:** Fall rates, injury rates, repeat fall rates	**Setting:** 3 geriatric wards **Population:** 825 consecutive geriatric patients	Medication adjustment, environmental assessment, wristbands	*Falls:* • 25 percent decrease in falls in the intervention group, but not statistically significant (relative risk = 0.75; 95% CI = 0.53–1.05). • No reduction in recurrent fallers. *Injuries:* No reduction in injuries.
Flicker 2005[248]	Multimodal interventions in acute and long-term care	RCT	**Design:** Randomized, placebo-controlled, double-blind trial **Outcomes:** Falls and fall-related fractures	**Setting:** Multicenter study in 60 assisted living facilities and 89 nursing homes across Australia **Population:** 625 residents (avg. age 83 years) with vitamin D deficiency	Vitamin D 10,000 IU once, then 1,000 IU daily plus 600 mg calcium or placebo plus 600 mg calcium	*Falls:* 27 percent decrease in falls in intervention group (incident rate ratio = 0.73; 95% CI = 0.57–0.95). *Injuries:* 31 percent decrease in injuries, but not statistically significant (odds ratio = 0.69; 95% CI = 0.40–1.18).

Source	Safety Issue Related to Clinical Practice	Design Type[§§]	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Klay 2005[246]	Multimodal interventions in acute and long-term care	Pretest, post-test study	**Design:** Pretest, post-test **Outcomes:** Urinary tract infections, pressure ulcers, and falls	**Setting:** Connecticut long-term care center **Population:** 42 female residents who were incontinent or had urgency related to overactive bladder	Individualized continence program	*Falls:* 58 percent reduction in falls after treatment with individual continence program.
Fonda 2006[260]	Multimodal interventions in acute and long-term care	Pretest, post-test study	**Design:** Pretest, post-test **Outcomes:** Fall rates, fall-related injuries	**Setting:** Long-term care setting, Australia **Population:** All patients admitted to the unit	Multistrategy approach: work practice changes, environmental/ equipment changes, staff education	*Falls:* 19 percent reduction in the number of falls per 1,000 patient days (12.5 v 10.1; P = 0.001). *Falls:* 77 percent reduction in the number of falls resulting in serious injuries per 1,000 patient days (0.73 v 0.17; P < 0.001).
Schwendi-mann 2006[261]	Multimodal interventions in acute and long-term care		**Design:** Serial survey design **Outcomes:** Fall rates, fall-related injuries	**Setting:** 300-bed urban public hospital **Population:** Adult patients in internal medicine, geriatrics, and surgery	Interdisciplinary falls-prevention program	*Falls:* Decrease in fall rates, but not statistically significant (pre-9.0, post-7.8; P = 0.086). *Injuries:* No change in injury rate.

Evidence Table 9. Studies Examining Interventions to Prevent Injury in Acute and Long-Term Care (listed chronologically)

Source	Safety Issue Related to Clinical Practice	Design Type***	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lauritzen 1993[263]	Physical interventions to prevent fall-related injuries in acute care	RCT	**Design:** RCT **Outcomes:** Hip fractures	**Setting:** 10 of the 28 wards in a nursing home **Population:** 665 older patients (67 percent female)	External hip protectors	*Fractures:* 56 percent decrease in hip fractures for patients wearing hip protectors (relative risk = 0.44; 95% CI = 0.21–0.94).
O'Halloran 2004[264]	Physical interventions to prevent fall-related injuries in acute care	RCT	**Design:** Cluster RCT **Outcomes:** Hip fracture	**Setting:** 127 nursing and residential homes in Northern Ireland **Population:** 4,117 elderly residents	Hip protectors, staff education	*Fractures*: Slight increase in hip fractures in the intervention group (adjusted rate ratio = 1.05; 95% CI = 0.77–1.43).
Ray 2005[266]	Multimodal interventions to prevent fall-related injuries in acute care	RCT	**Design:** Cluster RCT **Outcomes:** Serious fall-related injuries	**Setting:** 112 long-term care facilities **Population:** 10,558 residents ≥ 65 years, not bedridden	Staff safety education plan with tailored interventions	*Injuries:* • No difference in injury rates (adjusted rate ratio = 0.98; 95% CI = 0.83–1.16). • 21 percent decrease in injury rates for patients with prior fall in facilities with the best compliance, but not statistically significant (adjusted rate ratio = 0.79; 95% CI = 0.57–1.10).
Sato 2005[136]	Physiologic interventions to prevent fall-related injuries in acute care	RCT	**Design:** Double blind RCT **Outcomes:** Hip fractures	**Setting:** Stroke unit at hospital in Japan **Population:** 280 male poststroke patients ≥ 65 years	Risedronate 2.5 mg or placebo	*Fractures*: 81 percent decrease in hip fractures in risedronate group (relative risk = 0.19, 95% CI = 0.04–0.89).
Sato 2005[137]	Physiologic interventions to prevent fall-related injuries in acute care	RCT	**Design:** Double blind RCT **Outcomes:** Hip fractures	**Setting:** Stroke unit at hospital in Japan **Population:** 187 female poststroke patients ≥ 65 years	Risedronate 2.5 mg or placebo	*Fractures*: 86 percent decrease in hip fractures in the risedronate group, but this was not statistically significant (relative risk = 0.14; 95% CI = 0.02–1.2).

*** Study Design Type: (1) Meta-analysis, (2) Randomized controlled trials, (3) Nonrandomized trials, (4) Cross-sectional studies, (5) Case control studies, (6) Pretest and post-test (before and after) studies, (7) Time series studies, (8) Noncomparative studies, (9) Retrospective cohort studies, (10) Prospective cohort studies, (11) Systematic literature reviews, (12) Literature reviews, nonsystematic/narrative, (13) Quality-improvement projects/research, (14) Changing-practice projects/research, (15) Case series, (16) Consensus reports, (17) Published guidelines, (18) Unpublished research, reviews, etc.

Chapter 11. Reducing Functional Decline in Hospitalized Elderly

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Background

The elderly, or those older than 65 years, currently represent 12.5 percent of the U.S. population, and are projected to increase to 20 percent of the population by 2030—growing from 35 million to 72 million in number.[1, 2] By 2050, 12 percent of the population, or one in eight Americans, will be 75 years of age or older.[3] In 2002, the elderly accounted for 12.7 million (41 percent) of the 31.7 million hospitalizations in the United States,[4] and these numbers are expected to increase significantly as the population ages. Targeting the care needs of the hospitalized elderly and awareness of risks for illness-related complications are urgent concerns for managing acute health care conditions in this population.[4]

Hospitalization and Patient Safety Considerations for the Elderly

It is estimated that almost half of adults who are hospitalized are 65 years of age or older, although those older than 65 years represent only 12.5 percent of the population. The proportion of hospitalized adults who are elderly is only expected to increase as the population ages.[4] The average hospital length of stay for patients age 65 and older has decreased to 5.7 days, down from 8.7 days in 1990.[3] Shorter lengths of stay heighten the challenge to properly assess and address the care needs of older adults during hospitalization as well as their discharge needs. The focus of assessment and care is generally on resolving the immediate problem that triggered hospitalization; less attention is given to the underlying risk of functional decline and the vulnerability to hospital-associated complications.

A primary focus for improvement in health care is on promoting patient safety and avoiding injuries to patients.[5] This becomes especially important for hospitalized elders, who are at risk for functional decline due to altered mobility levels as well as iatrogenic risks. For the frail elderly in particular, hazards of hospitalization include falls, delirium, nosocomial infections, adverse drug reactions, and pressure ulcer development.[6–8]

A dissonance exists between the hospital environment and therapeutic goals for the hospitalized elderly. The hospital environment, a tertiary care setting, has traditionally focused on medically managing illness states, not on improving patient functioning. The environment is designed for the rapid and effective delivery of care—not for enhancing patient function. Hospital redesign to address the care needs of the elderly have been proposed.[9, 10] Consideration of the milieu as well as age-related physiological changes are important aspects of creating a safe hospital environment for the hospitalized elderly.

Age-Associated Changes

A number of known physiological changes occur with aging, including reduced muscle strength and aerobic capacity, vasomotor instability, baroreceptors insensitivity and reduced total body water, reduced bone density, reduced ventilation, and reduced sensory capacity.[4, 11, 12] Comorbid conditions and chronic illness may heighten these changes. Muscle mass and muscle strength are reduced with aging and contribute to a reduction of physical activity.[12] With aging, alterations in autonomic function, including baroreceptor insensitivity, occurs. Age-associated reduction in body water and plasma volume may predispose the elderly to syncope. Respiratory mechanics are also altered with aging, with reduced ventilation, increased residual capacity, and reduced arterial oxygen tension.[12] Other age-associated changes include reduced bladder capacity and increased urine production, prostrate enlargement, bone demineralization, loss of taste and smell, decreased skin integrity, and reduction in sensory input.[12, 13]

As a result, the elderly are at higher risk for adverse physiological consequences during acute illness, including impairment in functional status. Frailty—a state of musculoskeletal weakness and other secondary, widely distributed losses in structure and function—has been found to be attributed to decreased levels of activity and has been linked to the process of aging.[14] Advanced age, acute and chronic disease and illness, functional limitations, and deconditioning all contribute to the older adult's vulnerability to functional decline during hospitalization. Functional decline—the inability to perform usual activities of daily living due to weakness, reduced muscle strength, and reduced exercise capacity—occurs due to deconditioning and acute illness during hospitalization.[15]

Functional Status

Functional status is determined by the ability to perform activities of daily living (ADLs)—eating, dressing, bathing, ambulating, and toileting—and instrumental ADLs (IADLs)—shopping for groceries, meal preparation, housework, laundry, getting to places beyond walking distance, managing medications, managing finances, and using a telephone.[4] It is estimated that up to 8 percent of community-dwelling elders need assistance with one or more ADLs. Among those age 85 and older, the percentage who live at home but need assistance or who live in a nursing home increases significantly to 56 percent of women and 38 percent of men.[4] Chronic illness and comorbidities can directly impact functional status in the elderly. Chronic health care conditions that are most prevalent in the elderly include heart disease, hypertension, arthritis, diabetes, and cancer.[3] Acute illness due to chronic disease and chronic comorbidities accounts for a significant number of hospitalizations in the elderly.

Functional Decline During Hospitalization

During hospitalization, the elderly patient often experiences reduced mobility and activity levels. Functional decline, including changes in physical status and mobility, has been identified as the leading complication of hospitalization for the elderly.[16] The hazards of bed rest during hospitalization are well established and include immobility, accelerated bone loss, dehydration, malnutrition, delirium, sensory deprivation, isolation, sheering forces on the skin, and incontinence (see Table 1).[12, 17]

Bed rest results in a reduction of exercise capacity due to several physiologic changes that occur, including reductions in maximal stroke volume, cardiac output, and oxygen uptake.[17] The

muscle fatigue that results is associated with reduced muscle blood flow, red cell volume, capillarization, and oxidative enzymes.[17] Accelerated bone loss can lead to a higher risk for injury to bones and joints, including hips and spine.[18]

Table 1. Effects of Bed Rest

System	Effect
Cardiovascular	↓ Stroke volume, ↓ cardiac output, orthostatic hypotension
Respiratory	↓ Respiratory excursion, ↓ oxygen uptake, ↑ potential for atelectasis
Muscles	↓ Muscle strength, ↓ muscle blood flow
Bone	↑ Bone loss, ↓ bone density
GI	Malnutrition, anorexia, constipation
GU	Incontinence
Skin	Sheering force, potential for skin breakdown
Psychological	Social isolation, anxiety, depression, disorientation

Sources: Amella EJ. Presentation of illness in older adults. Am J Nurs 2004;104:40-52. Creditor MC. Hazards of hospitalization of the elderly. Ann Intern Med 1993;118: 219-23. Convertino VA. Cardiovascular consequences of bed rest: effect on maximal oxygen uptake. Med Sci Sports Exerc 1997;29:191-6.

Deconditioning, which results in a decrease in muscle mass and the other physiologic changes related to bed rest, contributes to overall weakness.[19] Functional decline can then occur as a consequence of those physiologic changes and result in inability to perform usual ADLs.[19]

Low levels of mobility and bed rest were common occurrences during hospitalization for the elderly.[20] Deconditioning and functional decline from baseline was found to occur by day 2 of hospitalization in elderly patients.[21] Loss of functional independence during hospitalization resulted from not only the effects of acute illness, but also from the inability to maintain function during hospitalization.[22] In assessing physical activity of 500 hospitalized elderly patients, those who remained in bed or who had chair activity rarely received physical therapy, had physician orders for exercises, or performed bedside strengthening exercises.[21] Comparisons of functional assessment at baseline and day 2 of hospitalization in 71 patients over the age of 74 years demonstrated declining ability in mobility, transfer, toileting, feeding, and grooming.[23] Between day 2 and discharge, 67 percent demonstrated no improvement and 10 percent experienced further decline, highlighting the potential for delayed functional recovery in the hospitalized elderly.[23] A followup of 489 hospitalized elders age 70 years and older revealed that the prevalence of lower mobility in hospitalized elderly was significant, with 16 percent experiencing low levels of mobility, 32 percent experiencing intermediate levels of mobility, and 29 percent experiencing a decline in an ADL activity.[20] Yet for almost 60 percent of bed-rest episodes, there was no documented medical indication for limiting mobility status.

Preadmission health and functional status of the elderly can indicate risk of further functional decline associated with hospitalization. In examining the baseline functional status of 1,212 hospitalized patients age 70 years and older, the use of ambulation assistive devices, such as canes and walkers, was predictive of functional decline associated with hospitalization.[24] Use of a walker was associated with a 2.8 times increased risk for decline in ADL function by the time of hospital discharge ($P = 0.0002$). Moreover, 3 months after discharge, patients who had used an assistive device prior to hospitalization were more likely to have declined in both ADL status ($P = 0.02$) and IADL status ($P = 0.0003$).[24] Other risk factors found to be predictive of

functional decline in the elderly during hospitalization included having two or more comorbidities, taking five or more prescription medications, and having had a hospitalization or emergency room visit in the previous 12 months.[25]

Associations between functional status and other risk factors such as cognitive status must also be considered. Hospital-related complications or inadequate hospital care have been linked to the development of delirium in the hospitalized elderly.[26] Impairment in cognitive status was found to be associated with changes in functional status in the hospitalized elderly. A study of 2,557 patients from two teaching hospitals examined the association between level of impaired performance on a cognitive status screen and maintenance and recovery of functioning from admission through 90 days after discharge. Performance on a brief cognitive screen on admission was strongly related to subsequent change in function. Among patients who needed help performing one or more ADLs at the time of admission, 23 percent of patients with moderate to severely impaired cognitive performance, 49 percent of patients with mildly impaired cognitive performance, and 67 percent of patients with little or no impairment in cognitive performance recovered the ability to independently execute an additional ADL by discharge ($P < 0.001$).[22] Additional studies identified that prolonged recovery and continued ADL limitations occurred after hospitalization. In following 1,279 patients age 70 years and older after hospital discharge, a study found that 59 percent reported no change in ADL status, 10 percent reported improvement, and 39 percent reported declined ADL status at discharge when compared to preadmission status. At 3 months after discharge, 40 percent reported a new ADL or IADL disability compared with preadmission, reflecting the potential for continued functional decline after hospitalization for acute illness.[27]

Yet, the loss of functional independence is not an inevitable consequence of hospitalization for the elderly.[28, 29] Evidence exists that targeted interventions can impact the degree of functional independence for hospitalized elders.[30]

Research Evidence

Targeted measures that have proven beneficial in mitigating functional decline during hospitalization have included comprehensive geriatric assessments to identify patients at risk, structured geriatric care models, dedicated hospital units for acute care of the elderly, and the use of specific resources to enhance care for the hospitalized elder.

Comprehensive Geriatric Assessment

Comprehensive geriatric assessment (CGA) is used to create a plan of care for hospitalized elders. A specific goal of the CGA is early identification of elder care needs in order to provide interventions to minimize high-risk events such as falls or the onset of delirium.[31]

A CGA should include assessment of ADL and IADL performance as well as assessment of cognition, vision and hearing, social support, and psychological well-being.[19] A number of geriatric assessment tools can be used to make initial and ongoing evaluations of hospitalized elders. Commonly used tools include the Katz Index of Independence in Activities of Daily Living,[32] the Lawton Instrumental Activities of Daily Living Scale,[33] and the Hospital Admission Risk Profile (HARP), among others (see Table 2).

Table 2. Commonly Used Geriatric Assessment Measures*

Instrument	Areas of Assessment	Reference
SPICES	Sleep, problems with eating or feeding, incontinence, confusion, evidence of falls, skin breakdown	Fulmer 1991[59] Wallace 1998[66]
Geriatric Institutional Assessment Profile	Hospital staff knowledge of geriatric care principles, organizational environment	Abraham 1999[41]
Hospital Admission Risk Profile (HARP)	ADL, IADL, cognitive status	Sager 1996[34]
Lawton Instrumental Activities Daily Living Scale	IADL activities: medication management, housekeeping, food preparation, transportation, shopping, managing finances, laundry	Lawton 1969[33]
Functional Independence Measure (FIM)	Functional status in 7 areas: self-care, locomotion, communication, social cognition, cooperation, problem-solving, sphincter control	Kidd 1995[67] Keith 1987[68]
Timed UP and Go Test	Mobility, balance, gait, transfer ability, walking	Podsiadlo 1991[69]
2 Minute Walk Test	Exercise tolerance and exercise capacity	Brooks 2001[70]

* For additional geriatric assessment resources, the Try This series can be found at www.hartfordign.org/resources/education/tryThis.html.

As part of CGA, baseline admission assessments have proved beneficial in identifying patients at risk for functional decline during hospitalizations. The HARP was used in one study to assess preadmission risk factors among more than 800 patients age 70 years and older who were hospitalized for acute medical illness.[34] The HARP includes assessment of ADL status, IADL status, and cognitive status. Researchers found that three factors independently predict functional decline: increasing age, lower admission cognitive status, and lower preadmission IADL function. Patients at low risk of functional decline were more likely to recover ADL function and avoid nursing home placement at 3 months after discharge.

Another functional status instrument that can be used to assess baseline activity and functional levels is the Mobility Classification Tool, described by Callen and colleagues.[35] The tool may prove useful for nurses to assess, quantify, and communicate baseline levels and changes in mobility. Baseline assessments can provide useful information for structuring care during hospitalization and establishing goals for the care.

Aside from the use of formal assessment instruments that measure ADL and IADL function, a general idea of functional status can be ascertained by assessing mobility and activity performance during hospitalization. The frequency of hallway ambulation in hospitalized elders was examined in an observational study of 118 patients age 55 years and older in a single setting.[36] While all patients were considered by their primary nurse as able to walk the hallways,

72.9 percent did not walk at all per 3-hour period of observation, 18.6 percent walked once, 5.1 percent twice, and only 3.4 percent walked more than twice.[35] The median time of ambulation was 5.5 minutes. Of the 32 patients who walked in the hallways, 46.8 percent (n = 15) did so alone, 41 percent (n = 13) walked with a therapist, 41 percent (n = 13) walked with a member of the nursing staff, and 18.8 percent (n = 6) walked with a family member.

Based on the results of the CGA, functional problems or potential problems are identified and specific interventions can be implemented to promote functional ability in hospitalized elders. A number of interventions, including structured exercise, progressive resistance strength training, and walking programs, have been implemented to target elder care functioning during hospitalization.[35, 37, 38] A randomized control trial of a hospital-based general exercise program with 300 hospitalized elders that was started during hospitalization and continued for 1 month after discharge did not affect length of stay, but did demonstrate better IADL function at 1 month after discharge.[38] Measures to improve endurance—including exercise to enhance orthostatic stability, daily endurance exercise to maintain aerobic capacity, or specific resistance exercises to maintain musculoskeletal integrity[17, 39, 40]—need further study on their impact in reducing functional decline in hospitalized elders. As hospital-based exercise programs require coordination and focused implementation plans, strategies for adopting them need to recognize the shortened length of hospital stay and the effects of acute illness on the patients' ability to participate.

In addition to utilizing tools to assess the elderly hospitalized patient, assessments of the hospital culture for providing elder care can also be beneficial. The Geriatric Institutional Assessment Profile was specifically developed to assess hospital workers' knowledge, attitudes, and perceptions of caring for elders, as well as the adequacy of the institutional environment to meet hospitalized elders' needs.[41] It is recommended to help identify both the strengths in elder care and the opportunities for improvement.[42]

Structured Geriatric Care Models

For more than 20 years, the concept of hospital-based geriatric assessment and interdisciplinary team care to improve outcomes for hospitalized elders has been implemented in various models. Early studies on the use of geriatric evaluation and geriatric evaluation units demonstrated an impact on reducing disability and nursing home placement.[43–45] Several hospital-based geriatric resource models of care have also demonstrated benefits in promoting evidence-based care for hospitalized elders, including the use of geriatric interdisciplinary team training[46] and the use of a geriatric resource nurse.[47] National programs for geriatric interdisciplinary team training were created in 1997 to enhance the knowledge of caring for elders among a variety of health professions. While evaluation data have demonstrated improvement of geriatric interdisciplinary team trainees, most notably in attitudinal measures,[46] further study on the impact on geriatric care planning is needed.

Several focused models of care designed to prevent functional decline of the hospitalized elderly have demonstrated significant results. The Hospital Elderly Life Program, a structured screening program for hospitalized patients age 70 years and older, concentrates on admission screening of six risk factors: cognitive impairment, sleep deprivation, immobility, dehydration, vision loss, and hearing impairment.[16] More than 1,500 patients were screened, and targeted interventions based on the presence of admission risk factors were instituted. Patients were followed by an interdisciplinary team that included a geriatric nurse specialist, Elderly Life specialists, and geriatricians who worked in conjunction with the patient's primary care nurse to

formulate an individualized plan of care. Use of the program demonstrated significant results: only 14 percent of patients had a decline on ADL scores, compared to a decline in 33 percent of the control group.

Acute Care for Elderly (ACE) units. Models of care incorporate a variety of interventions to promote positive outcomes for the hospitalized elderly. Specific programs have also been tested on specialized units within the hospital setting. These units, termed Acute Care for the Elderly (ACE units), provide dedicated care to the hospitalized elderly.

Originating in the early 1990s, the ACE unit concept has been adopted by organizations as a strategy to provide care to elderly patients during hospitalization.[48–49] ACE units promote a focused model of care that integrates geriatric assessment into medical and nursing care of patients in an interdisciplinary environment.[50] The focus is to provide expert care while simultaneously keeping patients mobile and preventing the loss of normal daily routines.[49] ACE units include specially designed environmental changes to promote activity such as ambulation in hallways, exercise facilities, and social gathering areas.[51] Multidisciplinary teams composed of geriatric physicians; nurses; dietician; social worker; pharmacist; and occupational, speech, and physical therapists regularly discuss the plan of care for each patient.[49] Major components of the ACE unit concept include patient-centered nursing care (daily assessment of functional needs by nursing, nursing-based protocols to improve outcomes, daily rounds by a multidisciplinary team), a prepared environment, planning for discharge, and medical care review.[10, 52]

Another model, designed to improve functional outcomes of acutely ill hospitalized elders, was tested in a randomized control trial with 1,794 patients 70 years of age and older in one unit of a hospital. A number of interventions were implemented under the direction of the primary nurse, including baseline and ongoing assessment of risk factors; following protocols to improve self-care, continence, nutrition, mobility, sleep, skin care, and cognition; conducting daily rounds with a multidisciplinary team; and environmental enhancements such as handrails, uncluttered hallways, large clocks and calendars, elevated toilet seats, and door levers.[29] Results indicated that 21 percent of intervention patients were classified as *much better* in ADL activity abilities, 13 percent as *better*, 50 percent as *unchanged*, 22 percent as *worse*, and 9 percent as *much worse*. In the control group, 13 percent were classified as *much better*, 11 percent as *better*, 54 percent as *unchanged*, 13 percent as *worse*, and 8 percent as *much worse* ($P = 0.0009$). While the program interventions improved functional status in a significant percentage of the patients, the majority of the patients in both the intervention and control groups were unchanged or worse at the time of discharge. At 3 months after discharge, the groups did not differ significantly in terms of ADL or IADL abilities.[29] The results of this study suggested that while targeted interventions can improve functional independence in the hospitalized elderly, some patients will continue to experience functional decline, despite focused interventions.

Research comparing ACE units and standard medical care units has demonstrated positive outcomes, with improvements in ADL function and fewer transfers to nursing home settings after discharge.[29] A randomized controlled study of 1,531 elders age 70 years and older demonstrated that use of an ACE unit improved processes of care and promoted patient and provider satisfaction without increasing hospital length of stay or costs.[51] Additional study on the cost effectiveness of ACE units has demonstrated significant reductions in average length of stay (0.8 day) and a cost savings of $1,490 compared to control patients on two medical-surgical units, a savings that translated to $1.3 million in 9 months[48] as well as no increase in hospital costs.[53]

The NICHE model. An additional model focusing on improving hospital care for the elderly, the Nurses Improving Care of Health System Elders (NICHE) project, was initiated in the early

1990s. The project is a national program focused on promoting evidenced-based care for elders.[42, 54] Resources include best practice protocols, educational materials, nursing care models to replicate, and assessment tools. A unique series of online assessment tools, Try This, is available at www.hartfordign.org/resources/education/tryThis.html. Assessments of the NICHE program indicate that fewer patients were acutely confused at discharge,[55] restraint use was reduced by more than 60 percent, serious injuries related to falls were reduced by 30 percent, there were beginning signs of reduction in the incidence of aspiration pneumonia and urinary tract infection, and patient mobility equipment was standardized.[56] Outcome reports from implementation of NICHE also included increased nursing knowledge of geriatric care, decreased length of stay, and reduced costs.[42, 56–58] The NICHE model of care is currently a voluntary program, and while additional outcomes-based research is needed, implementation of the program components by all hospital settings would facilitate best practices for elder care.

The geriatric resource nurse model is the most widely used NICHE model. In the geriatric resource nurse model, unit-based nurses acquire competency in elder care and improve care by modeling best practices and providing consultation for elder care.[42, 56, 57] Implementation reports highlight anecdotal evidence of benefit, but researched-based outcome evaluations is limited. One study of 173 hospitalized elders demonstrated improvements in outcome measures, including functional and cognitive status from admission to discharge when managed by the geriatric resource nurse model; however, a comparison of a subset of the intervention patients and a control group of patients revealed no differences in patient outcomes.[30] Further research on this model of care for hospitalized elders is required.

Other Measures to Enhance Care for the Hospitalized Elder

Additional resources to promote hospital-based elder care that are evidence based include nursing staff education to enhance geriatric assessment and care, promotion of nursing certification in geriatric care, and promotion of family participation in caring for hospitalized elders.[59–62] Other focused interventions—including geriatric consultation on specific units, comprehensive discharge planning, and nutritional support—have had beneficial effects on clinical outcomes of hospitalization of the elderly.[63, 64] Ongoing initiatives that have the potential for impacting the care of hospitalized elders include strategies for enhancing geriatric content in nursing school curriculum, advanced practice nurse training in geriatric care, centers of geriatric nursing excellence, and geriatric nursing scholar work. Yet, much remains to be learned about not only the causes of functional decline during hospitalization for the elderly, but also the best approaches for comprehensively modifying the hospital care environment to promote best outcomes. As nurse staffing levels have been demonstrated to impact the quality of hospital care,[65] exploration of innovative models of nurse staffing to enhance care for the hospitalized elderly is also needed. In addition, there is limited research on hospital designs to improve functioning for hospitalized elders. Hallway walking is not always encouraged, and hospital hallways are often designed for transport of supplies, equipment, staff, and patients. The effect of environmental designs to enhance functioning of hospital elders, such as designated walking tracts on nursing units with shock-absorbing flooring and railings solely for patient use, require further exploration.

Table 3. Summary of Key Points Based on Research Evidence

- Functional status or the ability to perform self-care and physical needs activities is an important component of independence for the elderly. Maintaining function is central to fostering health and independence in the hospitalized elderly.
- The hospitalized elderly are at risk for decreased mobility and functional decline.
- Hospitalization has been shown to be associated with low mobility and functional disability.
- Comprehensive initial and ongoing geriatric assessments assist in identifying the older adult at risk for decline, enabling timely and targeted implementation strategies.
- Targeting risk factors—cognitive impairment, prehospitalization functional impairment, and low social activity level—that can contribute to functional decline during hospitalization can promote better outcomes for elders.
- Encouraging activity during hospitalization can help to prevent functional decline. Interventions such as structured exercise, progressive resistance strength training, and walking programs have been implemented to target elder care functioning during hospitalization.
- Redesign of the environment and processes of hospital care can improve the quality of the care delivered to the hospitalized elderly.
- Key elements and features of successful intervention programs targeting functional outcomes in the hospitalized elderly include
    - Baseline and ongoing assessment of risk factors
    - Protocols aimed at improving self-care, continence, nutrition, mobility, sleep, skin care, and cognition
    - Daily rounds with a multidisciplinary team
    - Protocols to minimize adverse effects of selected procedures (e.g., urinary catherization) and medications (e.g., sedative-hypnotic agents) and limit the use of mobility restrictors (lines, tubes, and restraints)
    - Environmental enhancements, including handrails, uncluttered hallways, large clocks and calendars, elevated toilet seats, and door levers
    - Encouraging mobilization during hospitalization
- Specialty geriatric nursing care can positively impact elder care in the hospital setting.
- The potential for delayed functional recovery should be considered in discharge planning for hospitalized elders.

Evidence-Based Practice Implications

Table 4 outlines several evidence-based strategies for care of the hospitalized elder. A number of evidence-based practice guidelines that pertain to hospitalized elder care can be used to structure care to promote best practices in a variety of areas, including pain management, strategies for assessing and treating delirium, fall prevention for older adults, prevention of pressure ulcers, and changing the practice of physical restraint use in acute care. The guidelines can be found at www.guideline.gov.

Table 4. Evidence-Based Strategies for Care of the Hospitalized Elder.

- Conduct an institutional assessment of your facility to determine knowledge and awareness of principles of geriatric care and best practices.
- Consider integrating baseline and ongoing assessment of hospitalized elders.
- Integrate established protocols aimed at improving self-care, continence, nutrition, mobility, sleep, skin care, and cognition.
- Conduct daily rounds with a multidisciplinary team.
- Institute protocols to minimize adverse effects of selected procedures (e.g., urinary catherization) and medications (e.g., sedative-hypnotic agents).
- Use environmental enhancements for elder care, including handrails, uncluttered hallways, large clocks and calendars, elevated toilet seats, and door levers.
- Consider participation in best practice models for elder care, including Geriatric Interdisciplinary Team Training (GITT) and Nurses Improving Care of Health System Elders (NICHE).
- Utilize established resources, including geronurseonline (www.geronurseonline), University of Iowa Gerontological Nursing Intervention Research Center resource (http://www.nursing.uiowa.edu/centers/gnirc/protocols.htm), and NICHE online resources (www.hartfordign.org/resources/education/tryThis.html).

A number of important considerations for addressing potential risks for the hospitalized elder are outlined in Table 5.

Table 5. Practice Implications to Avert Potential Risks

Potential Risks for the Hospitalized Elderly	Practice Implication
1. Decreased mobility and functional decline	Conduct comprehensive initial and ongoing geriatric assessment to formulate targeted strategies to enhance mobility levels and functional status, such as structured exercise, progressive resistance strength training, and walking programs.
2. Adverse effects of immobility and bed rest	Incorporate the use of practice guidelines to address potential adverse effects, including prevention of skin breakdown**,** fall prevention, treating delirium, prevention of pressure ulcers, and management of urinary incontinence.
3. Altered nutrition or dehydration	Incorporate the use of practice guidelines to enhance nutritional status and hydration during acute illness.
4. Impaired sleep and rest	Integrate established protocols aimed at improving sleep and rest during hospitalization.
5. Alterations in self-care	Promote participation in activities of daily living; promote normal daily routine activities.
6. Cognitive alterations	Conduct ongoing assessment of cognitive status changes and implementation of measures to address confusion and delirium.

Potential Risks for the Hospitalized Elderly	Practice Implication
7. Complications of acute illness (e.g., infection, aspiration, pneumonia)	Use multidisciplinary care models to address management of acute illness and implementation of prevention measures.

Research Implications

To improve the quality and safety of care for hospitalized elderly patients, the following questions deserve further investigation:

- What interventions are the most effective in enhancing functional status in the hospitalized elderly?
- What is the impact of single-site successful models of care in multiple hospital care settings?
- What is the cost effectiveness of intervention programs aimed at targeting functional decline in the hospitalized elderly?

Future research on reducing functional decline in the hospitalized elderly should target the following significant gaps in research:

- Additional research on the impact of models of care for the hospitalized elderly (including NICHE) is needed to build evidence-based practice recommendations. Most of the existing "evidence" comes from small randomized studies, nonrandomized studies, case studies, and expert opinion.
- Hospital design outcomes research is warranted to further evaluate the impact of redesign interventions in enhancing outcomes for hospitalized elders.
- Most research on interventions targeting functional status during hospitalization of the elderly was conducted at single-site locations. Therefore, it is not clear if the findings can be generalized to other settings. Additional research is needed that focuses on multidisciplinary interventions with larger sample sizes and in multicenter, randomized clinical studies.
- A conceptual model for targeting functional decline in the hospitalized elderly is needed. Factors to be considered include the fact that the elderly are a heterogeneous group—some are frail upon admission and others are robust. The hospitalized elderly come to the hospital with different comorbidities and reasons for admission. Polypharmacy in the elderly needs to also be considered. In addition, the tertiary care environment is not a living environment, creating a dissonance between the goals of restorative care and environmental function.
- While structured models of care focusing on assessment, physical therapy, ADL protocol use, and multidisciplinary team care have demonstrated significant benefits on independence for hospitalized elders, relatively simple interventions such as hallway walking, communal dining, and group therapy need to be further examined.
- Nursing-focused interventions aimed at promoting functional independence for hospitalized elders need further exploration in formal research studies.

Conclusion

This chapter has presented an overview of research and evidence-based practices for elderly care during hospitalization to prevent functional decline. A number of other chapters in this book further address related areas, such as averting patient falls, preventing pressure ulcers, symptom management, and other aspects of care for the hospitalized elder. Continued research and dissemination of best practices will lead to additional strategies that nurses can use to improve the quality of health care and outcomes for hospitalized elders. Assessment of function and targeting interventions during hospitalization are critically important to acute care of older adults.[71] The impact of functional decline on resource utilization and health care costs may further reinforce the need to assess and intervene to prevent functional decline.[72] Additional research on factors influencing functional decline will also provide information for nurses to present to administrators to develop programs to identify and mitigate functional decline in the hospitalized elderly.

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Chapter 12. Pressure Ulcers: A Patient Safety Issue

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Background

Pressure ulcers remain a major health problem affecting approximately 3 million adults.[1] In 1993, pressure ulcers were noted in 280,000 hospital stays, and 11 years later the number of ulcers was 455,000.[2] The Healthcare Cost and Utilization Project (HCUP) report found from 1993 to 2003 a 63 percent increase in pressure ulcers, but the total number of hospitalizations during this time period increased by only 11 percent. Pressure ulcers are costly, with an average charge per stay of $37,800.[2] In the fourth annual HealthGrades Patient Safety in American Hospitals Study, which reviewed records from about 5,000 hospitals from 2003 to 2005, pressure ulcers had one of the highest occurrence rates, along with failure to rescue and postoperative respiratory failure.[3] Given the aging population, increasingly fragmented care, and nursing shortage, the incidence of pressure ulcers will most likely continue to rise.

Preventing pressure ulcers has been a nursing concern for many years. In fact, Florence Nightingale in 1859 wrote, "If he has a bedsore, it's generally not the fault of the disease, but of the nursing"[4] (p. 8). Others view pressure ulcers as a "visible mark of caregiver sin"[5] (p. 726) associated with poor or nonexistent nursing care.[6] Many clinicians believe that pressure ulcer development is not simply the fault of the nursing care, but rather a failure of the entire heath care system[7]—hence, a breakdown in the cooperation and skill of the entire health care team (nurses, physicians, physical therapists, dietitians, etc.).

Although the prevention of pressure ulcers is a multidisciplinary responsibility, nurses play a major role. In 1992, the U.S. Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research) published clinical practice guidelines on preventing pressure ulcers.[8] Much of the evidence on preventing pressure ulcers was based on Level 3 evidence, expert opinion, and panel consensus, yet it served as a foundation for providing care. Although the AHRQ document was published 15 years ago, it still serves as the foundation for providing preventive pressure ulcer care and a model for other pressure ulcer guidelines developed afterward. Nurses are encouraged to review these comprehensive guidelines. The document identifies specific processes (e.g., risk assessment, skin care, mechanical loading, patient and staff education, etc.) that, when implemented, could reduce pressure ulcer development, and the literature suggests that following these specific processes of pressure ulcer care will reduce the incidence of ulcers. Research also suggests that when the health care providers are functioning as a team, the incidence rates of pressure ulcers can decrease.[9] Thus, pressure ulcers and their prevention should be considered a patient safety goal.

Incidence, Mortality, and Costs

The incidence rates of pressure ulcers vary greatly with the health care settings. The National Pressure Ulcer Advisory Panel (NPUAP) says the incidence ranges from 0.4 percent to 38 percent in hospitals, from 2.2 percent to 23.9 percent in skilled nursing facilities, and from 0 percent to 17 percent for home health agencies.[10] There is ample evidence that the majority of pressure ulcers

occur relatively early in the admissions process. For patients in the hospital, they can occur within the first 2 weeks.[11] With the increased acuity of elderly patients admitted and decreased lengths of stay in hospital, new data suggest that 15 percent of elderly patients will develop pressure ulcers within the first week of hospitalization.[12] For those elderly residents admitted to long-term care, pressure ulcers are most likely to develop within the first 4 weeks of admission.[13]

Mortality is also associated with pressure ulcers. Several studies noted mortality rates as high as 60 percent for older persons with pressure ulcers within 1 year of hospital discharge.[14, 15] Most often, pressure ulcers do not cause death; rather the pressure ulcer develops after a sequential decline in health status. Thus, the development of pressure ulcers can be a predictor of mortality. Studies further suggested that the development of skin breakdown postsurgery can lead elders to have major functional impairment post surgical procedure.

The cost to treat pressure ulcers can be expensive; the HCUP study reported an average cost of $37,800.[2] Cost data vary greatly, depending on what factors are included or excluded from the economic models (e.g., nursing time, support surfaces). It has been estimated that the cost of treating pressure ulcers is 2.5 times the cost of preventing them.[16] Thus, preventing pressure ulcers should be the goal of all nurses.

Etiology

Pressure ulcers develop when capillaries supplying the skin and subcutaneous tissues are compressed enough to impede perfusion, leading ultimately to tissue necrosis. Since 1930, we have understood that normal blood pressure within capillaries ranges from 20 to 40mm Hg; 32mm Hg is considered the average.[17] Thus, keeping the external pressure less than 32 mm Hg should be sufficient to prevent the development of pressure ulcers. However, capillary blood pressure may be less than 32 mm Hg in critically ill patients due to hemodynamic instability and comorbid conditions; thus, even lower applied pressures may be sufficient to induce ulceration in this group of patients. Pressure ulcers can develop within 2 to 6 hours.[18, 19] Therefore, the key to preventing pressure ulcers is to accurately identify at-risk individuals quickly, so that preventive measures may be implemented.

Risk Factors

More than 100 risk factors of pressure ulcers have been identified in the literature. Some physiological (intrinsic) and nonphysiological (extrinsic) risk factors that may place adults at risk for pressure ulcer development include diabetes mellitus, peripheral vascular disease, cerebral vascular accident, sepsis, and hypotension.[20] A hypothesis exists that these physiological risk factors place the patients at risk due to impairment of the microcirculation system. Microcirculation is controlled in part by sympathetic vasoconstrictor impulses from the brain and secretions from localized endothelial cells. Since neural and endothelial control of blood flow is impaired during an illness state, the patient may be more susceptible to ischemic organ damage (e.g., pressure ulcers).[21]

Additional risk factors that have been correlated with pressure ulcer development are age of 70 years and older, current smoking history, dry skin, low body mass index, impaired mobility, altered mental status (i.e., confusion), urinary and fecal incontinence, malnutrition, physical restraints, malignancy, history of pressure ulcers, and white race.[22–25] Although researchers have noted that the white race is a predictor of pressure ulcers, the small number of nonwhite patients in

most pressure ulcer studies makes this finding questionable. The few studies that have included sufficient numbers of black people for analysis purposes have found that blacks suffer more severe pressure ulcers than nonblacks.[26, 27] Only one nursing study found that blacks had a higher incidence rate of pressure ulcer than whites.[28] In a study funded by AHRQ using the New York State Inpatient Data Set 1998–2000, Fiscella and colleagues[29] found that African Americans were more likely to develop pressure ulcers than other races in hospitals. Moreover, a 2004 study investigating black/white differences in pressure ulcer incidence found that after controlling for eight resident characteristics and three facility characteristics, race was significantly associated with pressure ulcer incidence (hazard ratio comparing blacks with whites = 1.31, 95% confidence interval = 1.02–1.66).[30]

Risk Assessment

What tool and how often a pressure ulcer risk assessment should be done are key questions in preventing pressure ulcers. Due to the number of risk factors identified in the literature, nurses have found the use of risk assessment tools helpful adjuncts to aid in the identification of patients who may be at high risk. Most health care institutions that use pressure ulcer risk assessment tools use either the Braden Scale or Norton Scale, with the Braden scale being the most widely used in the United States. The Braden Scale is designed for use with adults and consists of 6 subscales: sensory perception, moisture, activity, mobility, nutrition, and friction and shear.[31] It is based on the conceptual schema of linking the above clinical situations to the intensity and duration of pressure or tissue tolerance for pressure.[32] The copyrighted tool is available at http://www.bradenscale.com.braden.pdf. The scores on this scale range from 6 (high risk) to 23 (low risk), with 18 being the cut score for onset of pressure ulcer risk. Research has shown that hospital nurses could accurately determine pressure ulcer risk 75.6 percent of the time after an interactive learning session on the Braden scale.[33] Nurses were best at identifying persons at the highest and lowest levels of risk and had the most difficultly with patients with mild levels of risk (scores of 15–18).[34]

The Norton Scale was developed in the United Kingdom and consists of five subscales: physical condition, mental condition, activity, mobility, and incontinence.[35] The total score ranges from 5 (high risk) to 20 (low risk).

The Braden Scale and Norton Scale have been shown to have good sensitivity (83 percent to 100 percent, and 73 percent to 92 percent, respectively) and specificity (64 percent to 77 percent, and 61 percent to 94 percent, respectively), but have poor positive predictive value (around 40 percent and 20 percent, respectively).[36] The Norton and Braden scales show a 0.73 Kappa statistic agreement among at-risk patients, with the Norton Scale tending to classify patients at risk when the Braden scale classifies them as not at risk. The net effect of poor positive predictive value means that many patients who will not develop pressure ulcers may receive expensive and unnecessary treatment. Moreover, optimal cutoff scores have not been developed for each care setting (e.g., medical intensive care versus operating room). Thus, nurses still need to use their clinical judgment in employing preventive pressure ulcer care. A recent systematic review of risk assessment scales found that the Braden Scale had the optimal validation and the best sensitivity/specificity balance (57.1 percent/67.5 percent) when compared to the Norton Scale (46.8 percent/61.8 percent) and Waterlow Scale (82.4 percent/27.4 percent).[37] It should be noted that the Waterlow skill is a pressure ulcer prediction tool used primarily in Europe.

In recent years, several new prediction tools have been developed (FRAGMMENT Score and

Schoonhoven Prediction Rule); however, these tools lack sufficient evidence to evaluate their predictive validity.[38, 39] Thus, the use of a validated pressure ulcer risk assessment tool like the Braden Scale should be used, given the fair research-based evidence. The U.S. Centers for Medicare and Medicaid Services (CMS) recommends that nurses consider all risk factors independent of the scores obtained on any validated pressure ulcer prediction scales because all factors are not found on any one tool.[40]

The usefulness of clinical informatics to assess and prevent pressure ulcers has been explored. A quality improvement study involving 91 long-term care facilities evaluated the usefulness of Web-based reports alerting nursing staff to a resident's potential risk for pressure ulcers.[41] Only one-third of long-term care facilities used the Web-based reports regularly to identify at-risk patients. Several key characteristics of facilities that were high users emerged:

- Administrative level and nursing staff buy-in and support
- Development of an actual process integrating the risk reports into ongoing quality improvement processes
- Having "facility champions" to keep the effort focused and on track

There is no agreement on how frequently risk assessment should be done. There is general consensus from most pressure ulcer clinical guidelines to do a risk assessment on admission, at discharge, and whenever the patient's clinical condition changes. The appropriate interval for routine reassessment remains unclear. Studies by Bergstrom and Braden[42, 43] found that in a skilled nursing facility, 80 percent of pressure ulcers develop within 2 weeks of admission and 96 percent develop within 3 weeks of admission. The Institute for Healthcare Improvement has recently recommended that in hospitalized patients, pressure ulcer risk assessment be done every 24 hours[44] rather than the previous suggestion of every 48 hours.[45]

Implementing a Prevention Plan

Preventing pressure ulcers can be nursing intensive. The challenge is more difficult when there is nursing staff turnover and shortages. Studies have suggested that pressure ulcer development can be directly affected by the number of registered nurses and time spent at the bedside.[46, 47] In contrast, however, one recent study suggested that there was no correlation between increasing the nurse-to-patient ratio and the overall incidence of pressure ulcers.[48] Donaldson and colleagues[49] noted that this particular study was limited by the fact that the researchers could not affirm compliance with ratios per shift and per unit at all times. Given that the cost of treatment has been estimated as 2.5 times that of prevention, implementing a pressure ulcer prevention program remains essential.

A growing level of evidence suggests that pressure ulcer prevention can be effective in all health care settings. One study examined the efficacy of an intensive pressure ulcer prevention protocol to decrease the incidence of ulcers in a 77-bed long-term care facility.[50] The pressure ulcer prevention protocol consisted of preventive interventions stratified on risk level, with implementation of support surfaces and turning/repositioning residents. The sample included 132 residents (69 prior to prevention intervention and 63 after prevention intervention). The 6-month incidence rate of pressure ulcers prior to the intensive prevention intervention was 23 percent. For the 6-months after intensive prevention intervention, the pressure ulcer incidence rate was 5 percent. This study demonstrated that significant reductions in the incidence of pressure ulcers are possible to achieve within a rather short period of time (6 months) when facility-specific intensive prevention interventions are used. A subsequent study by the same researchers was undertaken to

evaluate the cost effectiveness of the pressure ulcer prevention protocol after a 3-year period. The implementation of a pressure ulcer prevention protocol showed mixed results. Initial reductions in pressure ulcer incidence were lost over time. However, clinical results of ulcer treatment improved and treatment costs fell during the 3 years.[51]

A more recent nursing study examined the effects of implementing the SOLUTIONS program, which focuses pressure ulcer prevention measures on alleviating risk factors identified by the Braden Scale, in two long-term care facilities.[52] The quasi-experimental study found that after 5 months of implementing the SOLUTIONS program, Facility A (150 beds) experienced an 87 percent reduction in pressure ulcer incidence (from 13.2 percent to 1.7 percent), which was highly significant ($P = 0.02$). Facility B (110 beds) experienced a corresponding 76 percent reduction (from 15 percent to 3.5 percent), which was also highly significant ($P = 0.02$). Gunningberg and colleagues[52] investigated the incidence of pressure ulcers in 1997 and 1999 among patients with hip fractures and found significant reductions in incidence rates (55 percent in 1997 to 29 percent in 1999). The researchers attributed these reductions in pressure ulcer incidence rates to performing systematic risk assessment upon admission, accurately staging pressure ulcers, using pressure-reducing mattresses, and continuing education of staff. Thus, the use of comprehensive prevention programs can significantly reduce the incidence of pressure ulcers in long-term care.

The use of quality improvement models, where systematic processes of care have been implemented have also been shown to reduce overall pressure ulcer incidence. In one study involving 29 nursing homes in three States, representatives of the 29 nursing homes attended a series of workshops, shared best practices, and worked with one-on-one quality improvement mentors over 2 years.[53] This study found that six of eight prevention process measures (based on AHRQ prevention guidelines) significantly improved, with percentage differences between baseline and followup ranging from 11.6 percent to 24.5 percent. Another study using similar methods involving 22 nursing homes found 8 out of 12 processes of care significantly improved.[7] Moreover, the study found that pressure ulcer incidence rates decreased in the nursing homes. Nursing homes with the greatest improvement in quality indicator scores had significantly lower pressure ulcer incidence rates than the facilities with the least improvement in quality indicator scores ($P = 0.03$).

In the acute care setting, several studies have attempted to demonstrate that the implementation of comprehensive pressure ulcer prevention programs can decrease the incidence rates. However, no studies could be found that eliminated pressure ulcers. One large study evaluated the processes of care for hospitalized Medicare patients at risk for pressure ulcer development.[7] This multicenter retrospective cohort study used medical record data to identify 2,425 patients ages 65 and older discharged from acute care hospitals following treatment for pneumonia, cerebral vascular disease, or congestive heart failure. Charts were evaluated for the presence of six recommended pressure ulcer prevention processes of care. This study found that at-risk patients who used pressure-reducing devices, were repositioned every 2 hours, and received nutritional consults were more likely to develop pressure ulcers than those patients who did not receive the preventive interventions. One explanation for this finding may be the amount of time (48 hours) before the preventive measures were implemented. Given the acuity of patients entering hospitals, waiting 48 hours may be too late to begin pressure ulcer prevention interventions. Thus, despite this one study, there is significant research to support that implementing comprehensive pressure ulcer prevention programs reduces the incidence of pressure ulcers.

A key component of research studies that have reported reduction of pressure ulcers is how to

sustain the momentum over time, especially when the facility champion leaves the institution. It is clear from the evidence that maintaining a culture of pressure ulcer prevention in a care setting is an important challenge, one that requires the support of administration and the attention of clinicians.

Skin Care

Although expert opinion maintains that there is a relationship between skin care and pressure ulcer development, there is a paucity of research to support that. How the skin is cleansed may make a difference. One study found that the incidence of Stages I and II pressure ulcers could be reduced by educating the staff and using a body wash and skin protection products.[54]

The majority of skin care recommendations are based on expert opinion and consensus. Intuitively nurses understand that keeping the skin clean and dry will prevent irritants on the skin or excessive moisture that may increase frictional forces leading to skin breakdown. Individualized bathing schedules and use of nondrying products on the skin are also recommended. Moreover, by performing frequent skin assessments, nurses will be able to identify skin breakdown at an early stage, leading to early interventions. Although there is a lack of consensus as to what constitutes a minimal skin assessment, CMS recommends the following five parameters be included: skin temperature, color, turgor, moisture status, and integrity.[40]

The search for the ideal intervention to maintain skin health continues. One study compared hyperoxygenated fatty acid compound versus placebo compound (triisotearin) in acute care and long-term care patients.[55] These researchers found that using hyperoxygenated fatty acid significantly (p-0.006) reduced the incidence of ulcers. Pressure ulcer incidence was lower in an intervention group of acute care patients when topical nicotinate was applied (7.32 percent) compared to lotion with hexachlorophene, squalene, and allantoin in the control group (17.37 percent).[56]

There are several key recommendations to minimize the occurrence of pressure ulcers. Avoid using hot water, and use only mild cleansing agents that minimize irritation and dryness of the skin.[8, 57] Avoid low humidity because it promotes scaling and dryness, which has been associated with pressure ulcer development.[23] During skin care, avoid vigorous massage over reddened, bony prominences because evidence suggest that this leads to deep tissue trauma. Skin care should focus on minimizing exposure of moisture on the skin.[58] Skin breakdown caused by friction may be mitigated by the use of lubricants, protective films (e.g., transparent and skin sealants), protective dressings (e.g., hydrocolloids), and protective padding.

Mechanical Loading

One of the most important preventive measures is decreasing mechanical load. If patients cannot adequately turn or reposition themselves, this may lead to pressure ulcer development. It is critical for nurses to help reduce the mechanical load for patients. This includes frequent turning and repositioning of patients.

Very little research has been published related to optimal turning schedules. The first such nursing study was an observational one that divided older adults into three turning treatment groups (every 2 to 3 hours [n = 32], every 4 hours [n = 27], or turned two to four times/day [n = 41]).[59] These researchers found that older adults turned every 2 to 3 hours had fewer ulcers. This landmark nursing study created the gold standard of turning patients at least every 2 hours. Some

researchers would suggest that critically ill patients should be turned more often. However, one survey study investigating body positioning in intensive care patients found that of 74 patients observed, 49.3 percent were not repositioned for more than 2 hours.[60] Only 2.7 percent of patients had a demonstrated change in body position every 2 hours. A total of 80–90 percent of respondents to the survey agreed that turning every 2 hours was the accepted standard and that it prevented complications, but only 57 percent believed it was being achieved in their intensive care units. A more recent study by DeFloor and colleagues[61] suggests that depending on the support surface used, less-frequent turning may be optimal to prevent pressure ulcers in a long-term care facility. Several nurse researchers investigated the effect of four different turning frequencies (every 2 hours on a standard mattress, every 3 hours on a standard mattress, every 4 hours on a viscoelastic foam mattress, and every 6 hours on a viscoelastic foam mattress). The nurse researchers found that the incidence of early pressure ulcers (Stage I) did not differ in the four groups. However, patients being turned every 4 hours on a viscoelastic foam mattress developed significantly less severe pressure ulcers (Stage II and greater) than the three other groups. Although the results of this study may indicate less turning may be appropriate when using a viscoelastic foam mattress, additional studies are needed to examine optimal turning schedules among different populations. Reddy and colleagues[62] have raised questions about the methodology in the Defloor and colleagues study, leading them to recommend that it may be too soon to abandon the every-2-hours turning schedule in favor of every 4 hours based on this one study. Thus, there is emerging research to support the continued turning of patients at least every 2 hours.

How a patient is positioned may also make a difference. Lateral turns should not exceed 30 degrees.[63, 64] One randomized controlled trial that studied a small sample of 46 elderly patients in the 30-degree-tilt position and the standard 90-degree side-lying position found no significant difference in the development of pressure ulcers between the two groups.[65]

Support Surfaces

The use of support surfaces is an important consideration in pressure redistribution. The concept of pressure redistribution has been embraced by the NPUAP.[66] You can never remove all pressure for a patient. If you reduce pressure on one body part, this will result in increased pressure elsewhere on the body. Hence, the goal is to obtain the best pressure redistribution possible.

A major method of redistributing pressure is the use of support surfaces. Much research has been conducted on the effectiveness of the use of support surfaces in reducing the incidence of pressure ulcers. A comprehensive literature review by Agostini and colleagues[67] found that there was adequate evidence that specially designed support surfaces effectively prevent the development of pressure ulcers. However, a major criticism of the current support surface studies was poor methodologic design. Agostini and colleagues noted that many studies had small sample sizes and unclear standardization protocols, and assessments were not blind.

Reddy and colleagues[62] have provided a systematic review of 49 randomized controlled trials that examined the role of support surfaces in preventing pressure ulcers. No one category of support surface was found to be superior to another; however, use of a support surface was more beneficial than a standard mattress. A prospective study evaluating the clinical effectiveness of three different support surfaces (two dynamic mattress replacement surfaces and one static foam mattress replacement) found that an equal number of patients developed pressure ulcers on each surface (three per surface).[68] The researchers concluded no differences in the support surface effectiveness, yet large differences in the cost. (Dynamic mattress replacements cost

approximately $2,000 per mattress, compared to $240 per mattress for static foam mattress replacements.) Given the similar clinical effectiveness, cost should be considered in determining the support surface.

Four randomized controlled trials evaluated the use of seat cushions in pressure ulcer prevention, and found no difference in ulcer incidence among groups except between foam and gel cushions.[62] Despite the dearth of research that correlates seat cushions and preventing pressure ulcers, expert opinion supports the use of seat cushions.

The CMS has divided support surfaces into three categories for reimbursement purposes.[68] Group 1 devices are those support surfaces that are static, they do not require electricity. Static devices include air, foam (convoluted and solid), gel, and water overlays or mattresses. These devices are ideal when a patient is at low risk for pressure ulcer development. Group 2 devices are powered by electricity or pump and are considered dynamic in nature. These devices include alternating and low-air-loss mattresses. These mattresses are good for patients who are at moderate to high risk for pressure ulcers or have full-thickness pressure ulcers. Group 3 devices, also dynamic, comprises only air-fluidized beds. These beds are electric and contain silicone-coated beads. When air is pumped through the bed, the beads become liquid. These beds are used for patients at very high risk for pressure ulcers. More often they are used for patients with nonhealing full-thickness pressure ulcers or when there are numerous truncal full-thickness pressure ulcers. The NPUAP has suggested new definitions for support surfaces that move away from these categories and divide support surfaces into powered or nonpowered.[69] Whether these new definitions will be embraced by CMS is yet to be determined.

There remains a paucity of research that demonstrates significant differences in the effectiveness of the various classifications of support surfaces in preventing or healing pressure ulcers. Therefore, nurses should select a support surface based on the needs and characteristics of the patient and institution (e.g., ease of use, cost). It is imperative to have the pressure redistribution product (e.g., mattress or cushion) on the surface where the patients are spending most of their time, in bed or a chair. However, being on a pressure-redistributing mattress or cushion does not negate the need for turning or repositioning.

Nutrition

Controversy remains on how best to do nutritional assessment for patients at risk for developing pressure ulcers. The literature differs about the value of serum albumin; some literature reports that low levels are associated with increased risk.[70] While the AHRQ pressure ulcer prevention guideline suggests that a serum albumin of less than 3.5 gm/dl predisposes a patient for increased risk of pressure ulcers, one study reveals that current dietary protein intake is a more independent predictor than this lab value.[8, 42] In the revised Tag F-314 guidance to surveyors in long-term care, CMS recommends that weight loss is an important indicator.[40] Evaluation of the patient's ability to chew and swallow may also be warranted.

The literature is unclear about protein-calorie malnutrition and its association with pressure ulcer development.[70] Reddy and colleagues[62] suggested that the widely held belief of a relationship between nutrition intake and pressure ulcer prevention was not always supported by randomized controlled trials. Some research supported the finding that undernourishment on admission to a health care facility increases a person's likelihood of developing a pressure ulcer. In one prospective study, high-risk patients who were undernourished on admission to the hospital were twice as likely to develop pressure ulcers as adequately nourished patients (17 percent and

9 percent, respectively).[71] In another study, 59 percent of residents were undernourished and 7.3 percent were severely undernourished on admission to a long-term care facility. Pressure ulcers occurred in 65 percent of the severely undernourished residents, while no pressure ulcers developed in the mild-to-moderately undernourished or well-nourished residents.[15]

Reddy and colleagues[62] concluded that nutritional supplementation was beneficial in only one of the five randomized controlled trials reviewed in their systematic analysis of interventions targeted at impaired nutrition for pressure ulcer prevention. Older critically ill patients who had two oral supplements plus the standard hospital diet had lower risk of pressure ulcers compared to those who received only the standard hospital diet.[72]

Empirical evidence is lacking that the use of vitamin and mineral supplements (in the absence of deficiency) actually prevents pressure ulcers.[73] Therefore, oversupplementing patients without protein, vitamin, or mineral deficiencies should be avoided. Before enteral or parental nutrition is used, a critical review of overall goals and wishes of the patient, family, and care team should be considered.[74] Despite the lack of evidence regarding nutritional assessment and intervention, maintaining optimal nutrition continues to be part of best practice.

Management of Pressure Ulcers

When a pressure ulcer develops, nursing's patient safety goal is to assist the health care team in closing the ulcer as quickly as possible. Nursing is also concerned with preventing further ulcer deterioration, keeping the ulcer clean and in moisture balance, preventing infections from developing, and keeping the patient free from pain.

Many aspects of managing pressure ulcers are similar to prevention (mechanical loading, support surfaces, and nutrition). Clearly, the health care team has to address the underlying causes (intrinsic and extrinsic) or the pressure ulcer will not close. In 1994, AHRQ published clinical practice guidelines on treating pressure ulcers.[75] Much of the evidence related to treating pressure ulcers was based on Level C evidence, requiring one or more of the following: one controlled trial, results of at least two case series/descriptive studies in humans, or expert opinion. Although the AHRQ document was published 13 years ago, it provides the foundation for treating pressure ulcers. The document identified specific indices (e.g., wound assessment, managing tissue load, ulcer care, managing bacterial colonization/infection, etc.). The following section supplements this document.

Cleansing

Once the pressure ulcer develops, the ulcer should be cleaned with a nontoxic solution. Cleaning the ulcer removes debris and bacteria from the ulcer bed, factors that may delay ulcer healing.[76] No randomized control studies could be found that demonstrated the optimal frequency or agent for cleansing a pressure ulcer. A Cochrane review of published randomized clinical trials found three studies addressing cleansing of pressure ulcers, but this systematic review produced no good trial evidence to support any particular wound cleansing solution or technique for pressure ulcers.[77] Therefore, this recommendation remains at the expert opinion level. Nurses should use cleansers that do not disrupt or cause trauma to the ulcer.[78] Normal saline (0.9 percent) is usually recommended because it is not cytotoxic to healthy tissue.[79] Although the active ingredients in newer wound cleansers may be noncytotoxic (surfactants), the inert carrier may be

cytotoxic to healthy granulation tissue.[80] Thus, nurses should be cognizant of the ingredients in cleansing agents before using them on pressure ulcers.

Assessment and Staging

The nurse should assess and stage the pressure ulcer at each dressing change. Experts believe that weekly assessments and staging of pressure ulcers will lead to earlier detection of wound infections as well as being a good parameter for gauging of wound healing.[40, 75] There are no universal parameters for assessing a pressure ulcer. Most experts agree that when a pressure ulcer develops its location, size (length, width, and depth), and color of the wound; amount and type of exudate (serous, sangous, pustular); odor; nature and frequency of pain if present (episodic or continuous); color and type of tissue/character of the wound bed, including evidence of healing (e.g., granulation tissue) or necrosis (slough or eschar); and description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) should be assessed and documentd.[75, 81] Upon identifying the ulcer characteristics, the initial stage of the should be completed.

The staging system is one method of summarizing certain characteristics of pressure ulcers, including the extent of tissue damage. Hence, whether the nurse observes the epidermis, dermis, fat, muscle, bone, or joint determines the stage of pressure ulcer. Knowing the appropriate stage aids in determining the management of the pressure ulcer. However, staging of pressure ulcers can vary, because different nurses may observe different tissue types. In a survey of nurses' wound care knowledge, less than 50 percent of new nurses (fewer than 20 years of nursing experience) did not feel confident in consistently identifying all stages of pressure ulcers, as compared to 30 percent of the more experienced nurses (more than 20 years of nursing experience).[82] Achieving consistency in staging will provide optimal pressure ulcer management.

Pressure ulcer staging systems differ, depending on geographic location. The Europeans use a four-stage system.[83] For Grade 1, nonblanchable erythema of intact skin, discoloration of the skin, warmth, edema, and induration or hardness may be used as indicators, particularly on individuals with darker skin. For Grade 2, indicators include partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister. Grade 3 includes full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. Grade 4 includes extensive destruction; tissue necrosis; or damage to muscle, bone, or supporting structures, with or without full thickness skin loss.

The most widely used staging system in the United States was developed in 1989 by the NPUAP.[84] This staging system was modified from Shea's original system.[85] The staging system rates the pressure ulcer from superficial tissue damage (Stage I) to full thickness skin loss involving muscle or bone (Stage IV). If the pressure ulcer is covered with necrotic tissue (eschar), it should be noted as unstageable. In skilled nursing facilities, nurses must stage a pressure ulcer covered with necrotic tissue as Stage IV.[86] In home care and nursing homes, nurses must stage pressure ulcers because staging is linked to reimbursement of medical expenses.

In 2007, the NPUAP revised the staging system to include deep tissue injury, an ulcer often described as a purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.[87] The NPUAP also reclassified blisters and unstageable pressure ulcers. The NPUAP staging definitions were refined with input from an online evaluation of their face validity, accuracy clarity, succinctness, utility, and

discrimination. The new staging system has six stages: suspected deep tissue injury, Stage I, Stage II, Stage III, Stage IV, and Unstageable. Table 1 presents the NPUAP definition, and Table 2 illustrates the differences between the old and new pressure ulcer staging systems.

Table 1. National Pressure Ulcer Definition

	Previous NPUAP Definition	2007 NPUAP Definition	2007 NPUAP Further Descriptions to Accompany Revised Definition
Pressure Ulcer Definition	A localized area of tissue necrosis that develops when soft tissue is compressed between a bony prominence and an external surface for a prolonged period of time.	A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction.	A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.

Table 2. National Pressure Ulcer Staging System

Pressure Ulcer Stage	Previous NPUAP Staging Definitions	2007 NPUAP Definitions	2007 NPUAP Descriptions to Accompany Revised Definitions
Deep Tissue Injury	A pressure-related injury to subcutaneous tissues under intact skin. Initially, these lesions have the appearance of a deep bruise, and they may herald the subsequent development of a Stage III–IV pressure ulcer, even with optimal treatment.	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.	• The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler, as compared to adjacent tissue. • Deep tissue injury may be difficult to detect in individuals with dark skin tones. • The area may rapidly evolve to expose additional layers of tissue, even with optimal treatment.
Stage I	An observable pressure-related alteration of intact skin whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following parameters: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), sensation (pain, itching), and/or a defined area of persistent redness in lightly pigmented skin; in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.	Intact skin with nonblanchable redness of a localized area, usually over a bony prominence.	• The area may be painful, firm, soft, warmer, or cooler, as compared to adjacent tissue. • Stage I may be difficult to detect in individuals with dark skin tones. • May indicate at-risk persons (a heralding sign of risk).
Stage II	Partial thickness skin loss involving the epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion,	Partial thickness loss of dermis presenting as a shallow open ulcer with a red, pink wound bed without slough. May also present as	Presents as a shiny or dry shallow ulcer without slough or bruising. This stage should not be used to describe skin tears, tape burns, perineal

Pressure Ulcer Stage	**Previous NPUAP Staging Definitions**	**2007 NPUAP Definitions**	**2007 NPUAP Descriptions to Accompany Revised Definitions**
	blister, or shallow crater.	an intact or open/ruptured serum-filled blister.	dermatitis, maceration, or excoriation.
Stage III	Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.	Full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle are *not* exposed. Slough may be present but does not obscure the depth of tissue loss. *May* include undermining and tunneling.	• The depth of a Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue, and Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage III pressure ulcers. • Bone/tendon is not visible or directly palpable.
Stage IV	Full thickness skin loss with extensive destruction; tissue necrosis; or damage to muscle, bone, or supporting structure (such as tendon, or joint capsule).	Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. *Often* includes undermining and tunneling.	• The depth of a Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue, and these ulcers can be shallow. • Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, or joint capsule), making osteomyelitis likely to occur. • Exposed bone/tendon is visible or directly palpable.
Unstagable		Full thickness tissue loss in which *actual* depth of the ulcer is *completely* obscured by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the wound bed.	Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, or adherent, intact without erythema or fluctuance) eschar on the heels serves as the "the body's natural (biological) cover" and should not be removed.

The Stage I pressure ulcer may be more difficult to detect in darkly pigmented skin. A quality improvement study in several nursing homes found that by empowering the nursing assistants with education (skin assessment), use of pen lights to assess darker skin, mirrors, and financial reward, the researchers were able to reduce the Stage I pressure ulcers in residents with darkly pigmented skin.[88] One method for delineating Stage I pressure ulcers in darkly pigmented skin may be the use of high-resolution ultrasound. Although ultrasound is widely used as a safe and cost-effective technique for noninvasive visualization of specific human anatomy, its use for skin assessment is just now available. Ultrasound utilizes the echoes of sound waves to create images of soft tissue anatomy.[89] A probe transmits sound waves into the body. High-frequency ultrasound (20MHZ)

will provide high resolution images of the skin and underlying soft tissue, and because the images are related to tissue density (not pigment), the clinician's assessment ability is enhanced significantly. A recent study strongly suggests that clinicians should consider high-frequency ultrasound as an improved method for identifying and implementing good pressure ulcer preventive care.[90]

The assessment and staging of pressure ulcers remains at the expert opinion level.

Debridement

The presence of necrotic devitalized tissue promotes the growth of pathologic organisms and prevents wounds from healing.[91] Experts believe that debridement is an important step in the overall management of pressure ulcers. No randomized control trials could be found that demonstrated that one debridement technique is superior. Thus, the best method of debridement is determined by the goals of the patient, absence or presence of infection, pain control, amount of devitalized tissue present, and economic considerations for the patient and institution.[92–94] There are five types of debridement: sharp, mechanical, autolytic, enzymatic, and biosurgery.

Sharp debridement (use of scalpel or laser) is probably the most effective type of debridement because of the time involved to remove the devitalized tissue.[95] Sharp debridement should always be considered when the patient is suspected of having cellulites or sepsis.[96] Mechanical debridement uses a nonselective, physical method of removing necrotic tissue and debris from a wound using mechanical force. One common form of mechanical treatment is wet-to-dry gauze to adhere to the necrotic tissue, which is then removed. Upon removal of the gauze dressing, necrotic tissue and wound debris are also removed. The challenge with mechanical debridement is the possibility that healthy granulation tissue may be removed as well, along with the devitalized tissue, thereby delaying wound healing and causing pain. Thus, CMS suggests that this method of debridement be used in limited circumstances.[40]

Autolytic debridement involves the use of semiocclusive (transparent film) and occlusive dressings (hydrocolloids, hydrogels, etc.), which creates an environment for the body's enzymes to break down the necrotic tissue.[97] Enzymatic debridement uses proteolytic enzymes (i.e., papain/urea, collagenase) to remove necrotic tissue.[98] This form of debridement is considered drug therapy; therefore it should be signed on the medication record. Finally, biosurgery (maggot therapy) is another effective and relatively quick method of debridement.[99] This type of debridement is especially effective when sharp debridement is contraindicated due to the exposure of bone, joint, or tendon.[99]

Bacterial Burden

Managing bacterial burden is an important consideration in pressure ulcer care. All pressure ulcers contain a variety of bacteria. Pressure ulcer bacterial contamination should not impair health.[100] Of great concern is when a colony of bacteria reaches 10^5 or 10^6 organisms per gram in the ulcer.[101] At these levels, the pressure ulcer can be considered infected. Healing can be impeded when wounds have high levels of bacteria. Robson and Heggers[101] found in 32 pressure ulcers that spontaneous healing occurred only when the microbial population was controlled.

Experts agree that swab cultures should not be used to determine wound infection.[102] Rather a tissue biopsy should be conducted to determine the qualitative and quantitative assessment of any aerobic and anaerobic organisms present.[103] Clinical signs that the pressure ulcer may be infected

include malodorous, purulent exudate; excessive draining; bleeding in the ulcer; and pain.[104, 105] One study investigating the validity of clinical signs and symptoms used to identify localized chronic wound infections found signs associated with secondary wounds (i.e., serous exudate, delayed healing, discoloration of granulation tissue, friable granulation tissue, pocketing at the base of the wound, foul odor, and wound breakdown) were better predictors of wound infection than the classic signs of infection (i.e., increasing pain, erythema, edema, heat, and purulence).[106] Overall, these researchers concluded that increasing pain and wound breakdown were both sufficient clinical indicators of infected wounds with 100 percent specificity. Thus, when these signs are present, the nurse should seek additional treatments for the patient. This will help to safeguard the patient from further ulcer complications.

The use of oral antibiotics or topical sulfa silverdiazine has also been found to be effective in decreasing the bioburden in the ulcer bed.[107, 108] Treatment using silver-impregnated dressings has been shown to be somewhat effective in decreasing bacterial bioburden load. One in vivo study found that silver-based dressings decreased specific bacteria (e.g., Eschericha coli, Candida albicans, and Staphylococcus aureas).[109] However, a systematic review of the research literature found only three randomized controlled trials covering 847 participants. This Cochrane review determined that based on only three randomized controlled trials, there remains insufficient evidence to recommend the use of silver-containing dressings or topical agents for treatment of infected or contaminated chronic wounds.[110]

The use of antiseptics to reduce wound contamination continues to be a controversial topic. The ideal agent for an infected pressure ulcer would be bactericidal to a wide range of pathogens and noncytotoxic to leukocytres. In vitro studies of 1 percent povidone-iodine have been found to be toxic to fibroblast, but a solution of 0.005% sodium hypochlorite ($P = 0.001$) caused no fibroblast toxicity and was still bactericidal to Staphylococcus aureus.[111] Another common antiseptic with conflicting data is sodium hypochlorite (Dakins solution). Studies suggest that 0.005 percent concentration of sodium hypochlorite to be bactericidal; however, its use can also cause inhibition of fibroblast and neutrophil migration necessary for pressure ulcer healing.[112] Conversely, other in vitro studies suggest that 0.005 percent sodium hypochlorite did not inhibit fibroblasts. McKenna and colleagues examined the use of 0.005 percent sodium hypochlorite, 0.001 percent povidone-iodine, 0.0025 percent acetic acid, and 0.003 percent hydrogen peroxide on various clinical isolates.[111] These researchers found that sodium chlorite significantly inhibited ($P = 0.001$) the growth of all bacteria tested (Staphylococcus aureas, Escherichia coli, Group D enterococci, Pseudomonas aeruginosa, and Bacteroides fragilis) without inhibiting fibroblast activity, whereas povidone-iodine and acetic acid reduced only specific bacteria.

Exudate Management

The use of dressings is a major component in maintaining a moist environment. There are more than 300 different modern wound dressings available to manage pressure ulcers.[113] Most dressings can be broken down into seven classifications: transparent films, foam islands, hydrocolloids, petroleum-based nonadherents, alginates, hydrogels, and gauze. Few randomized controlled studies have been conducted to evaluate the efficacy of dressings within a specific classification. Therefore, no one category of wound dressings (independent of gauze) may be better than another category. Most research evaluating the effects of dressings usually compare gauze (standard) to modern wound dressings (nongauze).[114, 115, 116] These studies are inherently flawed because gauze dressings are not classified as a modern wound dressing; thus equivalent comparisons cannot be

made. The studies usually have small sample sizes; thus inferences can be difficult to make. However, one study investigating wound-healing outcomes using standardized validated protocols found that primarily using nongauze protocols of care matched or surpassed the best previously published results on similar wounds using gauze-based protocols of care, including protocols applying gauze impregnated with growth factors or other agents. Thus, nongauze protocols of care should be used to accelerate pressure ulcer healing.[117]

Nutrition

The use of high-protein diets for patients with protein deficiency is essential to wound healing. One small study (n = 12) has suggested that 1.25 g protein/L/kg/day to 1.50 g protein/L/kg/day is needed to promote wound healing.[118] However, Mulholland and colleagues[119] suggested in a 1943 journal article that as much as 2.0 g protein/L/kg/day is essential for wound healing. To underscore that increasing protein does have a positive effect on wound healing, researchers investigated 28 malnourished patients with a total of 33 truncal pressure ulcers.[120] The researchers found that patients who received the 24-percent protein intake had significant decrease ($P = 0.02$) in truncal pressure ulcer surface area compared to the group on 14-percent protein intake. Clearly, increasing protein stores for patients with pressure ulcers who are malnourished is essential; however, it is unclear from the literature what the optimum protein intake requirement is for patients with pressure ulcers. Most promising: the use of amino acids such as argine, glutamine, and cysteine have been noted to assist in ulcer healing.[121] However, there remains a paucity of data to substantiate these claims; thus their use should be tempered with the overall goals of the patient.

Pain Management

Pressure ulcers can be painful. In particular, patients with Stage IV ulcers can experience significant pain.[122, 123] A cross-sectional study of patients with a mix of chronic wounds found that wound stage was positively related to severity of pain.[123] Moreover, pain catastrophizing was positively related to pain intensity and higher levels of affective distress and depressive symptoms. Hence, the goal of pain management in the patient with pressure ulcers should be to eliminate the cause of pain, to provide analgesia, or both. This goal was supported recently by the World Union of Wound Healing Societies consensus document, *Principles of Best Practice: Minimizing Pain at Wound Dressing-Related Procedures.*[124] Pain at dressing-related procedures can be managed by a combination of accurate assessment, suitable dressing choices, skilled wound management, and individualized analgesic regimens. Dressing removal can potentially cause damage to delicate tissue in the wound and surrounding skin. Thus, clinicians should use multiple methods to address the pressure ulcer pain. This may include using dressing that mitigates pain during dressing changes, such as dressings containing soft-silicone, and administering analgesic prior to dressing changes.

Monitoring Healing

Presently, there are two instruments that are often used to measure the healing of pressure ulcers. The Pressure Ulcer Scale for Healing (PUSH) was developed by the NPUAP in 1997.[125] The PUSH tool is copyrighted and available on NPUAP's Web site.[84] It quantifies the pressure ulcer with respect to surface area, exudate, and type of wound tissue. Using a Likert scale from 1

to 10 for length and width, a Likert scale from 1 to 3 for exudate amount, and a Likert scale from 1 to 4 for tissue type, the nurse can determine whether a pressure ulcer is healing or nonhealing. Each of the three ulcer characteristics is recorded as a subscore, then the subscores are added to obtain the total score. A comparison of total scores measured over time provides an indication of the improvement or deterioration of the pressure ulcer.

Few studies have been published that measure the validity and reliability of the PUSH tool. A study investigating the PUSH tool's content validity found that it had both content validity (P = 0.01) and correlational validity (P = 0.05) to monitor the changing pressure ulcer status.[126] Moreover, a recent prospective study by Gardner and colleagues[106] of 32 pressure ulcers found that 21 ulcers (66 percent) healed during the 6-month study period, and 11 (34 percent) did not heal. The PUSH scores decreased significantly (P = 0.001) over time among the healed ulcers but did not among the unhealed ulcers. Thus, the PUSH tool was shown to be a valid instrument for measuring healing in a clinical setting.

The Bates-Jensen Wound Assessment Tool (BWAT; formerly the Pressure Sore Status Tool, PSST) was developed in 1992 and is also widely used.[127] The BWAT consists of 15 items. The first 2 items are related to location and shape of the ulcer. The remaining 13 items are scored on the basis of descriptors of each item and ranked on a modified Likert scale (1 being the healthiest attribute of the characteristic and 5 being the least healthy attribute of the characteristic). The 13 BWAT characteristics that are scored are size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, skin color surrounding wound, peripheral tissue edema, peripheral tissue induration, granulation tissue, and epithelialization. The 13 item scores are summed to provide a numerical indicator of wound health or degeneration.

There is a paucity of validation studies for the BWAT. However, content validity has been established by a panel of 20 experts. Interrater reliability was established by the use of two wound, ostomy, and continence nurses who independently rated 20 pressure ulcers on 10 patients. Interrrater reliability was established at r = 0.91 for first observation and r = 0.92 for the second observation (P = 0.001).[128] A recent study examined wound-healing outcomes with standardized assessments using the BWAT. Most of the 767 wounds selected to receive the standardized protocols of care were Stage III–IV pressure ulcers (n = 373; mean healing time 62 days). Partial thickness wounds healed faster than same-etiology full thickness wounds.[117] This finding further adds to the validation of the BWAT tool for measuring wound healing.

Adjunctive Therapies

The use of adjunctive therapies is the fastest growing area in pressure ulcer management. Adjunctive therapies include electrical stimulation, hyperbaric oxygen, growth factors and skin equivalents, and negative pressure wound therapy. Except for electrical stimulation, there is a paucity of published research to substantiate the effectiveness of adjunctive therapies in healing pressure ulcers.

Electrical stimulation is the use of electrical current to stimulate a number of cellular processes important to pressure ulcer healing.[129] These processes include increasing the fibroblasts, neutrophil macrophage collagen, DNA synthesis, and increasing the number of receptor sites for specific growth factors.[129] Eight randomized controlled studies were found in the literature. Electrical stimulation appears to be most effective on healing recalcitrant Stages III and IV pressure ulcers.[130] A meta-analysis of 15 studies evaluating the effects of electrical stimulation on the healing of chronic ulcers found that the rate of healing per week was 22 percent for the

electrical stimulation group compared to 9 percent for the control group.[131] Thus, electrical stimulation should be considered for nonhealing pressure ulcers.

Negative pressure wound therapy is widely used, although few randomized controlled trials have been published. This therapy promotes wound healing by applying controlled localized, negative pressure to the wound bed.[132–134] In one prospective study investigating nonhealing pressure ulcers, 24 patients were randomized into two groups (wet-to-moist dressings or vacuum-assisted closure).[133] Those patients receiving negative pressure wound therapy had a 66-percent reduction in wound depth ($P = 0.0001$), compared to the wet-to-moist dressings group, which had a 20-percent wound depth reduction.[133] Much more research is needed on the benefits of negative pressure wound therapy for treating pressure ulcers, but there is emerging evidence that this therapy may be helpful in assisting the healing of pressure ulcers.

The use of growth factors and skin equivalents in the healing of pressure ulcers remains under investigation, although the use of cytokine growth factors (e.g., recombinant platelet-derived growth factor-BB [rhPDGF-BB]) and fibroblast growth factors (bFGF) and skin equivalents have been shown to be effective in diabetic and venous ulcers. Three small randomized controlled trials have suggested that growth factors had beneficial results with pressure ulcers, but the findings warrant further exploration.[135–137] When we learn more about the healing cascade, the appropriate use of growth factors in pressure ulcer treatment may become clearer.

The use of electroceuticals—highly refined electromagnetic fields that can accelerate the body's natural anti-inflammatory response, thereby aiding wounds to heal faster—is showing some promising results. One animal study used a prospective, randomized, double-blind, placebo-controlled design to evaluate the effect of a specific noninvasive radiofrequency-pulsed electromagnetic field signal on tendon tensile strength at 21 days after transection in a rat model.[138] This study found an increase in tensile strength of up to 69 percent (136.4 ± 31.6 kg/cm^2) at the repair site of the rat Achilles' tendon at 3 weeks after transection and repair, compared with the value (80.6 ± 16.6 kg/cm^2) in nonstimulated control animals. Although electroceuticals are promising, additional research is needed to recommend them for pressure ulcer treatment.

The use of therapeutic ultrasound for pressure ulcers has also been explored. A Cochrane review found three published randomized clinical trails using therapeutic ultrasound.[139] It was concluded that there was no evidence of the benefit of ultrasound therapy in the treatment of pressure ulcers. Thus, additional studies are needed before this therapy can be supported.

Evidence-Based Practice Implications

Much progress has been made in identifying patients at risk for pressure ulcers. The use of pressure ulcer prediction tools (e.g., Braden Scale) have led to nursing's sensitivity to earlier preventive measures. Research has shown that using the AHRQ guidelines on pressure ulcer prediction and prevention can lead to decreased incidence of pressure ulcers. Moreover, internalizing these guidelines throughout the health care system can lead to pressure ulcer reductions.

Much progress has been made in understanding effective wound treatments. Treatments range from using traditional therapies (keeping the wound moist, appropriate repositioning, support surfaces, and proper nutrition) to the wise use of adjunctive therapies. Although many studies in pressure ulcer prevention and treatment have small sample sizes, there is a growing body of evidence to suggest that newer wound modalities can be effective in preventing and treating pressure ulcers.

Research Implications

Since the original publications of the AHRQ pressure ulcer prevention and treatment guidelines in 1992 and 1994, some progress has been made in our understanding of pressure ulcer care. Nursing research is needed to address many gaps in our understanding of pressure ulcer prevention and treatment. Many risk factors for pressure ulcer development have been identified; however, a hierarchy of risk factors has not been determined. Thus, research to determine the essential risk factors is still needed. There also remains a dearth of research determining the role that race and ethnicity may have on pressure ulcer development. A small body of research is emerging to suggest that people of color may have an increased risk for pressure ulcer development. Thus, nurses must actively recruit minority participants to further explore this important variable. Another promising area of nursing research is the use of pressure ulcer prediction tools. Although the Braden Scale was originally published nearly two decades ago, it remains the gold standard. As the patient population continues to change, nursing research is needed to develop and validate newer pressure ulcer prediction tools.

There is a paucity of research on the effects of good skin care on pressure ulcer development. Randomized clinical trials are needed to validate specifics aspects of skin care (bathing schedules, cleansing solutions, water temperature, etc.) and their association with pressure ulcer development. Nursing research can also play a major role in closing the knowledge gap regarding optimal turning/repositioning schedules. Emerging research suggests that turning/repositioning every 2 hours may not be necessary when using dynamic support surfaces. However, randomized controlled trials with large numbers of participants are greatly needed. Evidence is still unclear as to whether there are large differences in the effectiveness of various support surfaces (e.g., Group II) to prevent pressure ulcers.

The role of protein-calorie malnutrition and pressure ulcer development remains understudied. Moreover, research into dietary supplements (vitamins, minerals, etc.) in the absence of a dietary deficiency is lacking. Additional nursing studies are needed to investigate whether the use of dietary supplements have any effect on pressure ulcer prevention. Recent nursing studies suggested that a comprehensive approach to prevention can lead to significant decreases in pressure ulcer incidence. However, studies investigating methods to sustain these decreases in pressure ulcer development are greatly needed. Additional research is also needed to further our understanding of risk level and titration of preventive measures

Staging of pressure ulcers remains more of an art than a science. Additional nursing research is needed to determine effective methods of classifying pressure ulcer depth with good validity and reliability. There is also a dearth of nursing research on the optimal solution and frequency for cleansing a pressure ulcer. Moreover, nursing research is needed to determine the optimal method for removing devitalized tissue in a pressure ulcer. No randomized controlled trials could be found that determined the best debridement method for healing pressure ulcers. Nursing research has identified some clinical characteristics of infected pressure ulcers. However, additional research is needed on the most effective method for treating an infected or contaminated pressure ulcer.

Numerous dressings are currently available to manage wound exudate. However, few randomized controlled trials have been conducted to determine optimal dressings within a classification (e.g., hydrocolloid, alginate). Many adjunctive therapies are currently being used, but few have extensive research to substantiate their effectiveness in healing pressure ulcers. Nursing research investigating the role of skin substitutes, growth factors, negative pressure wound therapy, and electroceuticals in healing pressure ulcers is greatly needed. Finally, nursing

research evaluating the cost effectiveness of adjunctive treatments in healing pressure ulcers is warranted, given rising health care costs.

Conclusion

The prevention of pressure ulcers represents a marker of quality of care. Pressure ulcers are a major nurse-sensitive outcome. Hence, nursing care has a major effect on pressure ulcer development and prevention. Prevention of pressure ulcers often involves the use of low technology, but vigilant care is required to address the most consistently reported risk factors for development of pressure ulcers. The literature suggested that not all pressure ulcers can be prevented, but the use of comprehensive pressure ulcer programs can prevent the majority of pressure ulcers. When the pressure ulcer develops, the goals of healing or preventing deterioration and infection are paramount. Randomized controlled trials are needed to determine optimal management strategies dependent on stage and comorbidities/severity of illness. Nursing remains at the forefront of protecting and safeguarding the patient from pressure ulcers.

Search Strategy

The electronic databases MEDLINE® (1980–2007), CINAHL® (1982–2007), and EI Compedex*Plus (1980–2007) were selected for the searches. Evaluations of previous review articles and seminal studies that were published before 1966 were also included. Research conducted worldwide and published in English between the years 1930 and 2007 was included for review. Moreover, studies using descriptive, correlational, longitudinal, and randomized controlled trials were included.

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Evidence Table. Pressure Ulcers—Risk, Assessment, and Prevention

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Allman 1986[22]	Pressure ulcer risk factors	Prospective cohort study	Cross-sectional, pressure ulcer development	Hospital, 21 years and older		Hypoalbuminemia, fecal incontinence, and fractures remained significantly and independently associated with having a pressure sore (odds ratios = 3.0, 3.1, and 5.2, respectively).
Allman 1995[14]	Pressure ulcer risk identification	Prospective cohort study	Prospective cohort study, time to in-hospital development of a Stage II or greater pressure ulcer	Urban teaching hospital		Age of 75 years or more, dry skin, nonblanchable erythema (a Stage I pressure ulcer), previous pressure ulcer history, immobility, fecal incontinence, depleted triceps skin fold, lymphopenia (lymphocyte count < 1.50 x 10(9)/L), and decreased body weight (< 58 kg) were significantly associated with pressure ulcer development by univariate Kaplan-Meier survival analyses ($P < 0.05$ by log-rank test).
Anthony 2000[70]	Pressure ulcer prediction	Prospective cohort study	Noncomparative study, pressure ulcer development	Skilled nursing facility, elderly		Serum albumin (low) can be a useful predictor of pressure ulcer development.
Baier 2003[53]	Pressure ulcer prevention	Quality improvement	Prospective cohort study, implementation of AHRQ guidelines and pressure ulcer development	Skilled nursing facilities, quality improvement teams in 29 nursing homes	Quality improvement teams	Six of eight prevention process measures improved significantly, with percent difference between baseline and followup ranging from 11.6% to 24.5%. Three of four treatment process measures improved significantly, with 5.0%, 8.9%, and 25.9% differences between baseline and followup. For each process measure, between 5 and 12 facilities demonstrated significant improvement between baseline and followup, and only 2 or fewer declined for each process measure.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bates-Jensen 1992[127]	Pressure ulcer healing	Prospective cohort study	Cross-sectional, pressure ulcer healing			The Pressure Sore Status Tool interrater reliability was established at $r = 0.91$ for first observation and $r = 0.92$ for the second observation ($P < 0.001$). Interrater reliability was $r = 0.99$ for rater one and $r = 0.96$ for rater two ($P < 0.001$).
Baumgarten 2003[30]	Pressure ulcer prevalence	Prospective cohort study	Prospective cohort study, pressure ulcer development among newly admitted residents from hospitals, home, or other settings.	Skilled nursing facilities, 65 years and older		Admission from a hospital was significantly associated with pressure ulcer prevalence on admission (OR = 2.2).
Bergstrom 1987[35]	Pressure ulcer prediction	Quality improvement	Prospective cohort study	Acute intensive care unit	The Braden scale score and skin assessment	Twenty-four of 60 consecutively admitted patients developed pressure ulcers with the total score of 16 as the cut-off.
Bergstrom 1992[13]	Pressure ulcer risk identification	Prospective cohort study	Prospective cohort study, pressure ulcer presence or absence	Skilled nursing facility, 65 years and older, 70% female		Best predictors of pressure sore development were the Braden scale score (< 16), diastolic blood pressure, temperature, dietary protein intake, and age.
Bergstrom 1992[42]	Pressure ulcer prevention guidelines	Published guideline	Systematic literature review (Level 11) and consensus reports (Level 16), pressure ulcer prevention	Hospital, skilled nursing facilities, and home care, elderly population		Development of guidelines to prevent pressure ulcers.
Bergstrom 1998[43]	Pressure ulcer prediction	Quality improvement	Prospective cohort study	Tertiary care hospitals, Veterans Administration Medical Centers, and skilled nursing facilities	The Braden scale score and skin assessment	One hundred eight of 843 subjects (12.8%) developed pressure ulcers. Braden scale scores were significantly lower ($P = 0.0001$) in those who acquired pressure ulcers then those who did not. Total score of 18 is the cut-off score for prediction of pressure ulcers.
Berlowitz 1989[24]	Pressure ulcer	Prospective cohort	Cross-sectional,	Skilled nursing		Factors associated with pressure

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
	predictors	study	pressure ulcer development	facility, elderly		ulcer development included altered level of consciousness (OR = 4.1), bed- or chair-bound (OR = 1.9), and hypoalbuminemia (OR = 1.8).
Brandeis 1990[25]	Pressure ulcers and mortality	Retrospective cohort studies	Use of large database, pressure ulcer development and mortality, hospitalization	Skilled nursing facilities, elderly		Pressure ulcers were associated with an increased rate of mortality, but not associated with increased transfers from skilled nursing facilities to hospitals for treatment.
Breslow 1993[120]	Pressure ulcers and dietary protein	Prospective cohort study	Nonrandomized trial, pressure ulcer healing	Skilled nursing facility, patients ages 72 years and older with malnutrition	Dietary supplement	Significant truncal decrease in pressure ulcers sizes when using 24% protein.
Cuddigan 2001[10]	Pressure ulcer incidence	Systematic literature review	Systematic literature review (Level 11), pressure ulcer incidence and prevalence	Hospital, skilled nursing facilities, and home care		Pressure ulcer incidence rates (e.g., hospitals, 0.4% to 38%; skilled nursing facilities, 2.2% to 23.9%; and home care, 0% to 17%).
DeFloor 2004[61]	Pressure ulcers	Prospective cohort study	Randomized controlled trial, pressure ulcer development	Skilled nursing facilities, 60 years and older	Turning every 2, 3, 4, or 6 hours using either standard mattress or viscoelastic foam	The incidence of Stage I pressure ulcers was not different between the groups. However, the incidence of Stage II pressure ulcers and higher in the 4-hour turning group with viscoelastic was 3%, compared with incidence figures in the other groups varying between 14.3% and 24.1%.
Donaldson 2005[48]	Licensed nurse-patient ratios and pressure ulcer development	Retrospective	Cross-sectional, pressure ulcer development	Hospitals, adult, surgical, and definitive-observation units, nurse-patient ratios	Staffing ratios	Impact of mandated nurse-patient ratios did not reveal significant changes in incidence of pressure ulcer development.
Ek 1985[58]	Pressure ulcers and massage	Prospective cohort study	Nonrandomized trial, pressure ulcer development, pressure ulcer development using massage	Hospital, patients older than 60 years with and without cerebral hemorrhage	Massage	The effect of massage over areas at risk for pressure ulcer varies greatly between patients and within patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fuhrer 1993[26]	Pressure ulcer development	Prospective cohort study	Prospective cohort study, pressure ulcer development	Community, patients with spinal cord injury (100 men and 40 women)		Thirty-three percent (n = 46) presented with one or more ulcers of at least Stage I severity when visually examined. Twenty-one individuals had more than one ulcer, the maximum number of ulcers being seven. Of 87 ulcers for which severity ratings were available, 30 (34.5%) were Stage I, 33 (37.9%) were Stage II, and 24 (27.6%) were either Stage III or IV. Individuals with an ulcer exhibited more paralysis and were more dependent on others in activities of daily living. A greater proportion of blacks had more severe ulcers (Stages III and IV) than their white counterparts.
Gardner 1999[131]	Pressure ulcers	Meta-analysis	Nonrandomized trial, pressure ulcer healing		Electrical stimulation	Rate of healing per week was 22% for electrical stimulation samples and 9% for control samples. The net effect of electrical stimulation was 13% per week, an increase of 144% over the control rate.
Guralnik 1988[23]	Pressure ulcer predictors	Retrospective cohort studies	Use of large database, pressure ulcer development	Skilled nursing facilities, 55 years and older		Pressure ulcer development was associated with current smokers, inactivity, poor self-assessed health status, and anemia.
Hellwell 1997[80]	Cytotoxicity evaluation	Prospective cohort study		Polymorphonuclear leukocytes (PMNs)	Ten commercial wound cleaners	The non-antimicrobial wound cleansers had toxicity indexes of 10 to 1,000, while the toxicity indexes of antimicrobial wound cleansers were 10,000.
Horn 2005[47]	Nurse-patient ratios and pressure ulcer development	Retrospective	Cross-sectional, pressure ulcer development	Skilled nursing facility, registered nurse-patient ratios	Staffing ratios	More registered nurse care time per resident was associated with the development of fewer pressure ulcers.
Johnson-Pawlson 1996[46]	Nurse-patient ratios and pressure ulcer development	Retrospective	Cross-sectional, pressure ulcer development	Skilled nursing facility, registered nurse patient ratios	Registered nurse staffing ratios	The ratio of registered nurse to residents is directly related to a measure of quality of care deficiencies.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kloth 1988[129]	Pressure ulcer healing	Prospective cohort study	Randomized controlled trial, pressure ulcer healing	Skilled nursing facility, patients ages 20 to 89 years, Stage IV pressure ulcers	High voltage monophasic pulsed current	Patients in treatment group healed at a mean rate of 44.8% a week and healed 100% over a mean period of 7.3 weeks. Patients in the control group increased in area an average of 11.6% a week and increased 28.9% over mean period of 7.4 weeks.
Lyder 1998[20]	Pressure ulcer prediction and prevention	Unpublished research	Retrospective cohort study (Level 9), pressure ulcer development	Hospitals, Medicare beneficiaries		The number of risk factors is associated with pressure ulcer development ($P \leq 0.001$). Patients with ≥ three risk factors were associated with an increased incidence (26.3%) of pressure ulcers, in comparison to those with one or two factors ($P = 0.001$).
Lyder 2001[12]	Pressure ulcer prevention	Quality improvement research	Retrospective cohort study (Level 9), pressure ulcer incidence	Hospital, Medicare beneficiaries	AHRQ pressure ulcer prevention guidelines	Hospital compliance with AHRQ prevention guidelines varied greatly for daily skin assessment (94%), risk identification (22.6%), use of pressure-reducing devices (7.5%), nutritional consult (34.3%), and repositioning patient every 2 hours (66.2%).
Lyder 2002[51]	Pressure ulcer prevention	Retrospective and prospective quasi-experimental	Pressure ulcer prevention program	Two long-term care facilities (A = 150 beds, B = 110 beds)	Pressure ulcer prevention program	An 87% decrease in pressure ulcers in facility A (13.2% to 1.7%) and a 76% decrease in pressure ulcers in facility B (15% to 3.5%).
Lyder 2004[7]	Pressure ulcer prevention	Quality improvement research	Retrospective cohort study (Level 9), pressure ulcer development	Hospitals, Medicare beneficiaries	Implement systematic risk assessment, repositioning, support surfaces	Statistically significant increases in the identification of high-risk patients, repositioning of bed-bound or chair-bound patients, nutritional consults in malnourished patients, and staging of acquired Stage II pressure ulcers from baseline and followup medical record abstractions.
Meaume 2005[108]	Silver in chronic wounds	Prospective cohort study	Randomized (stratification according to	13 centers with 99 participants	Silver-releasing hydroalginate	The study suggests that treating wounds with a high risk of infection with silver-releasing hydroalginate

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
			wound type) opened label multicenter comparative two-arm parallel-group		dressing	dressing had a favorable influence on wound prognosis.
Ooka 1995[68]	Support surfaces	Prospective cohort study	A new-product evaluation with convenience sampling	Surgical intensive care unit	Dynamic and static mattresses	All three mattresses were comparable in effectiveness.
Pang 1998[36]	Pressure ulcer risk identification	Prospective cohort study	Prospective cohort study, validity of pressure ulcer prediction scales	Hospital, 21 years and older, pressure ulcer free	Pressure ulcer prediction scales	Both the Norton and Waterlow scales had relatively high sensitivity (81% and 95%, respectively), whereas the Braden Scale had both high sensitivity (91%) and specificity (62%). All three scales had relatively high negative predictive values (>90%), but the Braden Scale had better positive predictive value.
Perneger 2002[38]	Pressure ulcers	Prospective cohort study	Cross-sectional, pressure ulcer development	Teaching hospital, patients older than 60 years		The FRAGMMENT score (sum of friction, age, mobility, mental status) was linearly related to pressure ulcer risk, and its area under the receiver operating characteristic curve (0.80) was higher than for the Norton (0.74; $P = 0.006$) and Braden (0.74; $P = 0.004$) scores.
Reddy 2006[62]	Pressure ulcer prevention	Systematic literature review, pressure ulcers	Systematic literature review	59 randomized controlled trials grouped into three categories		Giving current evidence, use of support surfaces, repositioning, optimizing nutritional status, and hydration of sacral skin are appropriate.
Romanelli 2003[107]	Pressure ulcer infection	Systematic literature review	Systematic literature review			Use of systemic antibiotics in infected pressure ulcers should be based on culture results. Therapy should be specific to isolated pathogens to avoid widespread use of antimicrobial drugs that contribute to the proliferation of drug-resistant organisms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rosen 2005[88]	Pressure ulcer prevention	Quality improvement	Prospective cohort study, pressure ulcer development	Skilled nursing facilities, elderly	Staff empowerment, real-time feedback	Empowering staff with real-time feedback led to significant reduction of new pressure ulcers (*P =0.* 05).
Roth 2004[123]	Pressure ulcer and pain	Prospective cohort study	Cross-sectional, pressure ulcer pain			McGill Pain questionnaire was more sensitive to pain experience than a single rating of pain intensity. Moreover, wound stage (larger) was positively related to severity of pain, and pain catastrophizing was positively related to pain intensity.
Schoonhoven 2002[39]	Pressure ulcer risk	Prospective cohort study	Prospective cohort study, pressure ulcer development	Hospitals, patients admitted to surgical, internal, neurological, or geriatric units, 18 years and older		The weekly incidence of patients with pressure ulcers was 6.2% (95% confidence interval 5.2% to 7.2%). The area under the receiver operating characteristic curve was 0.56 (0.51 to 0.61) for the Norton scale, 0.55 (0.49 to 0.60) for the Braden scale, and 0.61 (0.56 to 0.66) for the Waterlow scale; the areas for the subpopulation, excluding patients who received preventive measures without developing pressure ulcers and excluding surgical patients, were 0.71 (0.65 to 0.77), 0.71 (0.64 to 0.78), and 0.68 (0.61 to 0.74), respectively. In this subpopulation, using the recommended cut-off points, the positive predictive value was 7.0% for the Norton, 7.8% for the Braden, and 5.3% for the Waterlow scales.
Stotts 2001[126]	Pressure ulcer healing	Retrospective	Cross-sectional, pressure ulcer healing	Skilled nursing facility		The Pressure Ulcer Scale for Healing tool accounted for 58% to 74% of the wound healing variance over a 10-week period in Study 1, and 40% to 57% of the wound healing variance over a 12-week period in Study 2. Thus the PUSH

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
						tool is a valid and sensitive measure of pressure ulcer healing.
Thomas 1996[15]	Pressure ulcers and mortality	Prospective cohort study	Prospective cohort study, time to death from admission to 1-year posthospital discharge.	Urban teaching hospital		Development of an in-hospital pressure ulcer was associated with greater risk of death at 1 year (59.5% versus 38.2%, *P* = 0.02). However, pressure ulcer development did not remain independently associated with decreased survival after adjusting for other predictors of mortality.
Torra 2005[55]	Hyperoxygenated fatty acid	Prospective cohort study	Double-blind randomized clinical trial	Multicenter	Hyper-oxygenated fatty acid preparation	Pressure ulcer incidence during the study was 7.32% in the intervention group versus 17.37% in the placebo group (*P* = 0.006).
Xakellis 1998[49]	Pressure ulcer prevention	Quality improvement research	Cost-effectiveness evaluation	77-bed long-term care facility	A guideline-based pressure ulcer prevention protocol	Pre-protocol: 16 out of 69 patients developed 26 pressure ulcers. Post-protocol: 3 out of 63 patients developed 5 pressure ulcers.
Xakellis 2001[50]	Pressure ulcer guidelines	Retrospective and prospective quasi-experimental longitudinal	Cost effectiveness of a guideline-based pressure ulcer prevention protocol over time	77-bed long-term care facility	A guideline-based pressure ulcer prevention protocol	Time to ulcer development varied among three groups (log rank = 8.81, *P* = 0.01). Time to ulcer healing (log rank = 9.49, *P* = < 0.01). Cost of treatment decreased (F = 5.5, *P* = < 0.01). Cost of prevention increased (F = 15, *P* = < 0.01).

Chapter 13. Patient Safety and Quality in Home Health Care

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Background

Home health care is a system of care provided by skilled practitioners to patients in their homes under the direction of a physician. Home health care services include nursing care; physical, occupational, and speech-language therapy; and medical social services.[1] The goals of home health care services are to help individuals to improve function and live with greater independence; to promote the client's optimal level of well-being; and to assist the patient to remain at home, avoiding hospitalization or admission to long-term care institutions.[2–4] Physicians may refer patients for home health care services, or the services may be requested by family members or patients.

The Centers for Medicare and Medicaid Services (CMS) estimates that 8,090 home health care agencies in the United States provide care for more than 2.4 million elderly and disabled people annually.[5] To be eligible for Medicare reimbursement, home health care services must be deemed medically necessary by a physician and provided to a home-bound patient. In addition, the care must be provided on an intermittent and noncontinuous basis.[5] Medicare beneficiaries who are in poor health, have low incomes, and are 85 years of age or older have relatively high rates of home health care use.[6] Common diagnoses among home health care patients include circulatory disease (31 percent of patients), heart disease (16 percent), injury and poisoning (15.9 percent), musculoskeletal and connective tissue disease (14.1 percent), and respiratory disease (11.6 percent).[7]

Delivering Health Care in the Home

The home health care environment differs from hospitals and other institutional environments where nurses work. For example, home health care nurses work alone in the field with support resources available from a central office. The nurse-physician work relationship involves less direct physician contact, and the physician relies to a greater degree on the nurse to make assessments and communicate findings. Home health care nurses spend more time on paperwork than hospital nurses and more time dealing with reimbursement issues.[8, 9] Certain distinctive characteristics of the home health care environment influence patient safety and quality of outcomes: the high degree of patient autonomy in the home setting, limited oversight of informal caregivers by professional clinicians, and situational variables unique to each home.

Respect for patient autonomy is valued in hospital-based care. Nonetheless, many decisions are made by clinicians on behalf of hospitalized patients. In home health care, clinicians recognize that the care setting—the home—is the inviolable domain of the patient. Therefore, compared to the hospitalized patient, the home health care patient often has a greater role in determining how and even if certain interventions will be implemented. For example, in a hospital, nurses, physicians, and pharmacists may all play a role in ensuring that the patient receives antibiotics at therapeutically appropriate intervals. At home, however, the patient may

choose to take the medication at irregular times, despite advice about the importance of a regular medication schedule. Thus, interventions to promote patient safety and quality care must account for the fact that patients will sometimes choose to act in ways that are inconsistent with the relevant evidence, and the clinician's best efforts may not result in desired outcomes.

In addition to deliberate choices made by informed and capable patients regarding their care, individual patient variables may also influence home-based outcomes in ways that are different from those patients who are hospitalized. Ellenbecker and colleagues[10, 11] reported that reading skill, cognitive ability, and financial resources all affect the ability of home health care patients to safely manage their medication regimens. Yet, none of these variables may play a meaningful role in the safe administration of medications to hospitalized patients.

In addition to self-care, some home-bound patients receive assistance from family members or other informal caregivers. Professional clinicians have no authority over these caregivers. Further, the home environment and the intermittent nature of professional home health care services may limit the clinician's ability to observe the quality of care that informal caregivers deliver—unlike in the hospital, where care given by support staff may more easily be observed and evaluated. For example, because of limited access to transportation, a husband may decide not to purchase diabetic supplies for his dependent wife. This behavior may not come to the clinician's attention until an adverse event has occurred. Evidence-based interventions are predicated on careful assessment. However, limited opportunity to directly observe the patient and informal caregivers may hinder efforts to quickly determine the etiology of an adverse event. If a home health care patient is found with bruises that the patient can't explain, is the cause a fall, physical abuse, or a blood dyscrasia? In both self-care by patients and care by informal caregivers, safety and quality standards may not be understood or achieved.

Another distinctive characteristic of home health care is that clinicians provide care to each patient in a unique setting. There may be situational variables that present risks to patients that may be difficult or impossible for the clinician to eliminate. Hospitals may have environmental safety departments to monitor air quality and designers/engineers to ensure that the height of stair risers is safe. Home health care clinicians are not likely to have the training or resources to assess and ameliorate such risks to patient safety in the patient's home.

Finally, given the large number of elderly persons who receive care from Medicare-certified home health care agencies, it is reasonable to anticipate that some patients will be in a trajectory of decline. Due to both normal aging and pathological processes that occur more frequently with advancing age, some elderly persons will experience decreasing ability to carry out activities of daily living (ADLs), even when high-quality home health care is provided. Thus, an implicit goal of home health care is to facilitate a supported decline. That is, patients who do not show clinical signs of improvement may nonetheless receive quality care that results in a decelerated decline or increased quality of life. This is consistent with the American Nurses Association's assertion that promoting the patient's optimal level of well-being is a legitimate goal of home health care.[3]

Assessing Quality of Care in the Home

The goals and multidisciplinary nature of home health care services present challenges to quality measurement that differ from those found in a more traditional hospital setting. The CMS mandates reporting of home health care outcome measures. The Outcome-Based Quality Monitoring (OBQM) program monitors, reports, and benchmarks adverse events such as emergent care for injury caused by fall or accident, increased number of pressure ulcers, and substantial decline in three or more ADLs.[5]

Pay for performance, a mechanism that ties a portion of an agency's reimbursement to the delivery of care, is another CMS quality initiative anticipated in the near future.[12] In preparation, quality-improvement organizations and providers are working to identify and develop a set of performance measures proven effective in home care. A 2006 Medicare Payment Advisory Commission report to Congress identified patient safety as an important component of quality and the need to expand quality measures to include process and structural measures. An expanded approach to quality measurement should accomplish the following goals: broaden the patient population being evaluated, expand the types of quality measures, capture aspects of care directly under providers' control, reduce variations in practice, and improve information technology.[13]

In January 2007, the home health community, health care leaders, and quality-improvement organizations launched the Home Health Quality Improvement National Campaign 2007. The campaign focuses on improving the quality of patient care in the home health care setting by providing agencies with monthly best practice intervention tools. The goal is to prevent avoidable hospitalizations for home health care patients. The Home Health Quality Improvement National Campaign uses a multidisciplinary approach to quality improvement that includes key home health, hospital, and physician stakeholders.[14]

Research Evidence

In many respects, home health care clinicians and clinicians working in other settings have similar concerns about patient safety and care quality. For example, patient falls occur both in homes and in hospitals, and some measures aimed at preventing falls are equally applicable to both settings. However, the significant differences between home health care and other types of health care often require interventions tailored to the home health care setting.

This chapter includes an analysis of the evidence on promoting patient safety and health care quality in relation to problems frequently seen in home health care. The following six areas were selected for review:

- Medication management
- Fall prevention
- Unplanned hospital admissions
- Nurse work environment
- Functional outcomes and quality of life
- Wound and pressure ulcer management

Adverse events in these areas could jeopardize achievement of one or more home health care goals.

Medication Management

Nearly one-third of older home health care patients have a potential medication problem or are taking a drug considered inappropriate for older people.[15] Elderly home health care patients are especially vulnerable to adverse events from medication errors; they often take multiple medications for a variety of comorbidities that have been prescribed by more than one provider. The majority of older home health care patients routinely take more than five prescription drugs, and many patients deviate from their prescribed medication regime.[11] The potential of medication errors among the home health care population is greater than in other health care

settings because of the unstructured environment and unique communication challenges in the home health care system.[11]

A search of the literature identified only three studies testing interventions to improve medication management and adherence in home health care patients.[16–18] The studies are summarized in Table 1. All three studies used a controlled experimental design, with random assignment of patients to one or two treatment groups and a control group of usual care. The populations studied were elderly Medicare patients receiving home health care, ranging from 41 to 259 patients.

The interventions tested were patient education delivered by telephone or videophone with nurse followup, education tailored to individual patients, and medication review and collaboration among providers (e.g., nurse, pharmacist, physician) and patient. Specific outcomes included identifying unnecessary and duplicate medication, improving the use of specific categories of medication such as cardiovascular or psychotropic drugs, and identifying the extent of use of nonsteroidal anti-inflammatory drugs (NSAIDs). The effectiveness of the interventions was measured by improved medication management and adherence to drug protocols. Adherence was estimated objectively from medication refill history and medication event monitoring, and subjectively from patient self-report scores on pre- and postintervention questionnaires testing knowledge, understanding of disease, and adherence.

Evidence from these studies suggests that all of the interventions tested were at least somewhat effective. Medication use improved for patients receiving the intervention, while control groups had a significant decline in adherence to drug protocols. The educational interventions were most successful when individually tailored to patients' learning abilities. The interventions were most effective in preventing therapeutic duplication and improving the use of cardiovascular medications, less effective for patients taking psychotropic medication or NSAIDs. Generally, as knowledge scores improved, adherence improved. When more than one intervention was tested, there was generally no difference between the two intervention groups.

Evidence-Based Practice Implications

Nurses must be vigilant for the possibility of medication errors in the home health care setting, recognizing the associated risk factors. Technology provides many opportunities to improve communication with patients, to provide patients with accurate information, to educate them about their medications, and to monitor medication regimes. Paying close attention to at-risk patients is most effective; therefore, accurate documentation and review of medications during each patient encounter is important. The evidence suggests that frequent medication reviews and collaboration with other members of the health care team, especially pharmacists, will help to prevent adverse events associated with poor medication management.

Research Implications

More effective methods are needed to improve medication use in the home health care population. Research should continue to expand the knowledge of factors that contribute to medication errors in home health care and determine what interventions are the most effective in improving medication management in the home.

Table 1. Summary of Evidence Related to Medication Management

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fulmer 1999[18]	Medication compliance	Randomized controlled trial	Randomized controlled trial. Outcomes: prescribed cardiac medications taken	n = 50 patients, 65 years or older with congestive heart failure, receiving home care or clinic services	1. Daily videophone 2. Regular telephone reminders 3. Control: usual treatment	Control group medication compliance dropped significantly (*P* = .04) over time compared to intervention groups (telephone or videophone). No significant difference between the two intervention groups.
Gates 2005[17]	Medication improvement	Randomized controlled trial	Randomized controlled trial. Outcomes: medication knowledge and adoption of medication list	n = 41 patients from 2 homecare agencies, 2 educational groups	1. Video 2. Tailored to individual	Knowledge improved with education tailored to individual (group 2), Group 2 members were more likely to speak with a provider before purchase of an over-the-counter drug (*P* = .043) and were significantly more likely to keep an updated medication list (*P* = .003).
Meredith 2002[16]	Medication improvement	Randomized controlled trial	Randomized controlled trial: Outcomes: unnecessary therapeutic duplication and inappropriate cardiovascular, psychotropic, and NSAIDs use.	Medicare home health care patients, more than 65 years of age with at least one medication problem, from 2 large urban home care agencies; n = 130 intervention, n = 129 control	1. Medication program to identify potential med problems and collaboration with clinical pharmacist and nurse 2. Control: usual care	Medication use improved for 50% of intervention patients and 38% of control patients (*P* = .051). Intervention effect greatest for therapeutic duplication (*P* = .003), and intervention group improved in use of cardiovascular meds (*P* = .017). There were no differences in the groups for psychotropic medication or NSAID problems.

Fall Prevention

Emergent care for injury caused by falls or accidents at home is one of the most frequently occurring adverse events reported for patients receiving skilled home health care services.[19] Thirty percent of people age 65 and older living in the community fall each year. One in five of these fall incidents requires medical attention.[20] Falls are the leading cause of injury-related death for this population.[21] Among the elderly, Stevens[22] reported direct medical costs in 2000 totaled $179 million for fatal fall-related injuries and $19 billion for nonfatal injuries due to falls.

Although there is strong evidence of effective fall-prevention interventions for the general over-65 population,[20, 23, 24] knowledge of fall prevention in home health care is limited. For the general older population living in the community, evidence suggests that individualized home programs of muscle strengthening and balance retraining; complex multidisciplinary, multifactorial, health/environmental risk factor screening and intervention; home hazard assessment and modification; and medication review and adjustment can all reduce the incidence of falls.[20] However, patients in home health care are often older, sicker, and frailer than the average community-residing older adult, and it is not known if knowledge from other settings is transferable to home health care.

Research studies specific to home health care are predominantly retrospective, descriptive, correlational designs in single agencies, using matched control or randomized control groups to explore patient characteristics and other factors contributing to patient falls.[25–27] Findings suggest that factors related to falls for home health care patients are previous falls, primary diagnosis of depression or anhedonia, use of antipsychotic phenothiazines and tricyclic antidepressants, secondary diagnoses of neurological or cardiovascular disorders, balance problems, frailty, and absence of handrails.[25-27]

A literature review located only three studies testing interventions to prevent falls.[28–30] The studies are summarized in Table 2. All three interventions were quality-improvement programs in single agencies. The findings suggest that risk factor screening and intervention using a valid and reliable instrument and physical therapy aimed at improvement in gait and balance may reduce injury and emergent care for falls. Unfortunately, there is no evidence that the number of falls incurred by the home health care population can be reduced. It may be that improved provider assessments increased the number of falls reported and documented.

Evidence-Based Practice Implications

Home health care providers need to know the risk factors for falls and demonstrate effective assessment and interventions for fall and injury prevention. Falls are generally the result of a complex set of intrinsic patient and extrinsic environmental factors. Use of a fall-prevention program, standardized tools, and an interdisciplinary approach may be effective for reducing fall-related injuries.

Research Implications

There are several limitations in the current evidence on falls in home health care. Most of the research is descriptive, and there are no randomized controlled studies. Findings from small, single-agency quality-improvement projects cannot be generalized. It is not known if predictors for falls in home health care patients are the same as those for other community dwellers over

age 65. Research is needed to expand the knowledge of factors that contribute to falls in this population and to develop effective interventions. Research is also needed to explore factors to prevent injury from falls, as it is likely that the incidence of falls in this population cannot be completely eliminated.

Table 2. Summary of Evidence Related to Fall Prevention

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bright 2005[28]	Fall prevention/risk reduction	Quality improvement project/research	Observational study without controls. Outcomes: improvement in balance and gait, number of falls, and emergent care for falls or accidents.	Year 1 n = 153 patients and year 2 n = 183 patients age 62 and over and at risk for falls from 1 Midwest home care agency.	Fall prevention/risk reduction program: screening with Tinetti assessment, education, physical therapy intervention, and followup.	Emergent care for injury caused by fall or accident at home decreased from 2.58% to 1.72% within 7 months. Improvement in gait and balance scores from 15.59 to 18.43. There was no change in number of falls in home.
Sperling 2005[30]	Fall prevention (see also medication management)	Quality improvement project/research	Observational study without controls. Outcomes: patient falls.	n = 228 patients 65 years of age or older from a medical-centered home care agency.	Medication management model: medication review and oversight for patients at risk.	The number of reported falls increased, possibly related to increased staff awareness and better reporting.
Yuan and Kelly 2006[29]	Fall prevention/risk and injury reduction	Quality improvement project/research	Observational study without controls. Outcome: rate of falls, injury from falls.	Unknown number of at-risk patients for falls from 1 hospital-based home care agency.	Fall prevention program, multidisciplinary risk assessment with Morse scale, evidence-based guidelines.	Number of patient falls remained relatively stable, but fewer patients were injured in falls.

Unplanned Hospital Admissions

A primary goal of home health care is to discharge the patient to self or family care and avoid subsequent hospitalizations. Unplanned admission to the hospital is an undesirable outcome of home health care that causes problems for patients, caregivers, providers, and payers. Unplanned hospital admissions are associated with complications, morbidity, patient and family stress, and increased costs.[31] An estimated 1,034,034 home health care patients were hospitalized in 2004. The national rate of unplanned hospital admissions for home health care patients has gradually increased from 27 percent in 2000 to 28 percent in 2006,[32] and it is the only publicly reported home health care patient outcome that has never improved at the national level.[33]

Several researchers have explored the characteristics of home health care patients and other factors associated with hospitalization.[31, 34–39] The studies have been predominantly retrospective, descriptive, and correlation designs examining home care populations from single or multiple agencies.[31, 35–38] One study is a prospective study of a random sample of agencies.[39] Evidence suggests that unplanned hospital admissions are due mostly to an acute exacerbation of chronic disease—exacerbations that could be prevented through knowledge of risk factors, provider communication, and careful monitoring.[39] Risk factors associated with unplanned hospital admissions are polypharmacy,[31, 35] length of home health care episode,[34, 36] development of a new problem or worsening primary or secondary diagnosis,[36] wound deterioration and falling accidents,[31] and age.[31, 37] Based on this evidence most experts[31, 37] conclude that 20 to 25 percent of unplanned hospital admissions are preventable. For example, Shaughnessey and colleagues[2] found that agencies actively involved in Outcomes-Based Quality Improvement (OBQI) monitoring reduced their rate of patient hospitalizations when compared to non-OBQI agencies.

The Briggs National Quality Improvement and Hospitalization Reduction Study[33] convened a panel of experts to identity best practice strategies that agencies should implement to prevent unplanned hospitalizations. Recommended best practices included implementing a fall prevention program, front loading visits, management support, 24-hour on-call nursing coverage, medication management, case management, patient/caregiver education, special support services, disease management, positive physician and hospital relationships, data-driven services, safety and risk assessment, and telehealth. These recommendations were not empirically tested, however.

Only eight studies have tested the effectiveness of interventions to prevent unplanned hospital admissions for home health care patients. Five of these studies employed a randomized controlled trial design, and three used a nonrandomized control or comparison group design. The tested interventions consisted primarily of increasing the intensity of care provided through a disease management program, a team management home-based primary care program, a multidisciplinary specialty team intervention, advanced practice nurse (APN) transitional care, telehealth services, and intensive rehabilitative care prior to hospital discharge.[40–43] Most of these interventions were effective or somewhat effective in preventing or delaying hospitalization. Additionally, four of the studies reported lower mean costs or charges for the intervention groups related to lower hospital costs,[40, 42–44] and one study[45] reported higher costs for the intervention group based on the costs of the team-managed primary care intervention.

In these studies, patients with congestive heart failure (CHF) had fewer unplanned hospital admissions and longer survival times prior to first admission[39–42] if they received APN

transitional care, team-managed home-based primary care, or a multidisciplinary specialty team intervention.[40–43] Patients with CHF who received telecare and telephone interventions also had significantly fewer emergency room visits, but no change in hospital admissions.[42] Team-managed home-based primary care has been found to be most effective for people who are severely disabled.[45] Daly and colleagues [44] reported that long-term mechanically ventilated patients who received a disease management program intervention involving APN services and interdisciplinary coordination had significantly fewer mean days of hospitalization.

Results from one nonrandomized controlled study suggest that patients with chronic obstructive pulmonary disease (COPD) who received APN transitional care also experienced fewer unplanned hospital admissions.[46] Intrator and Berg[47] reported that patients hospitalized with hip fractures had fewer unplanned hospital admissions when they received home health care services following inpatient rehabilitation compared with those patients who received inpatient services only. Findings are summarized in Table 3.

Evidence-Based Practice Implications

Evidence suggests that specialized, coordinated, interdisciplinary care has a positive impact on unplanned hospital admissions in select home health care populations. Agencies can identify patient characteristics associated with hospitalization unique to their patient population. High-risk patients may require specialized interventions beyond the traditional scope of home health care services. Targeted interventions using process-of-care analysis and data available from the Outcome and Assessment Information Set (OASIS), within the framework of OBQI, may result in fewer unplanned hospital admissions for home health care patients.

Research Implications

The available evidence suggests that in addition to the use of APNs for care of complex cases, traditional home health care professionals, individually or through interdisciplinary practice, may be effective in preventing unplanned hospital admissions with targeted interventions. Although numerous strategies have been recommended by researchers and other home care experts, most interventions have not been empirically tested. Costs and benefits of the various interventions also need further exploration. The measurement of intervention costs and cost savings from prevented hospitalizations are not well understood. Some patient populations, due to the nature and complexity of advanced disease process, may require more intense and specialized home health care services that will not result in cost savings. On the other hand, use of seemingly more expensive transitional resources, such as APNs, have been proven cost effective, although adoption of such research-based best practices may be impeded by lack of reimbursement and incentives.[48] Research is needed to understand the impact of shifting care and cost to home health care on patient outcomes and home health care industry fiscal status.

Table 3. Summary of Evidence Related to Unplanned Hospital Admission

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Briggs 2006[33]	Hospitalization reduction	Quality improvement project/ consensus report, and retrospective cohort study	Nonexperimental descriptive Outcomes: 15 best practice strategies to prevent hospitalization. Type and percent of agencies implementing best practices.	Convenience sample of 400 agencies with lower-than-average hospitalization rates	Panel consensus on 15 best practice survey of agencies	Best practice strategies: Fall prevention Front loading visits Management support 24-hour on-call nursing coverage Medication management Case management Patient/caregiver education Special support services Disease management Physician relationships Data-driven services Safety and risk assessment Hospital relationships: Discharge staff and EM staff Telehealth. Successful agencies intentionally used one or more of these strategies. Most strategies did not involve extra expense.
Daly 2005[44]	Hospital admission	Randomized controlled trial	Randomized controlled trial. Outcomes: hospitalization rate, duration, and cost effectiveness	Chronically ill, long-term mechanically ventilated patients discharged from academic medical center: n = 231 intervention, n = 103 control	1. Disease management program, care coordination, family support, teaching, from a team of APNs, a geriatrician, and a pulmonologist 2. Usual care	Intervention group had significantly fewer mean days of hospitalization vs. control (P = .03). The average savings per patient in the intervention group was $21,549.

Table 3. Summary of Evidence Related to Unplanned Hospital Admission (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hughes 2000[45]	Hospital readmissions (See also Table 5)	Randomized controlled trial	Randomized controlled trial. Outcomes: hospital readmissions and costs over 12 months	Patients with a mean age of 70 years who had 2 or more ADL impairments or a terminal illness, CHF, or COPD. n = 981intervention, n = 985 control	1.Team-managed home-based primary care (HBPC): primary care manager, 24-hour contact for patients, prior approval of hospital admissions 2. Customary Department of Veterans Affairs and private sector care	Team-managed HBPC patients with severe disability experienced a 22% relative decrease in hospital readmissions (*P* = .03) vs. control group at 6 months, but it was not sustained at 12 months. Total mean per-person costs were 6.8% higher in the TM/HBPC group at 6 months ($19,190 vs. $17,971) and 12.1% higher at 12 months ($31,401 vs. $28,008 (*P* = .005).
Intrator and Berg 1998[47]	Hospitalization or nonskilled nursing facility admission	Retrospective cohort study	Observational study with controls. Outcomes: hospitalization and any nonskilled nursing facility admission.	324 patients age 70 or older who had acute hospitalization for hip fracture and were discharged to home after inpatient rehabilitation	1. Inpatient rehabilitation discharge with additional home care services 2. Inpatient rehabilitation with no additional home care	Patients who received additional home health care services (27.2%) were less likely to be hospitalized than those who received rehabilitation only (31.1%); they were also less likely to have a nonskilled nursing facility admission (11.3% vs. 23.3%), and more likely to survive the year with no subsequent Medicare claims (65.6% vs. 55%).

Table 3. Summary of Evidence Related to Unplanned Hospital Admission (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Jerant 2001[42]	Hospitalization for CHF and cost	Randomized controlled trial	Randomized controlled trial. Outcomes: CHF-related readmission charges and all-cause readmissions, emergency department (ED) visits, and associated charges	CHF patients discharged from 1 large medical center: n = 13 intervention (group 1), n = 12 intervention (group 2), and n = 12 control (group 3)	1. Home telecare 2. Telephone care 3. Usual care	Mean CHF-related readmission charges were 86% lower in the telecare intervention group and 84% lower in the telephone group than in the usual care group. The between-group difference was not statistically significant. Both intervention groups had significantly fewer CHF-related ED visits (*P* = 0.0342) and charges (*P* = 0.0487) than the usual care group. There was no statistically significant difference in all-cause readmissions between groups.
Naylor 2004[40]	Hospitalization (See also Table 5)	Randomized controlled trial	Randomized controlled trial. Outcomes: time to first hospitalization, number of hospitalizations, and costs	Patients age 65 and older from 6 academic and community hospitals, n = 118 intervention and n = 121 control	1. APN transitional care from hospital to home care 2. Routine care (58% received skilled home care services)	First time to readmission was longer for intervention (*P* = .026); intervention group had fewer readmissions at 52 weeks (104 vs. 162, *P* = .047) and lower mean cost ($7,636 vs. $12,481, *P* = .002).
Neff 2003[46]	Hospitalization, acute care, and emergency room visits (See also Table 5)	Nonrandomized controlled trial	Nonrandomized controlled trial. Outcomes: length of stay, hospitalization, emergent care.	Medicare patients age 62 or older, from a large home care agency, with a primary or secondary diagnosis of COPD, n = 39 control and n = 41 intervention	1.Transitional care APN model with pulmonary disease management team 2. Routine home care	Intervention group patients had a shorter length of stay (*P* < .05). Fewer rehospitalizations and acute care visits (*P* < .05) and more remained at home (*P* < .05).

Table 3. Summary of Evidence Related to Unplanned Hospital Admission (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rich 1995[43]	Hospitalization (See also Table 5)	Randomized controlled trial	Randomized controlled trial. Outcomes: hospital readmissions and cost.	Patients age 70 and older hospitalized with CHF in a large urban hospital, n = 142 intervention and n = 140 control	1. Intensive multidisciplinary inpatient intervention by specialized geriatric team, discharged with home care and telephone followup by research team member 2. Usual care	Intervention group had greater 90-day survival without readmission (66.9% vs. 54.3% for control; (*P* = .040) and had fewer readmissions for CHF (*P* = .04). Cost of hospital readmissions were higher in control group by an average of $1,058 per patient ($3,236 vs. $2,178, *P* = .03).
Shaughnessy 2002[2]	Hospitalizations (See also Table 5)	Pretest and post-test study	Observational study with control. Outcomes: measures of hospitalizations	2 groups of home care agencies 73 OBQI agencies (263,465 patients) intervention Non-OBQI agencies (248,621 patients) control	1. Clinical and administrative OBQI intervention at demonstration agencies, patient outcome reports for comparison with a reference population 2. Control: usual care	The intervention group had a decline in hospitalizations over a 3 and 4 year period (*P* < .001) with OBQI.

Nurse Work Environment

Evidence from the acute care setting suggests a relationship between nurses' work environment, patient safety, and quality of patient care.[49–51] A positive work environment is one that supports nurse autonomy and control over the work environment, including shared governance or decisionmaking.[52–55] It is an environment with strong and visible nursing leadership, organizational support, peer support, and positive physician collaboration.[53–55]

Research exploring the relationship of the work environment, patient safety, and quality in home health care is in early stages of development. There have been no randomized controlled studies to date. Feldman and colleagues[56] examined the relationship of patient adverse events with characteristics of the nurses' work environment at one very large urban home health care agency. Characteristics of 86 home health care teams within the agency were examined. Researchers reported that adverse events were lower for teams with higher patient volume and visits, fewer weekend admissions, more equitably distributed incentives, and more teamwork. Rates were higher when teams perceived supervisor support for adverse event reporting. This is the first rigorous study to identify organizational factors associated with potential adverse events, and there were limitations. It was a descriptive, correlational study, and the agency involved in the study is not typical of most agencies in the United States as it serves a disproportionately diverse urban population. Several of the findings approached significance only at a probability level (alpha) of 0.10.

Kroposki and Alexander[57] explored the relationships among patient satisfaction, nurse perception of patient outcomes, and organizational structure in a descriptive study. They reported that higher patient satisfaction scores were more likely in home health care agencies where nurses and supervisors had good working relationships, opportunity for shared decisionmaking was present, and formalization of organizational and professional guidelines existed. Limitations of this study included its descriptive, nonrandomized design of multiple agencies from one State and the lack of a reliable and validated tool to measure nurse perception of patient outcomes. Findings are summarized in Table 4.

Evidence-Based Practice Implications

Agencies should consider how characteristics of the work environment may be influencing patient safety and quality outcomes. It is necessary to explore the context of the environment when examining clinicians' practices in an effort to identify necessary system changes.

Research Implications

It is not known what characteristics of the home health care nursing work environment are related to patient safety and quality. Home health care research is needed to investigate the relationship of work environment characteristics, nurse satisfaction, and patient outcomes.

Table 4. Summary of Evidence Related to Nurse Work Environment

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Feldman 2001–2005[56]	Adverse events	Prospective cohort study	Observational study with controls. Outcomes: team-attributable patient adverse events.	51,560 patient care episodes from the largest U.S. home care agency with average age of patient 71 years	86 home care teams Staff perception of work environment, especially aspects of organizational and team culture climate	7% of the 51,560 episodes had an adverse event. Adverse events were lower for teams with higher volume of patient care episodes ($P \leq .05$), higher concentration of visits among staff ($P \leq .10$), fewer weekend admissions ($P \leq .01$), more weekend visits ($P \leq .01$), in noncongregate care setting ($P \leq .10$), and more care provided by nurses without bachelor's or higher education ($P \leq .10$). Adverse events were lower for teams with greater equity in distribution of incentives ($P \leq .10$), more teamwork ($P \leq .10$).
Kroposki and Alexander 2006[57]	Relationship of patient satisfaction, nurse perception of outcomes, and organizational characteristics	Cross-sectional study	Observational study with controls. Outcomes: relationship of nurse perception of outcomes and organizational structure to patient satisfaction.	Convenience sample of 325 patients and 205 nurses from 38 home care agencies in a southeastern State	Evaluation of patient satisfaction, nurse perception of patient outcomes, and organizational structure	Significant correlation between nurses' ability to meet client's psychosocial needs and patient satisfaction ($P < .05$). No other relationships existed between client satisfaction and outcome inventory components. There was a significant positive relationship between organizational attributes and patient satisfaction in agencies with shared decisionmaking and open communication ($P < .05$) and formal rules and procedures ($P < .05$).

Functional Outcomes and Quality of Life

The goal of care provided in the home is to restore or maintain patient physical and mental functioning and quality of life, or to slow the rate of decline to allow the patient to remain at home and avoid institutionalization. Most patients and family members prefer the home environment, when it is feasible. A patient's and family's ability to function independently and safely in the home increases the possibility of the patient remaining there.

Improving patient safety and quality of care by educating and assisting caregivers (families and providers) is an approach tested in several randomized controlled trials. The findings are summarized in Table 5. Archbold and colleagues[58] pilot tested preparedness, enrichment, and predictability (PREP), a formal nursing intervention designed to prepare family caregivers to provide care. While the study had many limitations, preliminary evidence on the effectiveness of the intervention suggests that families benefit from being informed and prepared.

Other researchers have tested interventions to improve nurse providers' knowledge and awareness.[59–61] Intervention studies to educate and inform nurse providers have been conducted in small and large urban and rural home health care settings, with nurses randomly assigned to an intervention group or a control group. The interventions generally provided nurses with additional education, extra resources for patients, and specialized patient information. In one frequently reported study, evidence-based care with specific disease-related information was sent to nurses by "just-in-time" e-mail reminders.[59, 60]

In all cases the interventions improved nurses' performance, which resulted in better patient outcomes. Patients of nurses in these studies showed significant improvement in pain management, quality of life, satisfaction with care, and other variables associated with improved quality of care, including better communication with providers, better medication management, and improved disease symptoms. Nurses' improved performance included increased documentation of critical patient assessments. In the case of "just-in-time" e-mail reminders, the intervention group that had additional clinical and patient resources had better patient outcomes, suggesting that the multifaceted approach or stronger dose of the intervention was more effective.

A number of randomized controlled trials have tested the effectiveness of specific interventions to improve patient safety and quality in disease management,[62, 63] urinary incontinence,[64, 65] level of ADL functioning,[44, 46, 66–68] quality of life, general health outcomes, and patient satisfaction.[44, 46, 59, 62, 66–70] Corbett[63] demonstrated that individualized patient education in foot care for diabetics was effective in improving patients' self-care. Scott and colleagues[62] demonstrated an improvement in quality of life in patients with CHF though a program of patient education and mutual goal setting. Dougherty and colleagues[64] and McDowell and colleagues[65] tested behavioral management interventions to treat urinary incontinence in the elderly and reported positive results based on behavior management interventions of self-monitoring and bladder training. Mann and colleagues[67] tested the introduction of assistive technology (canes, walkers, and bath benches) and changes made to the home environment (adding ramps, lowering cabinets, and removing throw rugs) with populations of frail elderly. These interventions were successful in slowing functional decline in the study patients.

Some of the research evidence suggests more efficient mechanisms for providing care. In exploring the amount of care that is effective, Weaver and colleagues[71] decreased (compared

with usual care) the number of post-hospitalization visits by patients with knee and hip replacements and added one preoperative home visit. No differences in functional ability, quality of life, or level of satisfaction between those patients receiving usual care (more visits) and those receiving the intervention (fewer postoperative visits and one preoperative visit) were found. Several studies have examined the use of technology in patient functioning and independence. Johnston and colleagues[69] tested real-time video nursing visits and found no difference in patient outcomes or level of satisfaction with usual care or care enhanced by video technology.

A number of randomized controlled trials have tested the outcomes of interventions based on the specialty of the provider combined with different models of care management, or interventions based solely on different models of care management.[44, 46, 65, 70, 71] Research examining the effect of APN providers on the quality of patient care suggests they have a positive effect. In two studies testing the transitional care model, APN-directed teams delivered care to patients with COPD[46] and CHF[70] and found improvements in the group in the transitional care model. Patients experienced fewer depressive symptoms and an increase in functional abilities when compared with patients receiving usual care.[46, 70] Patients in these studies also needed fewer nursing visits, had fewer unplanned hospital admissions, and had fewer acute care visits. A nurse practitioner's urinary incontinence behavioral therapy was effective in decreasing the number of patients' urinary incontinence accidents.[65] The Veterans Affairs Team-Managed Home-Based Primary Care was an add-on to care routinely provided in the Veterans Affairs Home-Based Primary Care program.[44] The added component emphasized continuity of care and team management with a primary care manager, 24-hour on-call nursing availability for patients, prior approval of hospital admissions, and team participation in discharge planning. The investigators found significant improvements in quality of life, functioning, pain management, and general health outcomes for terminally ill patients in this study, and an increase in satisfaction for nonterminally ill patients and family caregivers.

However, mixed results have been obtained from the research to date on the effectiveness of models of care management.[66, 68] Some intervention models have been less effective than others. The interventions are usually an add-on to routine care, and their effectiveness has been determined by a comparison to a control group of usual or routine home health care. An intervention model that does not appear to be effective is the Health Outcomes Management and Evaluation model tested by Feldman and colleagues[66] This model adds a consumer-oriented patient self-care guide and training to improve nurses' teaching and support skills. Study results showed no difference in patient quality of life or satisfaction. Tinetti and colleagues[68] compared the outcomes of a systematic, multicomponent rehabilitation program, including therapies for physical and functional impairments, to the outcomes from usual home-based rehabilitation care. No differences were found between the two groups.

Evidence-Based Practice Implications

The preceding discussion suggests that working closely with and supporting family caregivers is, and will continue to be, an important aspect of helping patients to remain in their homes. It also suggests that nurses' effectiveness in working with patients can be enhanced if nurses are supported in their work. Support can be provided by electronic communication, reminders of protocols, disease-specific educational materials for patients, and working with APN colleagues to serve as clinical experts for staff. Home health care nurses are relatively isolated in the field, and any mechanism to improve communication with supervisors in the office and with other providers will assist nurses in their practice. Incorporating the use of

remote technology to substitute for some in-person visits can improve access to home health care staff for patients and caregivers.[69]

Specific patient interventions can be helpful in improving patient health and quality of life. Interventions of individualized education and disease-specific programs, such as a behavioral management program for urinary incontinence or educational programs for foot care, should be incorporated into practice. The rate of a patient's functional decline can be slowed and costs reduced through a systematic approach to providing assistive technology and environmental interventions to frail elderly patients in their homes. A patient's need for these interventions can be determined with a comprehensive assessment and continued monitoring.

Research Implications

Evidence of the outcomes of health care provided in the home is limited; there are very few controlled experiments on which providers can base their practice. Research is limited in the areas of composition, duration, and amount of home health care services needed to ensure patient safety and quality. Research is needed to determine effective interventions to improve, maintain, or slow the decline of functioning in the home health care population.

More research is also needed to determine mechanisms to keep nurses informed and supported. Providing communication and support is a challenge when providers are geographically dispersed and spend most of their time in the field. Remote technology has the potential to reduce costs: it can substitute for some in-person visits, and it can improve access to home health care staff for patients and caregivers.

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Archbold 1995[58]	Family preparedness	Quasi-experimental retrospective without a control group	Nonrandom trial. Outcomes: care effectiveness scale, indicating greater preparedness, enrichment, and predictability.	Caregiver families referred to home care agency: n = 11 intervention and n = 11 standard home care	1. Nursing interventions, designed to increase preparedness (PR), enrichment (E), and predictability (P) in families providing care to older people. 2. Comparison	Intervention (PREP) group one standard deviation higher than the control group (*P* < .05), rated their assistance from PREP nurses significantly higher (*P* < .01); had lower mean hospital costs ($2,775) versus comparison group ($6,929).
Corbett 2003[63]	Diabetic foot care	Randomized controlled trial, pre/post-test	Randomized controlled trial pre/post test. Outcomes: patient self-report knowledge.	40 home care patients with diabetes from 1 home care agency, 2 groups	1. Intervention: individualized education about proper foot care 2. Control	The educational intervention improved patient's knowledge, confidence, and reported foot care behaviors.
Dougherty 2002[64]	Urinary incontinence	Randomized controlled trial	Randomized controlled trial Outcomes: severity and episodes of urine loss—frequency, interval, and quality of life.	218 older women from 7 rural counties in north Florida	1.Behavior management program—self-monitoring and bladder training 2. Control	Intervention group incontinence severity decreased by 61%. Control group incontinence severity increased by 184%.

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Feldman 2004[66]	Quality of life and patient satisfaction with care	Randomized controlled trial	Random assignment of nurses. Outcomes: service use and quality of life, satisfaction with care.	371 patients with CHF and 205 nurses from a large, urban, nonprofit home care agency	1. Formal nurse protocol of "Health Outcomes Management & Evaluation," patient self-care guide, and nurse training in teaching and support skills 2. Usual care	No difference in physician visit, patient mortality, quality of life, or patient satisfaction.
Feldman 2005[60]	Functional status, quality of life, and service use (see also Table 3)	Randomized controlled trial	Randomized controlled trial Outcome: clinical, functional, and quality of life status.	1,242 patients from a large, urban, nonprofit home care agency: 390 basic 404 augmented 448 control	1. Nurse e-mails highlighting clinical recom-mendations 2 Augmented: e-mails and additional clinician and patient resources 3. Usual care	Both intervention groups demonstrated improved patient clinical and functional outcomes (symptoms, physical limitations, quality of life, and social limitations) ($P \leq .05$). Both intervention groups demonstrated better management of medications ($P \leq .05$) Intervention group 1 scored higher on quality of life relative to control ($P \leq .05$).

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hughes 2000[45]	Functional ability, quality of life, patient satisfaction, and cost (see also Table 3)	Randomized controlled trial	Randomized controlled trial. Patient functional status, patient and caregiver HR-QoL and satisfaction, caregiver burden, hospital readmissions, and costs over 12 months.	1,966 patients average age of 70 with 2 or more ADL impairments or terminally ill, CHF or COPD 981intervention 985 control	1. Home-Based Primary Care: with team manager, 24-hour contact, prior approval readmissions, and team discharge planning 2. Home-Based Primary Care VA and private sector care	Significant improvements were seen in terminal intervention group (TM/HBPC) patients in HR-QoL scales of emotional role function, social function, bodily pain, mental health, vitality, and general health. TM/HBPC nonterminal patients had significant increases of 5 to 10 points in 5 of 6 satisfaction-with-care scales. The caregivers of terminal patients in the TM/HBPC group improved significantly in HR-QoL measures. Caregivers of nonterminal patients improved significantly in QoL measures and reported reduced caregiver burden (*P* = .008).
Johnston 2000[69]	Quality of patient care and cost	Quasi-experimental study with random assignment	Randomized controlled trial. Outcomes: medication compliance, knowledge of disease, self-care ability, service use, patient satisfaction, and costs.	212 patients with CHF, COPD, cerebral vascular accident, cancer, diabetes, anxiety, or need for wound care	1. Routine care and video visits, nurses and patients interact in real time, included equipment for assessing cardiopulmonary status 2. Routine care	No differences in the intervention or control groups in quality indicators, patient satisfaction, or use. No health care cost savings realized.

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mann 1999[67]	Functional ability (independence), quality of life (pain reduction), and costs	Randomized controlled trial	Randomized controlled trial. Functioning and pain, measured with valid and reliable instruments; health care costs.	Frail elderly persons referred from community agencies, hospitals, and home care agencies in New York State: n = 52 intervention, n = 52 control	1.Usual care, assistive technology, (canes, walkers, etc.), and environmental interventions (ramps, removal of rugs, etc.) 2. Usual care control	Both groups showed significant decline in functional motor score, with a significantly greater decline for the control group. Pain scores were significantly higher for the control group. Treatment group expended more costs than the control group. Control group had significantly more expenditures for institutional care and significantly greater expenditures for nurse visits and case manager visits.
McDonald 2005[59]	Quality of life (pain management) through provider behavior change	Randomized controlled trial	Randomized controlled trial. Outcome measure: Estimate of treatment effect on nurse-documented care practices and patient's pain management.	Nurses, from a large, urban, nonprofit home care agency: n = 121 basic, n = 97 augmented, and n = 118 control	1. Basic group – nurse e-mails highlighting clinical recom-mendations 2 Augmented group – additional clinician and patient resources 3. Usual care	Patients in augmented intervention improved significantly over the control in ratings of pain intensity at its worse (P = 0.05). Patients in basic intervention had better ratings of pain intensity on average (P < 0.05). In both intervention groups, evidence of nurse assessment increased.

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
McDowell 1999[65]	Functional ability (urinary continence)	Prospective, randomized controlled clinical trial with cross-over design	Randomized controlled trial, observational study with controls. Outcomes: bladder diaries, urinary accidents	Home health care patients ages 60 and older with urinary incontinence: n = 53 intervention, n = 52 control	1. Nurse practitioner delivered behavioral therapy of biofeedback-assisted pelvic floor muscle training, urge and stress strategies, and bladder retraining 2. Control	Intervention group had a significantly greater reeducation in urinary accidents per day ($P < .001$). Average number of accidents decreased from 4.0 to 1.7 after treatment ($P < .001$).
Naylor 2004[40]	Mortality, quality of life, and satisfaction	Randomized controlled trial	Randomized controlled clinical trial. Outcomes: patient report, physical and emotional quality of life, functional status, and satisfaction.	Patients 65 years of age or older with CHF discharged from Philadelphia academic and community hospitals: n = 118 intervention, n = 121 control	1.Transitional care intervention – 3-month APN-directed discharge plan and home care followup 2. routine care (1/2 home care)	Intervention had improvement in quality of life ($P < .05$), in functioning ($P < .05$), and in satisfaction ($P < .001$) vs. control group.
Neff 2003[46]	Quality of patient outcomes	Non-randomized trial controlled	Nonrandomized controlled trial. Outcomes: ADLs, IADLs, dyspnea, anxiety, and depression	Medicare patients from a large home care agency: n = 41 urban control group n = 39 rural	1.Transitional Care Model: APN pulmonary disease management team 2. Routine home care	Intervention group experienced fewer depressive feelings ($P < .05$) and better ADL status ($P < .05$). There were no differences in IADLs or dyspnea in the groups.
Scott 2004[62]	Quality of life and mental health	Randomized controlled trial	Randomized controlled trial. Outcomes: Mental Health Inventory and Quality of Life Index.	88 patients with heart failure from 2 nonprofit home care agencies in the Midwest	All got routine care and 1.Mutual goal setting, 2. Supportive educative 3. Placebo	Mutual goal setting group had significantly higher mental health scores ($P = .003$) at 6 months. Mutual goal setting and supportive education groups had significantly higher quality of life ($P = .01$) at 6 months.

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Tinetti 1999[68]	Functional status – self-care ADLs	Randomized controlled trial	Randomized controlled trial. Outcomes: a battery of self-report and performance-based measures of physical and social function.	304 persons age 65 who had undergone surgical repair of a hip fracture at two hospitals in New Haven, CT, from 27 home care agencies	1. Systematic multicomponent rehabilitation strategy addressing both modifiable physical impairments (physical therapy) and ADL disabilities (functional therapy) 2. Usual care	There was no significant difference in the proportion of participants in the two groups who recovered to prefracture levels in self-care ADL at 6 months (71% vs. 75%) or 12 months (74% in both groups), or in home management ADL at 6 months (35% vs. 44%) or 12 months (44% vs. 48%). There also was no difference between the two groups in social activity levels, two timed mobility tasks, balance, or lower extremity strength at either 6 or 12 months. Compared with participants who received usual care, those in the multicomponent rehabilitation program showed slightly greater upper extremity strength at 6 months (P = .04) and a marginally better gait performance (P = .08).
Vallerand 2004[61]	Quality of life (pain management)	Longitudinal, multilevel, randomized controlled trial	Randomized controlled trial. Outcomes: nurse knowledge and attitudes of pain management, patient's self-reported pain level.	Home care nurses: n = 100 intervention, n = 102 control, from 11 home care agencies in Midwest United States 5 intervention 6 control	1. Nurse education program – Power over Pain (POP) 2. Control	Patients of nurses' intervention group self-report worst pain scores decreased significantly (P < 0.04). Nurses' intervention group had significantly improved knowledge, attitudes, and perception of control over pain (P < 0.05).

Table 5. Summary of Evidence Related to Functional Outcomes and Quality of Life (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weaver 2003[71]	Functional status and quality of life	Randomized controlled trial	Randomized controlled trial. Outcomes: functional status, lower extremity functioning, health-related quality of life, satisfaction, use, and cost.	136 patients with surgical hip or knee replacements from a hospital home care agency.	1. Pre-op visit by nurse and physical therapist, 9 to 12 post-op home visits 2. Usual protocol with more visits (11 to 47)	There was no difference in functioning, quality of life, or satisfaction. Intervention group costs were 55% lower than control (due to fewer visits).

Wound and Pressure Ulcer Management

Adverse wound events are monitored under the OBQM program. Emergent care for wound infections, deteriorating wound status, and increase in the number of pressure ulcers are monitored and reported as adverse events.[70] The data are used to reflect a change in a patient's health status at two or more times, usually between home health care admission and transfer to a hospital or other health care setting. Data for these outcomes are collected using OASIS-designated intervals. Patient outcome measures related to surgical wounds that are monitored under the OBQI include improvement in the number of surgical wounds and improvement in the status of surgical wounds.[18]

Wound Management

Over a third of home health care patients require treatment for wounds, and nearly 42 percent of those with wounds have multiple wounds. Over 60 percent of wounds seen in home health care are surgical, while just under one-quarter are vascular leg ulcers and another one-quarter are pressure ulcers.[71] Most home health care nurses can accurately identify wound bed and periwound characteristics; the majority (88 percent) of wound treatments have been found to be appropriate.[72] The appropriateness of wound treatments in home health care is significantly related to wound healing. Patients with healing wounds had shorter home health care visits and shorter home health care lengths of stay.[71]

A literature review identified seven studies that tested interventions to improve wound care management in home health care.[73–79] Findings are summarized in Table 6. Three compared effectiveness of various wound treatments. Capasso and Munro[74] found no significant difference in wound closure between amorphous hydrogel dressings and wet-to-dry saline dressings, but costs were found to be significantly higher for the saline dressings due to the need for more nursing visits. Kerstein and Gahtan[76] found the percentage of venous leg ulcers healed using hydrocolloidal dressings was six times higher than with saline gauze dressings and nearly four times greater using an Unna boot; the hydrocolloidal dressings were most cost-effective. Use of negative pressure wound therapy resulted in successful closure of 43 percent of wounds that failed to respond to previous treatment.[78]

Four studies reported positive outcomes from interventions to improve and support home health care nurse practice.[73, 75, 77, 79] Use of telemedicine to provide consultation with wound management experts resulted in improved healing rates, decreased healing time, and decreased home visits and hospitalizations related to wounds.[73, 77] Fellows and Crestodina[75] studied the rate of bacterial contamination of normal saline solutions prepared from distilled water and table salt, a practice common for wound care in the home, and found refrigerated solutions essentially growth-free at 4 weeks. A quality improvement project reported a reduction in adverse events through structured nurse education, introduction of protocols, and competency review.[79]

Pressure Ulcer Management

Rodriques and Megie[80] found that 37 percent of wounds in home health care patients were pressure ulcers, with a mean wound duration of nearly 27 months. Nearly 1 in 10 patients admitted to home health care had pressure ulcers and approximately one-third were at risk of developing new ulcers; yet according to one study, only 27 percent of patients with existing

ulcers and 14 percent of those at risk were receiving appropriate pressure-reducing treatment.[81] Incontinence, limitations in ADLs, mobility impairment, skin drainage, recent fractures, anemia, use of oxygen, and recent institutional discharge were associated with pressure ulcer development.[81, 82] Guidelines from the Wound, Ostomy and Continence Nurses Society[83] call for an initial risk assessment for pressure ulcers of all patients on admission to home health care, and reassessment every visit thereafter, using a validated risk assessment tool. However, one study found that only 21 percent of agencies used a validated tool such as the Braden Scale[84] to identify patients at risk, nearly 8 percent performed no assessments on admission, and only 33 percent used risk prediction or pressure ulcer prevention protocols.[85] Just over half of agencies reported routine skin inspections by nurses of at-risk patients.

A literature review resulted in identification of five studies relating to pressure ulcer management in home health care. The findings are summarized in Table 7. Three studies were randomized controlled trials testing interventions to improve pressure ulcer healing.[86–88] One intervention tested the use of air-fluidized bed therapy with services of a nurse specialist;[87] a second intervention used noncontact normothermic wound therapy.[88] Both resulted in significant improvement in wound healing compared to conventional moist dressings. Overall healing rates were similar for polymer hydrogel and hydrocolloidal dressings, although debridement performance of the hydrogel dressing resulted in more favorable clinical evaluation.[86]

The remaining two studies evaluated the use of the Braden Scale for prediction of pressure ulcer risk in home health care patients, with mixed results. Ramundo[89] reported that the Braden Scale had validity in identifying at-risk patients, but limited predictive ability, while Bergquist[82] found that the summative score of the scale was significantly associated with pressure ulcer development. All subscale scores except nutrition were significantly and negatively associated with pressure ulcer development.

Evidence-Based Practice Implications

When compared with wet-to-dry or moist saline dressings, most wound treatments tested showed greater effectiveness or lower cost. Home health care nurses should be knowledgeable in the use of the full range of existing and emerging wound products, practices, and treatments and demonstrate skill in accurate wound assessment and staging. Provision of structured resources, expert consultation, and competency testing for home health care nurses can improve home health care wound management. Nurses must be knowledgeable in risk factors for pressure ulcer development and relevant preventive measures; they must assess every patient using a valid and reliable instrument, such as the Braden Scale, on admission to home health care and regularly thereafter.

Research Implications

Relatively little is known about the most effective practices for wound care in the home health care setting. Although studies have compared different treatments for wounds, the most efficacious treatments for different wounds are unknown in the presence of various risk factors found in the home health care setting. Randomized controlled clinical trials exist comparing different pressure ulcer treatments in the home, with the exception of care of other types of wounds. Promising findings from studies with small sample sizes should be replicated with larger samples and diverse populations.

Table 6. Summary of Evidence Related to Wound Management

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Capasso and Munro 2003[74]	Wound management, treatment, and cost	Retrospective cohort study	Observational study with control (Level 4) Outcomes: wound size, predominant tissue type, type of exudates; cost of treatment.	Patients 25 years of age or more with superficial wounds without undermined areas: 1. Arterial surgical wound dehiscence or 2. Nonhealing arterial or diabetic ulcerations In 3 home care agencies, n = 25 intervention, n = 25 control	1. Amorphous hydrogel dressings 2. Control wet-to-dry normal saline gauze dressings	No significant difference found in the rate of wound closure between the two types of dressings (*P* = .66). Costs were significantly higher (*P*= .006) for control ($3,774) than for the intervention dressings ($2,634) due to significantly higher numbers of required nursing visits (*P* = .003). There was no significant difference in the cost of wound care supplies.
Fellows and Crestodina 2006[75]	Wound management, treatment, and cost	Nonrandomized trial	Nonrandomized trial. Outcomes: bacterial growth on agar-agar plate (Level 2)	7 1-gallon jugs of normal saline prepared from distilled water with 8 tsp of table salt added	Saline solutions were tested for bacterial growth at 1-week intervals for 4 weeks or until growth appeared. 1. Researcher prepared, nonrefrigerated (2) 2. Researcher prepared, refrigerated (2) 3. Patient prepared, refrigerated (3)	Researcher-prepared, nonrefrigerated saline preparations showed bacterial growth in 2 weeks compared to refrigerated solutions, which remained bacteria-free at 4 weeks. Two patient-prepared, refrigerated solutions remained bacteria-free at 4 weeks, while the third showed trace growth.

Table 6. Summary of Evidence Related to Wound Management (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kerstein and Gahtan 2000[76]	Wound management, treatment, and cost	Nonrandomized controlled trial	Nonrandomized trial. Outcomes: complete wound healing, recurrence, and cost of treatment.	81 patients with venous ulcers, 47 in a home care agency and 34 seen in a physician's office n = 32 intervention (group 1) n = 33 intervention (group 2) n = 16 intervention (group 3)	1. Hydrocolloidal dressing and compression hosiery 2. Unna's boot 3. Saline gauze dressing and compression hosiery	13% of ulcers in the first intervention group did not heal or recur, compared to 21% of ulcers in the second intervention group and 88% percent in the third group. Hydrocolloid dressings were more cost effective than Unna's boot or saline-gauze dressings. No difference was found between home care or physician's office outcomes. Patients preferred home care, but costs were higher.
Kobza and Scheurich 2000[77]	Wound management, provider support	Nonrandomized controlled trial	Nonrandomized controlled trial. Outcomes: healing rates, average weeks to healing, average visits per wound patient, condition on discharge from home health.	76 patients ages 28 to 94 with Stage III or IV pressure ulcer, diabetic foot ulcer, venous stasis ulcer, or with orders for twice-daily dressing change (191 wounds), urban and suburban hospital-based home care agencies	Two-way in-home video visit via telemedicine for wound specialist with home health nurse present to evaluate wound and recommend treatment Baseline retrospective patient sample per agency	Intervention resulted in improved healing rates for all wounds except Stage III pressure ulcers; decreased average healing time for all wound categories; 58% discharges with wounds healed/ healing compared to baseline control of 37%; decreased average number of home health visits to 33 from 60 per patient; and a decreased number of hospitalizations related to wound complications of 6% with intervention from 18% at baseline.

Table 6. Summary of Evidence Related to Wound Management (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Philbeck 1999[78]	Wound management, treatment	Nonrandomized controlled trial	Nonrandomized controlled trial. Outcomes: reduction in wound area over time, wound volume, and healing rate; cost of treatment	1,032 Medicare home care patients with 1,170 wounds failing to respond to previous intervention; 989 wounds over 30 days old, 566 were Stage III or IV pressure ulcers	Negative pressure wound therapy	498 (43%) of wounds resulted in successful closure with intervention; 145 (12%) showed no improvement. Intervention averaged 57 days and resulted in average reduction of wound area and volume.
Sturkey 2005[79]	Wound management, provider support	Quality improvement project	Observational study comparing pre- and postintervention. Outcomes: OASIS Adverse Event Outcome Reports "Emergent Care for Wound Infection/ Deteriorating Wound Status"; number of visits required for wound care; State survey and JCAHO/Medicare survey observed breaches in infection-control practices.	One home care agency, Georgia	Educational program including best practice video and skills laboratory; education on wound care staging, healing and appropriate protocols; observation of actual practice in home using competency skills checklist; certification in negative wound pressure therapy	Adverse Event Outcome Reports, Emergent Care for Wound Infection/ Deteriorating Wound Status improved from 1.83% to 1.09%, compared to a national average of 1.27%; decreased average visits for wound patients by 30%; achieved no breaches observed during State or JCAHO survey visits.

Table 7. Summary of Evidence Related to Pressure Ulcer Management

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Berquist 2001[82]	Pressure ulcer management, prediction	Retrospective cohort study.	Retrospective cohort study without controls. Outcome measure: development of Stage I to IV pressure ulcers or no ulcer development.	1,684 patients age 60 years or older without pressure ulcers on admission, with documented Braden Scale scores, one large Midwestern urban home care agency	None	Braden Scale summative scores were significantly lower for subjects who developed pressure ulcers than subjects remaining free of pressure ulcers ($P <$ .01). All subscale scores except nutrition were significantly and negatively associated with pressure ulcer development ($P <$ .01), but only the summative score remained significantly associated on completion of a backward stepwise procedure ($P <$ .001).
Motta 1999[86]	Pressure ulcer management, treatment	Randomized controlled trial	Randomized controlled trial. Outcomes: healing rate, debridement using Bates-Jensen Pressure Sore Status Tool	Home care patients with Stage II or III pressure ulcer, in home care setting: n = 5 intervention (group 1), n = 5 intervention (group 2)	1. Polymer hydrogel dressing 2. Hydrocolloidal dressing	The overall healing rate for the two groups was similar. Intervention 1 had more favorable overall clinical evaluation based largely on its autolytic debridement effect.
Ramundo 1995[89]	Pressure ulcer management, prediction	Prospective cohort study	Observational study with control. Outcomes: Braden Scale scores, development of pressure ulcers	48 newly admitted patients free of skin breakdown who were unable to leave bed or chair, one suburban, community-based home health care agency	None	7 patients (17%) developed pressure ulcers; Braden Scale scores ranged from 11 to 22. At a score of 18, sensitivity of the tool was 100%; however, specificity was only 34%, indicating that the scale has validity in identifying patients at risk, but has limited predictive ability in home health care.

Table 7. Summary of Evidence Related to Pressure Ulcer Management (continued)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Strauss 1991[87]	Pressure ulcer management, treatment	Randomized controlled trial	Randomized controlled trial. Outcomes: wound status, inpatient hospital days, inpatient hospital charges, Medicare DRG, and physician payments.	Patients with Stage III or IV pressure ulcers and severely limited mobility, in home care setting: n = 47 intervention, n = 50 control	36 weeks of treatment, either 1. Air-fluidized bed therapy with services of a visiting nurse specialist, or 2. Control – conventional therapies	A higher proportion of intervention patients were classified as improved without statistical significance. Intervention patients spent significantly fewer days in the hospital (11.4 vs. 25.5 days, $P < .01$) and used significantly fewer total inpatient resources ($P < .05$). Total inpatient and outpatient resource utilization was lower, but not significant.
Whitney 2001[88]	Pressure ulcer management, treatment	Randomized controlled trial	Randomized controlled trial. Outcomes: wound healing and periwound temperature changes, measured using valid, reliable instruments.	Patients, age 18 or older with Stage III or IV pressure ulcers in primary care, home care, acute care, or long-term care facilities: n = 15 intervention, n = 14 control	1. Noncontact normothermic wound therapy 2. Control – moist dressings	The intervention group healed significantly faster (P =.01), and average periwound temperature increased significantly (P = .001).

Conclusion

Home health care clinicians seek to provide high quality, safe care in ways that honor patient autonomy and accommodate the individual characteristics of each patient's home and family. Falls, declining functional abilities, pressure ulcers and nonhealing wounds, and adverse events related to medication administration all have the potential to result in unplanned hospital admissions. Such hospitalizations undermine the achievement of important home health care goals: keeping patients at home and promoting optimal well-being. Nevertheless, the unique characteristics of home health care may make it difficult to use—or necessary to alter—interventions that have been shown to be effective in other settings. Therefore, research on effective practices, conducted in home health care settings, is necessary to support excellent and evidence-based care.

In reviewing the extant studies, the authors of this chapter found useful evidence in all selected areas. However, the number of studies was few and many questions remain. Replications of investigations originally conducted in health care settings other than the home, and studies considering home health care-specific issues are needed to support evidence-based clinical decisions. The available evidence suggests that the work environment in which home health care nurses practice may indirectly influence patient outcomes in many areas, and that technology can be used to support positive patient outcomes. Thus, studies that link nurse-related variables to improved care safety and quality are needed, as well as studies that focus directly on patients. The demographics of an aging society will sustain the trend toward home-based care. Home health care practices grounded in careful research will sustain the patients and the clinicians who serve them. Given the focused review of evidence-based studies comprising this chapter, many informative sources of use to the practicing home health care nurse are omitted. Table 8 lists additional key resources.

Table 8. Additional Resources

Source	Area(s) Addressed	Web Access
AHRQ Electronic Catalog	Pressure ulcer treatment	http://www.ahrq.gov/gils/00000108.htm http://www.ahrq.gov/gils/00000109.htm http://www.ahrq.gov/gils/00000110.htm
AHRQ Evidence-Based Practice Reports	Nurse work environment: Staffing and quality of patient care Wound healing technologies	http://www.ahrq.gov/clinic/tp/nursesttp.htm http://www.ahrq.gov/clinic/tp/woundtp.htm
AHRQ National Guideline Clearinghouse	Medication management Fall assessment and management Functional outcomes and quality of life: Continence promotion Diabetic foot complication prevention, ulcer management Pain assessment and management Wound management, lower extremity: arterial disease, neuropathic disease, venous disease Pressure ulcers: prediction, prevention, and treatment	http://www.guideline.gov/browse/guideline_index.aspx
Home Health Quality Improvement National Campaign (HHQI) (development in process)	Medication management Fall prevention Unplanned hospital admissions	http://www.homehealthquality.org/hh/
Journal of Wound Care (UK)	Wounds and pressure ulcers	http://www.journalofwoundcare.com
Journal of Wound, Ostomy and Continence Nursing	Functional outcomes Continence Wounds and pressure ulcers	http://www.jwocnonline.com
MedPac Report to Congress, Chapter 5: Adding quality measures in home health	Fall prevention Wound care of pressure ulcers	www.medpac.gov/publications%5Ccongressional_reports%5CJun06_Ch05.pdf
National Pressure Ulcer Advisory Panel	Pressure ulcers	www.npuap.org
Ostomy Wound Management	Wound management	http://www.o-wm.com

Search Strategy

The literature review for this chapter focused on identifying evidence-based practices that supported the goals of home health care: to promote independent functioning; to remain at home, avoiding hospital or nursing home admission; and to achieve optimal well-being. The search was conducted using multiple variations of key terms informed by the characteristics of home health care described at the beginning of this chapter, adverse events used in the OBQM,[5] goals of the Home Health Quality Improvement National Campaign 2007,[14] and the nurse-sensitive quality indicators developed by the American Nurses Association.[15] The Cumulative Index to Nursing & Allied Health, Cochrane Library, Medline, and ProQuest Nursing & Allied Health databases were searched, as well as the grey literature and government Web sites, including the CMS and Agency for Healthcare Research and Quality. Hand searches were conducted of the reference lists of retrieved articles. Search limitations were English language, United States or Canada, peer-reviewed journals or scholarly literature, published between 1990 and the first quarter of 2007. Studies cited in the evidence table were accepted for review using the following inclusion criteria:

- The study was published between 1990 and the first quarter of 2007, inclusive.
- The research was conducted in the United States or Canada.
- The study included an intervention that directly or indirectly influenced a patient outcome.
- The intervention took place under the auspices of a home health care agency.
- Subjects in the study had to be home health care patients (not community-residing or outpatient ambulatory) and 18 years of age or greater.

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Chapter 14. Supporting Family Caregivers in Providing Care

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Background

Most patients have families that are providing some level of care and support. In the case of older adults and people with chronic disabilities of all ages, this "informal care" can be substantial in scope, intensity, and duration. Family caregiving raises safety issues in two ways that should concern nurses in all settings. First, caregivers are sometimes referred to as "secondary patients," who need and deserve protection and guidance. Research supporting this caregiver-as-client perspective focuses on ways to protect family caregivers' health and safety, because their caregiving demands place them at high risk for injury and adverse events. Second, family caregivers are unpaid providers who often need help to learn how to become competent, safe volunteer workers who can better protect their family members (i.e., the care recipients) from harm.

This chapter summarizes patient safety and quality evidence from both of these perspectives. The focus is on the adult caregiver who provides care and support primarily for adults with chronic illnesses and chronic health problems. The focus is not on those with developmental disabilities. In the first section, we discuss the evidence for protecting the caregiver from harm. The second section addresses research aimed at protecting the care recipient from an ill-prepared family caregiver.

Caregivers as Clients

For centuries, family members have provided care and support to each other during times of illness. What makes a family member a "family caregiver"? Who are these family caregivers, what do they do, and what harm do they face? What does the research tell us about ways to assess the needs of these hidden patients and evidence-based interventions to prevent or reduce potential injury and harm? This section answers these questions and highlights the need for nurses to proactively approach family caregivers as clients who need their support in their own right.

Description of Caregiver Population

The terms *family caregiver* and *informal caregiver* refer to an unpaid family member, friend, or neighbor who provides care to an individual who has an acute or chronic condition and needs assistance to manage a variety of tasks, from bathing, dressing, and taking medications to tube feeding and ventilator care. Recent surveys estimate there are 44 million caregivers over the age of 18 years (approximately one in every five adults).[1] The economic value of their unpaid work has been estimated at $257 billion in 2000 dollars.[2] Most caregivers are women who handle time-consuming and difficult tasks like personal care.[3] But at least 40 percent of caregivers are men,[3] a growing trend demonstrated by a 50 percent increase in male caregivers between 1984

and 1994.[4] These male caregivers are becoming more involved in complex tasks like managing finances and arranging care, as well as direct assistance with more personal care.[5] Nurses are likely to see many of these caregivers, although many of them will not identify themselves as a caregiver.

Those caring for someone 50 years or older are 47 years old—on average—and working at least part-time.[1] If they are providing care to an elder who is 65 years or older, they are, on average, 63 years old themselves and caring for a spouse; one-third of these caregivers are in fair to poor health themselves.[6] In many cases, they are alone in this work. About two out of three older care recipients get help from only one unpaid caregiver.[7] In the last decade, the proportion of older persons with disabilities who rely solely on family care has increased dramatically—nearly two-thirds of older adults who need help get no help from formal sources.[4]

Caregiver Responsibilities

Caregivers spend a substantial amount of time interacting with their care recipients, while providing care in a wide range of activities. Nurses have a limited view of this interaction. Caregiving can last for a short period of postacute care, especially after a hospitalization, to more than 40 years of ongoing care for a person with chronic care needs. On average, informal caregivers devote 4.3 years to this work.[8] Four out of 10 caregivers spend 5 or more years providing support, and 2 out of 10 have spent a decade or more of their lives caring for their family member.[9] This is a day-in, day-out responsibility. More than half of family caregivers provide 8 hours of care or more every week, and one in five provides more than 40 hours per week.[1]

Most researchers in the caregiving field conceptualize the care that family members give as assistance with activities of daily living (ADLs) and instrumental activities of daily living (IADLs). But those concepts do not adequately capture the complexity and stressfulness of caregiving.[9] Assistance with bathing does not capture bathing a person who is resisting a bath.[10, 11] Helping with medications does not adequately capture the hassles of medication administration,[12] especially when the care recipient is receiving multiple medications several times a day, including injections, inhalers, eye drops, and crushed tablets. The need to make decisions on behalf of family members who are unable to do so is stressful, as this is contrary to the caregivers' normal role, and they are concerned that the decisions are correct. Supervising people with dementia and observing for early signs of problems, such as medication side effects, are serious responsibilities as family members are often unable to interpret the meaning or the urgency. The medical technology that is now part of home care and the frustrations of navigating the health care system for help of any kind is not even part of the ADL/IADL measures.[13] Being responsible for medical and nursing procedures like managing urinary catheters, skin care around a central line, gastrostomy tube feedings, and ventilators is anxiety provoking for the novice nursing student, but is becoming routine family care of persons with chronic illnesses living at home.

Family caregivers often feel unprepared to provide care, have inadequate knowledge to deliver proper care, and receive little guidance from the formal health care providers.[14-16] Nurses and family caregivers rarely agree about specific needs or problems during hospital admission or discharge,[17] in part because nurses are often unaware of the strengths and weaknesses of both the patient and caregiver. Due to inadequate knowledge and skill, family caregivers may be unfamiliar with the type of care they must provide or the amount of care needed. Family caregivers may not know when they need community resources, and then may not know how to

access and best utilize available resources.[18] As a result, caregivers often neglect their own health care needs in order to assist their family member, causing deterioration in the caregiver's health and well-being.[19-21]

Caregivers get very little help from health care professionals in managing their tasks and the emotional demands of caregiving. Among the greatest challenges for family caregivers is interacting with nurses and other professionals in the hospital setting, and a rough crossing back home, as the patient is "discharged to family."[22] Naylor's review[23] of nearly 100 studies published between 1985 and 2001 confirms that breakdowns in care during the transition from hospital to home result in negative outcomes. Health professionals in emergency departments and inpatient hospital settings do not adequately determine the after-care needs of older patients when they are being discharged.

Effective discharge planning is impeded by gaps in communication between the hospital and community interface, such as illegible discharge summaries and delays in sending information to the physician.[24] Focus groups of caregivers found that they experience their family member's discharge from the hospital as an abrupt and upsetting event because the hospital staff did not prepare them for the technical and emotional challenges ahead of them. Many caregivers felt abandoned at a critical time, and none of the focus group participants had been referred by any health care professional in the hospital to community-based organizations for emotional support—or any other kind of support.[22]

Hazards of Caregiving

Health professionals' lack of explicit attention to caregivers is a serious gap in health care in light of the more than two decades of research that documents the potential hazards of family caregiving. Caregivers are hidden patients themselves, with serious adverse physical and mental health consequences from their physically and emotionally demanding work as caregivers and reduced attention to their own health and health care.

Declines in physical health and premature death among caregivers in general have been reported.[21, 25] Given and colleagues[18, 19] and Kurtz and colleagues[26] found that family caregivers experience significant negative physical consequences as the patient's illness progresses. Elderly spouses who experience stressful caregiving demands have a 63 percent higher mortality rate than their noncaregiver age-peers.[21] Most recently, research documents that elderly husbands and wives caring for spouses who have been hospitalized for serious illnesses face an increased risk of dying prematurely themselves.[27]

Declines in caregiver health have been particularly associated with caregivers who perceive themselves as burdened.[21] Caregiver burden and strain have been related to the caregiver's own poor health status, increased health-risk behaviors (such as smoking), and higher use of prescription drugs.[28] Researchers have reported that caregivers are at risk for fatigue and sleep disturbances,[29] lower immune functioning,[30, 31] altered response to influenza shots,[32] slower wound healing,[33] increased insulin levels and blood pressure,[34, 35] altered lipid profiles,[36] and higher risks for cardiovascular disease.[37]

Burton and colleagues[38] examined the relationships between provision of care by family members and their health behaviors and health maintenance. These researchers found that, with a high level of caregiving activities, the odds of the caregiver not getting rest, not having time to exercise, and actually not recuperating from illness were also high. In addition, caregivers were more likely to forget to take their prescriptions for their own chronic illnesses. Providing care poses a threat to the overall health of caregivers, which can compromise their ability to continue

to be caregivers. If caregivers are to continue to be able to provide care, relief from the distress and demands of maintaining the required care must be considered.

Both highly negative and highly positive consequences of providing care may exist simultaneously.[39] It is plausible that positive consequences, such as rewards and satisfaction, may buffer the negative effects of caregiving. Positive aspects of caregiving are important,[40-42] some researchers are now using a caregiver rewards scale to better understand caregivers' experiences.[41, 42] Other researchers are exploring the positive aspects of care as the mutuality between the patient and caregiver develops.[40] Archbold and colleagues[40] demonstrated that mutuality and preparedness did reduce some of the strain on the caregiver. Picot and colleagues[41, 42] worked primarily with African American caregivers and found that the rewards perceived by caregivers were more important than coping. A specific Picot Caregiver Reward Scale of 25 items exists and has been widely used to show that both rewards and costs can exist in the same care situation.

Caregivers who attempt to balance caregiving with their other activities, such as work, family, and leisure, may find it difficult to focus on the positive aspects of caregiving and often experience more negative reactions, such as an increased sense of burden.[43-45] Regardless of amount of care provided, caregivers may become increasingly more distressed if they are unable to participate in valued activities and interests.[46] More than half of adult children who provide parent care are employed.[7] Caregiving responsibilities can have a negative effect on work roles as caregivers adapt employment obligations to manage and meet care demands.[47, 48] Caregivers who are employed report missed days, interruptions at work, leaves of absence, and reduced productivity because of their caregiving obligations. They have difficulty maintaining work roles while assisting family members.[46] On the other hand, employment provides some caregivers respite from ongoing care activities and serves as a buffer to distress.[49-51]

Low personal and household incomes and limited financial resources can result in increased caregiver risk for negative outcomes, particularly if there are substantial out-of-pocket costs for care recipient needs.[45] Caregivers who are unemployed or have low incomes may experience more distress because they may have fewer resources to meet care demands. Overall, financial concerns cause particular distress for caregivers during long treatment periods,[52, 53] as resources become depleted. Higher-income families, with greater financial resources to purchase needed care, might not become as distressed or burdened as those with limited resources.[54]

Caregiver burden and depressive symptoms are the most common negative outcomes of providing care for the elderly and chronically ill.[20, 55, 56] Caregiver burden is defined as the negative reaction to the impact of providing care on the caregiver's social, occupational, and personal roles[57] and appears to be a precursor to depressive symptoms.[58] Whether the caregiver develops negative outcomes seems to be directly related to the care recipient's inability to perform ADLs, either due to physical limitations or cognitive status.[51] If the care recipient wanders (associated with Alzheimer's disease) or displays unsafe behavior, the caregiver has to be alert and on call for supervision 24 hours per day. The constant concern for managing disruptive behaviors (such as turning on stoves, walking into the street, taking too many pills, yelling, screaming, or cursing) also affects the caregivers negatively.

Care recipients' functional, cognitive, and emotional status predicts caregiver burden and depression,[58-62] which may be manifested in feelings of loneliness and isolation, fearfulness, and being easily bothered, as the demands of caregiving limit their personal time.[58] Care recipient behavior such as screaming, yelling, swearing, and threatening are associated with increased

caregiver clinical depression.[63] Caregiver depression may also have a somatic component, such as anorexia, fatigue, exhaustion, and insomnia.[64]

Caregivers may suffer severe fluctuations in sleep patterns over time, which may affect depression[65] and exacerbate symptoms of chronic illnesses. Pain management is an intractable problem for caregivers that results in substantial caregiver distress, as caregivers assist with both nonpharmacologic and pharmacologic pain-management strategies.[66-68]

Research Evidence: Interventions for Caregivers as Clients

The literature provides substantial evidence that caregivers are hidden patients in need of protection from physical and emotional harm. Interventions directed to the family caregiver should serve two purposes (see Evidence Table). First, interventions can support the caregiver as client, directly reducing caregiver distress and the overall impact on their health and well-being. In this intervention approach, the caregiver is the recipient of the direct benefit and the patient benefits only secondarily. Second, interventions can be aimed to help make the caregiver become more competent and confident, providing safe and effective care to the patient, which can indirectly reduce caregiver distress by reducing their load or increasing their sense of certainty and control. In this section, we focus on the research evidence supporting caregivers as clients.

Despite the importance of information and support to help family caregivers, studies on interventions to increase support for family caregivers have lagged far behind those provided for patients. A focus on the family as a part of the patient's therapeutic plan of care is largely absent from interventional research and from general clinical practice as well. Few randomized clinical trials of educational interventions directed toward family caregivers have been conducted or published, and there is limited research to inform us about skills training for caregivers to prevent back injuries, infection, and other potential risks inherent in the caregiver situation.

Interventions To Reduce Burden and Distress

Recent meta-analyses of caregiver interventions found mixed results, which are important to note. Multicomponent interventions, rather than single interventions like support groups or education, significantly reduced burden.[69, 70] Other interventions found no reductions in burden, but significant improvements in caregiver knowledge and delayed nursing home admission for care recipients.[71] Sorenson and colleagues[72] found that interventions aimed at individual caregivers were more effective in improving caregiver well-being than group interventions, although group interventions were more effective in improving care-recipient symptoms. Reasons for this are unclear. The effectiveness of caregiver interventions lasts approximately 7 months. Few studies are funded for long-term followup.

Comprehensive counseling sessions for spouses caring for a person with dementia help reduce depression.[73] Counseling appeared to be effective in improving the quality of life for caregivers of stroke survivors.[74] However, even a simple one-to-one telephone call may be effective in helping the caregiver as client. An automated, interactive voice-response telephone support system for caregivers reduced burden for those caregivers with a lower sense of control over their situation.[75] Davis and colleagues[76] found an unexpected reduction in burden and distress for caregivers receiving friendly, socially supportive phone calls that provided some respite from caregiving, even without in-home caregiver skills training. Home visits and enhanced social support also can help reduce caregiver depression.[77, 78]

Zarit and colleagues[79] used a quasi-experimental design to demonstrate that caregivers who used adult day care services for their relatives with dementia had significantly lower levels of caregiver stress, anger, and depression after 3 months of this respite care than a control group of similar caregivers who did not obtain this intervention. Sorenson and colleagues[72] also found that respite/day care interventions effectively reduced caregiver depression and increased well-being.

Interventions To Improve Competence and Confidence

Smeenk and colleagues[80] investigated the quality of life of family caregivers who received a home care intervention that consisted of a specialist nurse coordinator, a 24-hour nurse telephone service with access to a home care team, a collaborative home care dossier and case file, and care protocols. The care dossier was used to assist with communication and coordination between caregivers and health professionals. The dossier included the lists of the patient's caregivers, discharge reports, nursing home case transfer reports, medication lists, and multidisciplinary reports. From these reports, specific patient intervention approaches were developed. The intervention significantly improved caregiver quality of life at 1 week and 4 weeks after discharge from the hospital.

Houts and colleagues[81] describe a prescriptive program that is based on research on problem-solving training and therapy. Designed to empower family members to moderate caregiver stress, the Prepared Family Caregiver model is summarized in the acronym COPE (Creativity, Optimism, Planning, and Expert information). COPE teaches caregivers how to design and carry out plans that focus on medical and psychosocial problems that are coordinated with care plans of health professionals. Although proponents of this program assert it has positive outcomes for caregivers, a formal evaluation of COPE was not found.

Teaching caregivers how to manage specific patient problems can improve the caregiver's well-being. For example, not being able to sleep at night is a serious problem for caregivers of people with Alzheimer's disease, as the caregivers become fatigued and exhausted, which can have an adverse effect on both the physical and emotional health of the caregiver. Teaching them how to improve their family members' nighttime insomnia through daily walks and exposure to light can improve sleep time for both the caregiver and care recipient.[82] Even caregivers providing end-of-life care can benefit from structured interventions. McMillan and colleagues[83] found that a skills and coping training intervention with family caregivers of hospice patients improved the caregivers' quality of life.

Caregivers as Providers

Twenty-five years of research have documented that the work of family caregiving can be stressful. That stress can adversely harm both the caregiver and the care recipient. This section addresses research aimed at protecting the care recipient from an ill-prepared or emotionally stressed family caregiver. It describes the link between the work of caregiving and patient harm, and examines interventions that aim to make the caregiver a better worker and less likely to harm the patient.

The Potential for Harm

Caregivers can place their family members at risk in two ways, and both situations are preventable. First, despite their good intentions and hard work, if caregivers do not have the knowledge and skills to perform their work, they may unintentionally harm their loved one. This risk for injury is directly related to lack of knowledge and competence, which can be improved through caregiver education and support. For example, a recent study confirmed that patients had many negative outcomes when untrained informal caregivers managed their home enteral nutrition or tube feeding.[84] Problems included tube displacement, tube clogging, infection, and dehydration—all of which can lead to a stressful caregiving situation and hospital readmission.

A second concern is that the demanding work of caregiving can put caregivers at risk of engaging in harmful behaviors toward their care recipients, particularly among caregivers of persons with cognitive impairments.[85] Depressed caregivers are more likely to harm their spouses. Caregivers who are at risk of depression while caring for spouses with significant cognitive or physical impairments are more likely to engage in neglect or abusive behaviors, such as screaming and yelling, threatening to abandon or use physical force, withholding food, hitting, or handling roughly.[63]

In general, family members may be challenged to find the capacity or ability to provide care, but Fulmer[86] found that caregivers who were in poor health or from low-income or dysfunctional situations might have the most limited capacity to provide needed care. They also might not understand the standard for quality and might not provide the level of care that is needed.

The risk of elder abuse. The presence of dementia and cognitive behavioral problems put the care recipient at risk for abusive behaviors by the caregiver.[86, 87] Neglect may also occur, including neglect of nutrition and access to food, unmanaged pain, urinary incontinence, and falls. Caregiver neglect may occur because the dementia patient is unable to communicate and the caregiver is unable to understand or know how to deal with nutritional intake and pain management. Mittelman and colleagues[88, 89] found that counseling and support for caregivers who face disruptive behaviors from their ill family members will decrease their stress over their multiyear caregiving responsibility.

Medication errors. With regard to caregiver knowledge and skills, an important example of the potential to harm the patient is caregivers' administration of medications. A substantial number of community-dwelling elders do not recall receiving any instructions on taking their medications.[90] They often rely on family members for help in taking them. Travis and colleagues[12] found that caregivers manage between one and 14 medications on a daily basis, have difficulty keeping so many prescriptions filled, and often miss doses due to their work schedules. Their responsibility to monitor for adverse or toxic effects in family members who are not capable of reporting problems themselves is important in preventing dehydration brought on by vomiting and diarrhea, and even more serious emergency situations. Caregivers need education to recognize both classic and atypical adverse drug effects they may see as their family member's condition changes, and help in developing the critical thinking skills that would enable them to manage these potential problems.

Neglect and family conflict. The caregiver's perception of the care situation is crucial in understanding the potential for harm. The amount of "bother" the caregiver perceives in relation to the patient's symptoms affects the caregiving context. Caregivers bothered by symptoms tend to inaccurately assess patients' symptoms, particularly patients' pain and patients' ability to care for self.[91-93]

Neglect is more common when the caregiver is depressed or distressed. It interferes with the person's ability to make observations and to identify needs or provide social stimulation for their ill family member. When caregivers themselves are distressed, burdened, or depressed, they might leave elders alone for long periods of time, ignore them, or fail to provide any companionship or interaction.[86] Annerstedt and colleagues report on the breaking point of caregivers providing care for patients with dementia.[59] When caregivers have a high level of burden, care becomes inadequate. The amount of care demands and time per week, impaired sense of own identity, clinical fluctuations in the patient, and nocturnal deterioration in the patient predict the caregiver breaking point.

When there is family conflict, there is less assistance to the patient. Bourgeois and colleagues[94] looked at the consequences of disagreement between primary and secondary caregivers and found divergence in perceptions. There was, however, more agreement on patient behaviors and caregiver strain. Primary caregivers with pessimistic secondary caregivers were less distressed than those with optimistic ones. Given and Given[18] found that secondary caregivers left the care situation over time and only returned with increased physical care needs. Caregivers may also relinquish caregiving when they are unsuccessful in maintaining a relationship or when the care becomes difficult, such as when the care recipient loses cognitive function. Conflicts can also occur with unfulfilled or mismatched aid. Negative interactions with kin include despairing comments on caregiving, caregiver health status, and criticisms of care decisions.[95, 96]

Research Evidence: Interventions for Caregivers as Providers

Interventions designed to help the caregiver become a more competent and confident provider are important to ensure that the patient receives safe and effective care. These interventions are aimed at: preventing abuse and neglect, and improving the caregiver's knowledge and skills; supporting caregivers with early identification of patient problems and managing patient care; developing psychomotor skills training for the safe administration of medications and use of equipment; and enhancing emotional and coping skills to deal with the caregiver's anger and frustration. In these situations, interventions, such as role playing and rehearsal, are designed to help the caregiver better understand how to communicate with the care recipient and manage negative reactions, or remove the care recipient from a dangerous caregiving situation. A focus on the former may help prevent the latter. All of these interventions can strengthen caregivers' competence and reduce harm to the patients under their care.

Strengthening Caregiver Competence

Strengthening caregivers' competence and confidence improves their *mastery*, defined as the amount of control that a person feels over the forces that are impinging upon him or her.[97] Caregivers with higher levels of mastery of the care situation have more positive responses to providing care[98, 99] because they perceive themselves as able to meet care demands.[100, 101] Caregiver mastery can reduce caregiver distress by influencing the availability of healthy problem-coping strategies to meet care demands.[102, 103] The control associated with caregiver mastery is also associated with a lower stress response and more positive health-related behaviors among caregivers.[104]

Caregivers require knowledge, skills, and judgment to carry out the tasks of care for patients, and research has shown that caregivers who feel prepared to deliver care (i.e., have the knowledge and skills needed) have less burden.[15] Providing care takes into account the following dimensions: (a) the nature of the tasks; (b) the frequency with which tasks are performed; (c) the hours of care provided each day; (d) the skills, knowledge, and abilities of caregivers to perform tasks; (e) the extent to which tasks can be made routine, and thus incorporated into daily schedules; and (f) the support received from other family members. Caring for patients ranges from providing direct care, performing complex monitoring tasks (e.g., monitoring blood sugar, titrating narcotic dosages for pain), interpreting patient symptoms (e.g., determining the fever level to report to a health care provider), assisting with decisionmaking, and providing emotional support and comfort. Each type of involvement demands different skills and knowledge, organizational capacities (e.g., obtaining needed community services or ordering the best wheelchair), role demands, and social and psychological strengths from family members.[16, 104, 105] Each of these is a potential area of concern for patient safety and caregiver distress.

Developing Task-Specific and Problem-Solving Skills

Despite the overall lack of interventional research with caregivers, there is some evidence that interventions designed to improve specific caregiving tasks are helpful. For example, Ferrell and colleagues[106] examined the impact of pain education on family caregivers who were providing care to elderly patients with cancer. The pain education program included pain assessment, pharmacologic interventions, and nonpharmacologic interventions. The pain education program helped improve caregivers' knowledge and attitudes about managing their family members' pain. Other researchers have found that interventions to build skills and problem-solving abilities help caregivers of persons with Alzheimer's disease by decreasing negative behavior in those they care for.[107] Weekly telephone interventions to help caregivers of stroke survivors problem-solve led to reduced depression.[108]

Another example of specific training found nurse-initiated interventions to teach older adults and their caregivers about safe medication administration resulted in significant improvements in the ability to name prescribed medications and their administration schedules correctly.[109] This knowledge base is essential for caregiver competence and patient safety.

Several interventions have been aimed at assisting caregivers to develop problem-solving skills. For example, Toseland and colleagues[110] and Blanchard and colleagues[111] implemented a randomized trial (Coping with Cancer) using a psychosocial intervention aimed at spouses of cancer patients. A six-session problem-solving intervention was designed to help spouses cope with the stress of caring for their partners. Intervention components included support, problem-solving, and coping skills. There was little change over time with respect to caregivers' levels of depression, perhaps because the level of caregiving activities was low. This kind of problem-solving training may be more critical for caregivers who spend more time providing care.

Psycho-Educational Interventions

The majority of intervention studies for caregivers have utilized a psycho-educational intervention. That is, the intervention emphasizes both the provision of information and a psychological/counseling approach to decrease caregiver distress. Although not explicated as such, these interventions aim to address caregivers as both clients and providers.

A randomized clinical trial designed to test the effects of a psycho-educational intervention for caregivers and patients with newly diagnosed cancer who had recently initiated chemotherapy had a positive effect on reducing caregiver depression.[112] Four months after attending a psycho-educational caregiver cancer education program that addressed symptom management, psychosocial support, and resource identification, the number of caregivers who reported being well informed and confident about caregiving increased.[113]

Training caregivers in a multiracial primary care setting about specific ways to manage behavioral disturbances appears promising.[114] Anger and depression management interventions decreased anger, hostility, and depression and improved the caregiver's sense of control.[115] Caregivers received moderate support from an AlzOnline's Positive Caregiving classes, in part because they felt an increased sense of control over their caregiving situation.[116] An intervention to teach management of behavioral problems and basic activities of living left caregivers feeling less upset and more capable of managing difficult behaviors.[100] Similar findings were demonstrated for a portable CD-ROM training program for caregivers of people with dementia.[117]

Navigating the Service Delivery System

Family members must interact with the health care system to obtain information, services, and equipment, as well as to negotiate with family and friends to enlist and mobilize support. Interventions to increase caregivers' knowledge about community services and how to access them can increase their sense of competence and reduce depression.[118] Caregivers' involvement in direct and indirect care changes over time, in response to the stage of illness and treatment, and caregivers must be able to adapt to changes in the amount, level, and intensity of care demands. Given and colleagues[19] describe that it was not the amount of care itself, but the change in care demands (either increased or decreased) that resulted in caregiver distress. Change requires constant adaptation and adjustment by the caregivers, which translates into adapting to different schedules, changing routines, and accommodating other roles for which family caregivers are responsible.

One of the most essential aspects of navigating the system is finding home- and community-based services, and determining what private and public programs might be available. The public sector side is particularly complex. People who are very frail and below or close to the poverty line can receive home care under Medicaid. Much of this care is provided through a home health agency. Through the authority of section 1915(c) of the Social Security Act, States can request Federal permission to provide a range of services, which may include respite service for family caregivers. Benefits vary by State, but research documents an increasing trend in the numbers of people served and dollars spent in Medicaid home- and community-based care. In addition, policymakers are facing pressure to increase these services to address the unmet needs of patients and their families.[119] A study examining the benefits and costs of home- and community-based services in Florida[120] found that people receiving these services had been diagnosed with at least three chronic health conditions and needed help with three or more ADLs and seven IADLs. With services, they were able to avoid institutionalization despite this high level of needs. Other research has shown that the presence of a caregiver can reduce nursing home stay by 3.2 days. These caregivers need help finding services.

Options for arranging flexible services are emerging from Medicaid-funded consumer-directed care programs, which allow people to select and manage paid home care workers, as well as purchase assistive devices or home modifications. The program gives people the

flexibility to adjust the frequency and timing of paid and unpaid services. Benjamin and colleagues examined the services of low-income Medicaid beneficiaries under agency-directed and community-directed services. People who directed their own services had positive outcomes. They were more satisfied with services and had fewer unmet needs.[121] Foster and colleagues[122] assessed the impact of consumer direction on caregiver burden in Arkansas and found that caregivers had greater satisfaction with the care recipient's care and were less worried about safety. Caregivers in the study reported less physical, emotional, and financial strain compared to the control group receiving traditional agency services. Primary informal caregivers who became paid caregivers reported substantial benefit compared to the group receiving agency services.

Evidence-Based Practice Implications

A review of the literature found that society depends on family caregivers to continue providing care for their loved ones, but does little to teach them how to do it and support them in this stressful work. At a minimum, nurses can recognize and respect their efforts, assess their needs, provide concrete instructions on the specific care they are giving (e.g., medication administration, dressing changes, and similar tasks), and refer them to potential sources of ongoing help. Nursing interventions in these areas can help reduce harm to caregivers and the patients they serve.

Respecting the Patient–Family–Professional Triad

The most important practice implication of this review of caregiving research evidence is that nurses can meaningfully change the course of caregiving for both the caregiver and care recipient by respecting the role that each has in managing ongoing care beyond the classic boundaries of professional patient care. For example, it is often not easy for the elderly patient in the hospital who is going to need postacute care to accept the need for family help, because they view themselves as independent. Nurses can help shift their views of classic independence as freedom from functional limitations to a context of family care in which giving and receiving assistance does not need to strip away autonomy.[123] It is also important to understand that burdened caregivers can successfully support their family member, but these caregivers may need help to bolster their sense of self-esteem.[124] They want to be part of the decisionmaking team.[125]

Nurses in all practice settings need to partner with patients and their families to move from the traditional nursing context of *doing for* clients in the "expert model of service delivery" to more mutuality in nurse-client relationships.[126] Nurses may need to "enact more empowering partnering approaches" and "reframe their professional image, role, and values"[126] to accomplish this. Listening skills and the ability to interpret body language and verbal communication are essential competencies in all encounters with patients and their family members.[127]

This model is consistent with Dalton's theory of collaborative decisionmaking in nursing practice triads, where the triad comprises the client, the nurse, and the caregiver.[128] In this vision of the caregiving environment, the nurse interacts with and assists not only consumers, but the informal caregiver as well. This kind of collaboration can increase feelings of control over health, the sense of well-being, and compliance with prescribed treatments.

Providing Information

Nurses need to communicate effectively with clients and caregivers to develop cost-effective plans of care and achieve positive client outcomes.[129] Communication is crucial across settings. The emergency room and hospital discharge planning processes, assisted living facility admission process, skilled nursing facility discharge process, and the home health care admission and discharge process are all critical points of interaction where health care professionals, patients, and family caregivers can benefit from respectful, high-quality communication.[130] In the managed care environment, providing concrete care information along with emotional support can help spouses of frail older adults better manage their caregiving situation.[118]

At all points in the patient's disease trajectory, caregivers need information to deal with the patient's care and treatment demands. Nurses and other health care providers should not expect caregivers to be responsible for sorting out relevant information and applying it to the care requirements for their family members. Research documents that caregivers have difficulty obtaining information from health care professionals, particularly physicians and nurses.[131-133] Professionals should be more responsive to patients' and family members' information needs.

It is important to provide information in a clear, understandable way through verbal, written, and electronic methods. Caregivers want concrete information about medications, tests, treatments, and resources. They also want time to have their questions answered. Nurses can provide anticipatory guidance for what the caregiver can expect.[134] This kind of information can relieve caregivers' distress arising from uncertainties about their ill family members' disease and treatment status and the care they may need.[135, 136] For example, teaching caregivers how to manage pain and other symptoms benefits both the patient and the caregiver. Caregivers who report more confidence in managing symptoms report less depression, anxiety, and fatigue.[137]

Caregiver Assessment

Given caregivers' essential role in caring for their family members and the hazards they face in doing so, their needs and capacities to provide care should be carefully assessed.[138] This assessment should focus on the caregiver as both client and provider before health professionals can assume caregivers are able to provide competent care without harming themselves or their family member.

Assessing the home and family care situation is important in identifying risk factors for elder abuse and neglect. Heath and colleagues[87] found that in-home geriatric assessments are needed to determine the risk for and occurrence of elder care recipient mistreatment. Fulmer's research[86] documents the need for interdisciplinary teams in emergency rooms to screen for elder neglect, with attention to risk factors associated with caregiver and elder vulnerability, such as the elder's cognitive and functional status and depression. Health care professionals who conduct detailed assessments of the caregiving situation through separate conversations with the patient and the caregiver are better prepared to provide guidance and collaborate with the family to prevent abuse and neglect.

Assessing the needs of older people living in the community is a prerequisite for helping caregivers find resources and adhere to a comprehensive plan of care. Outpatient geriatric evaluation and management can reduce caregiver burden, particularly for those who are less experienced caregivers.[139]

Linking Caregivers to Resources

Caregivers need adequate resources to assure minimization of risk to the patient.[140] To reduce the rough crossing that family caregivers experience as they navigate the discharge from hospital to home, there is a clear need to develop referral criteria and guidelines, accurate documentation, and prompt referral to continuing care professionals.[24] More case management programs may be useful to help ease this transition, promote safe and effective hospital discharges, and support caregivers in their ongoing, posthospital care. Nurses, preferably those trained in gerontological nursing, have a key role in case management for frail older people.[141]

Linking caregivers to resources throughout the disease trajectory is important because caregivers are often unaware that there are support services available to help them. A recent study of caregivers of people with Alzheimer's disease found that 75 percent had unmet needs, yet only 9 percent had used respite services and only 11 percent had participated in support groups.[142] Extending nursing care beyond the hospital boundary, nurses can help caregivers mobilize supportive resources in their natural network as well as formal services.[143]

Research Implications

Taken as a whole, interventions to improve caregiver outcomes have been varied. Intervention studies have typically been descriptive in nature, used small convenience samples, and have not included comparison groups. In addition, many studies have limited their samples to patients with only a single diagnosis. In the future, randomized trials are needed to substantiate the role of similar programs in enhancing caregiver skills and minimizing caregiver distress.

The majority of studies have focused on a single construct of the care situation (i.e., examining the correlation between the caregiver-patient relationship and caregiver burden). Researchers have given limited attention to the nature of the knowledge and skills of the caregiver, and to personality factors or dispositions of caregivers.[144, 145] Most of the intervention studies did not consider potential confounding or risk variables, such as prior family relationships, cultural variation, caregiver health status, stage of disease, hours of care, or competing caregiver role demands. In addition, little detail was provided about the intervention design. Finally, few studies described the nature of care tasks of the caregiver, so we are unaware whether caregivers were effectively managing symptoms, providing emotional support, providing direct care, monitoring patient status, or performing a combination of these tasks.

Recommendations for Future Research

Since much of the caregiving research remains descriptive, there are many gaps in the evidence-based research to promote patient safety and quality care for caregivers as secondary patients and caregivers as providers to vulnerable patients. To advance our knowledge in this field, we recommend several strategies for future research.

Because caregiving is a day-in, day-out role that fluctuates as the needs of the care recipient change, it is not well understood through cross-sectional research designs. It is essential that descriptive and longitudinal designs be employed to follow the care requirements over the course of the illness trajectory. Longitudinal research to date has uniform intervals between observations such as 3, 6, or 9 months, without concern for treatment protocol or stage of disease

or care demands. Further studies should take into consideration other time points that may better reflect the disease trajectory, such as time of initial diagnosis, protocols alterations, and points of disease exacerbation or decline. A special focus on safety, risk for negative outcomes, and adverse effects for both the caregiver and care recipient should be noted.

Key variables to include in these studies are the type and stage of the disease and the treatments because they will be related to the types of continuing therapy. These various therapies will be related to the needs of the patient and assistance with self-care, as well as the patient's ability to perform other customary daily activities. Are the demands on the caregiver such that they jeopardize his or her health? We also need larger population-based studies so we can have heterogeneous samples related to diagnosis, stage of disease, caregiver distress, care provided, patient impairment, and duration of care as they relate to caregivers' ability to provide safe care without jeopardizing their own well-being.

Research that uses carefully selected inception cohorts is needed so that variation in care demands can be understood. We will be in a far better position to describe how the course of the disease and associated treatment influence caregivers' responses if we start with inception cohorts of those caregivers beginning with initial treatment and proceeding through palliative care. Adverse patient care and caregiver situations, such as medication errors, falls, and subsequent hospitalizations, can be noted over time.

We need studies that target caregivers that are from minority and economically disadvantaged groups if we are to better understand their own needs and interventions to support them in providing safe care. Furthermore, focus on variations or adaptations needed to minimize caregiver distress related to ethnic, racial, cultural, or socioeconomic diversity is needed. We know very little about the distress and resource limitations of various vulnerable groups and the acceptability of various types of interventions to ethnically and racially diverse populations.

We need to investigate the interplay between the formal and informal systems of care for the ongoing needs of patients as well as caregivers. More research needs to be conducted that focuses on how family influences care-related decisions and the impact to clinically significant processes of care and/or client outcomes. There is very little research to suggest how variations in caregiver contact with the formal health care system interacts with the amount and types of responsibilities faced by family caregivers. Can prepared caregivers contribute to the quality of patient clinical outcomes as well as patient safety? What does competent and appropriate family care contribute to patient clinical outcomes? How does it affect cost and care utilization?

Future research should identify and test patient- and family-directed interventions and chart their impact upon the quality of care outcomes for patients. In addition, interventions should report the cost of care, as well as the cost of utilization of services. What are the costs of negative outcomes that result when safety and neglect or abuse are involved?

Interventions that can demonstrate improved patient outcomes are particularly essential to building a high-quality system of continuing care. Caregivers who face conflicts in competing demands related to caring for children, spouse, or parent and to maintaining their work roles are particularly threatened by and vulnerable to the demands for continuing home care. More appropriate home care and home care support (resulting in caregivers who are prepared to care and have adequate formal support) may lead to fewer patient or caregiver hospital readmissions, fewer interruptions in treatment cycles, shorter periods of work loss, and better patient and caregiver mental health. Quality of care and patient safety are concerns.

We need to design and test interventions to assist patients and their families to increase their preparedness to deal with the overall care process, to deal with both the direct and indirect care

demands. How do we increase their sense of control and mastery of their care situation? Future intervention studies should utilize multidisciplinary, randomized clinical trials (including physicians) to determine the unique contribution of educational programs versus social support versus psychological support on caregiver outcomes and patient outcomes.

Future studies should explore whether health care professionals can assist the caregiver to build effective buffers against being overwhelmed and distressed. Interventions that assist the caregiver to engage in activities that promote their own health should be carried out to identify strategies of health promotion. Research questions should address whether or not caregiver distress (i.e., depression and burden) affects caregiver decisionmaking and judgment about patient care, and to examine caregiver behavior and choices and the subsequent quality of care. Do these have a negative impact on the patient or on themselves?

Examining caregiver distress as it relates to quality of care is absent from the literature. Research is needed to understand the *quality* of care that family members provide and then determine how that care impacts the overall therapeutic plan and patient clinical outcomes.

Longitudinal studies of caregivers are needed to explore the complex interactions of caregiver physical health and mental health, and how self-care and health-promotion practices of the caregiver are altered. Exploration is needed of which self-care practices (i.e., nutrition, exercise, sleep, stress management, preventive and promotive health care) can influence caregiver distress and physical health status so that caregivers can continue to provide quality and positive care.

To better understand the effects of care on family caregivers and on patient outcomes, caregiver roles, responsibilities, knowledge, and skills need to be more rigorously explored and defined. For instance, what do caregivers do well? What do caregivers not do well? In what areas are the patient outcomes most likely to be compromised? In what areas is patient safety most in jeopardy? What areas cause caregivers more distress? Once these questions are answered, we can target interventions at those who are at risk and intervene early in the care situation, rather than late.

Finally, interventions must recognize professional or formal caregivers and family caregivers as partners in health care—partners who offer unique and vital skills and resources—and engage them in the entire plan of care. Such interventions are critical as we increase the focus on outcomes of care and as providers are paid for outcomes performance. Family members as partners are critical.

Conclusion

Family caregivers are critical partners in the plan of care for patients with chronic illnesses. Nurses should be concerned with several issues that affect patient safety and quality of care as the reliance on family caregiving grows. Improvement can be obtained through communication and caregiver support to strengthen caregiver competency and teach caregivers new skills that will enhance patient safety. Previous interventions and studies have shown improved caregiver outcomes when nurses are involved, but more research is needed. There is more to be learned about the effect of family caregivers on patient outcomes and areas of concern for patient safety. Nurses continue to play an important role in helping family caregivers become more confident and competent providers as they engage in the health care process.

Search Strategy

The research cited is a comprehensive but not exhaustive review of the caregiver literature. The literature search for this paper was done in the databases MEDLINE, CINAHL, and PsycINFO using variations of the terms "caregiver" and "long-term care" or "home care services," combined with other terms relating to patient safety and nursing practice. Other terms employed included "case management," "education and training," "medication," and "risk management." The search was limited to articles written in English, but not limited to the United States.

The search terms applied were usually kept very broad, and keyword searches were frequently employed more often than searches that relied upon the use of controlled descriptors, as the topics of patient and caregiver safety, which are often intertwined, are difficult to isolate through clearly defined identifiers. As a result, search results were large, and relevance was frequently determined through the reading and review of abstracts of large sets of retrieved publications. Relevant articles for this review were not always indexed using terms relating to nursing; the *potential* involvement of the nurse as a contributor to *improved* patient and caregiver safety was a determinant for inclusion. Some articles discussed the professional health care team in general terms, while others focused on the specific role of a nurse serving as a factor in *safe family caregiving*. The broad search strategies delivered high retrieval levels and the need to distill relevant evidence.

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Evidence Table: Supporting Family Caregivers in Providing Care

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Acton & Kang 2001[69]	Care burden	Meta-analysis	Various meta-analysis (Level 1) Effect sizes calculated; studies were grouped by intervention category; pooled effect size calculated for each intervention category (Level 3)	24 reports testing 27 treatments for adults with dementia.	Various educational	Multicomponent interventions have a small significant effect on burden. No effect on burden from support group, education, psycho-education, counseling, and respite.
Austrom 2004[114]	Nonpharmacologic methods, such as this collaborative stepped-care management intervention program, are the intervention of choice for behavioral disturbances, which can add to caregiver burden and affect quality of care.	Randomized controlled trial	Randomized controlled trial (Level 2). Questionnaires were periodically administered to evaluate frequency of behavioral disturbances in patients as well as a measure of the caregiver's reaction (Memory and Behavior Problems Checklist), and measure of severity of the caregivers depression (Patient Health Questionaire-9). (Level 3)	Minority Alzheimer's patients, who were less likely to visit specialty clinics, may find interventions more accessible if they were delivered through primary care clinics. Intervention of three basic components: (1) comprehensive screening and diagnosis protocol, (2) multidisciplinary team approach to care coordinated by a geriatric nurse practitioner, and (3) proactive longitudinal tracking system.	All participants receive Alzheimer caregiver guides, educational interventions, and specific protocols for common behavioral disturbances. Treatment group then received treatment recommendations for specific behavioral disturbances from a clinical treatment team of geriatric nurse practitioner, social psychologist, geriatrician, geriatric psychiatrist.	Study is ongoing. Preliminary data indicate that program is well received by patients, caregivers, and primary care physicians. Subjects are attending voluntary meetings more frequently than those not in the program.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Beach 2005[63]	Threatening behavior, verbal abuse	Convenience sample (descriptive)	Structured interviews (Level 5) Care recipients reports of harmful caregiver behavior, screaming, yelling swearing, threatening (Level 3)	265 caregiver/care recipient dyads	None	Harmful caregivers were associated with greater recipient ADL needs; spouse's greater caregiver cognitive physical symptoms; caregiver at risk for clinical depression.
Bowles 2003[146]	Home care referral can lead to better care	Noncompara-tive	Interviews with content analysis (Level 5) Identify patterns clinicians used when gathering information, determine information essential to discharge referral decisions, and explore why patients in need may not be referred for service (Level 3)	Patients discharged without home care referrals were presented as case studies to nurses, social workers, physicians, and discharge planners. Observations were recorded.	None	Three themes describe why patients may not receive referrals: (1) patient characteristics, (2) workload, and (3) staffing, educational issues.
Brodaty 2003[73]	Psychological distress in caregivers	Meta-analysis	Meta-analysis (Level 1) Various psychological morbidity and benefits (Level 3)	30 studies	34 interventions	Significant improvement in caregiver distress and caregiver knowledge. No improvement in caregiver burden.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Brown 2006[126]	Changing the home care nursing approach from the expert model of service delivery to a more client-centered empowering model can optimize the potential for improved interactions and understandings between the nurse and consumer, and greater professional autonomy for the nurse.	Non-comparative (interpretive phenomeno-logical using hermeneutic analysis)	Holistic interpretation of nurses' experiences through analysis of interviews (Level 5) Identified concepts were noted and categorized until themes and patterns emerged. Participant review and peer review of findings assured authenticity of data. (Level 4)	Purposeful sample consisting of 8 registered nurses who had in-depth experience in the flexible client-driven delivery approach, identified by a key informant within the home care program (Canada). Employed maximum variation sampling regarding age, education, experience in in-home nursing.	None	While interpretive research findings are not generalizable, this study identified pitfalls and suggests potential ways that nurses can implement practice change. Several barriers exist that impede nurses from evolving to a client-centered service model: system level (governmental financial), organizational (centralized allocation and control of service delivery), personal (remuneration, workload, working conditions). Home care nurses revealed a tendency to seek direction of physicians and managers rather than to exert professional autonomy within the scope of professional nursing practice. Empowering partnering approaches in nursing fosters sharing power to optimize the potential for nurse and client. Nurses may have to reframe their professional image, role, and values to enact this interaction.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Burton 1997[38]	High-level caregiving can increase odds of insufficient rest and exercise, and poorer outcomes while recovering from illness or threats to health.	Cross-sectional (descriptive)	Caregivers compared to noncaregivers (Level 4) Structure interviews in their home (Level 3)	Health effects study. 434 caregivers with a control matched 385.	None	Being a high-level caregiver increased odds of not getting rest, not having time to exercise, and not recuperating from illness and forgetting to take prescription meds when compared to noncaregivers.
Cameron 2006[99]	Complex rehabilitation has negative health outcome on caregivers.	Cross-sectional	Survey (Level 4) Identify aspects of the caregiver's emotional distress and psychological well-being; compare health-related quality of life of informal caregivers. Evaluated outcomes by CESD, postaffect scale SF36 (MO5). (Level 3)	Informal caregivers matched age and gender of ARD survivors.	None	Caregivers had more emotional distress, more lifestyle interference, lower misery. Caring for ARD survivors with more depression, poorer overall health quality compared to age and gender matched group lasted 2 years.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Campbell 2004[137]	Caregiver strain and burden	Cross-sectional (survey description)	Descriptive cross-sectional (Level 4) Quality of life, self-efficacy, mood (Level 3)	Age mean 57.6, intimate partners of patients with prostate cancer.	None	Caregiver self-efficacy was associated with both partner mood and caregiver strain. Caregiver self-efficacy scores were negatively correlated with partner depression, anxiety, and fatigue subscale scores since partners who reported greater overall confidence in assisting patients with symptom control also reported less depression, anxiety, and fatigue. The total self-efficacy score was negatively associated with strain. Increased self-efficacy in the caregiver led to better adjustment to the symptoms and increased mental health of the patient.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Coon 2003[115]	Anger and depression	Cross-sectional	Survey (Level 4) Anger, depression coping intervention (Level 3)	Female caregivers age 50+, older community dwelling, 169 females; psycho-educational and skill building, 2-hour workshops for 8 consecutive weeks followed by two booster sessions at 1-month intervals for 3 months. Two options: anger management or depression management, intervention study, R(2/CT) 3-4 months.	Psycho-educational small group over 3-4 months.	Anger and depression management interventions decreased anger, hostility, and depression and improved self-efficacy at 3 months. Anger management improved coping skills. RCT, effective. Self-efficacy impaired in both groups. Pretreatment depressive symptoms moderated intervention.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Crist 2005[123]	Understanding how care recipients feel about the care they receive and the level of autonomy that they retain while under care may facilitate better understanding between caregivers and recipients, and result in less anxiety and better relationships.	Non-comparative (hermeneutic interpretive phenomeno-logical)	Exploration of shared meanings through multiple, open-ended, in-depth interviews, observation (Level 5) 2-5 interviews were conducted with each elder. A 3-member investigator team co-constructed an emergent interpretation of the narratives within the specific context. (Level 4)	Convenience sample of 9 elders (5 women, 4 men) in urban and rural areas of the Pacific Northwest, recruited from three home health agencies, one adult day center, one neurological clinic. Elders were 65 or older and had an identified family member who provided assistance with at least one ADL.	None	Elders can incorporate family care into their lives while still viewing themselves as autonomous. Gerontological nurses, who traditionally measure independence as the level of a client's functional ability, may shift to understand the recipient's view of autonomy and independence is constructed independently and individually. Positive relationships between elders and caregivers resulted in personal growth; a positive family care context facilitated recipients' willingness to incorporate receiving family care into their lives.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Christakis 2006[27]	The hospitalization of a spouse with a serious illness may be associated with an increase in the risk of death of a partner.	Retrospective cohort	Cohort compiled from data in Medicare claims forms. (Level 4) Two statistical methods were applied (Cox regression and fixed-effects) to estimate the relationship between the hospitalization of a spouse and the subsequent death of the partner, while controlling for all constant characteristics of the spouses and their environment. (Level 1)	518,240 couples who were enrolled in Medicare in 1993, 65 years of age or older	None	Serious spousal illness and spousal death appear to be independently associated with the risk of death of the partner. Hospitalization for various diseases may differentially affect partners. Implications: training and assistance of spouses who serve as caregivers can lower costs and improve the health of patients and partners. Such interventions might decrease mortality among partners. Interventions may be more useful in certain diseases, such as stroke or dementia.
Dalton 2005[129]	Quality of care can be improved when client-caregiver-nurse (triad) communication occurs; caregivers can better understand care plans; coalition decisions within triads may increase the possibility that client interests are maintained.	Non-comparative (ethnographic, content analysis); exploratory	Observation, recording, and transcription of triad interactions. (Level 5) Qualitative and quantitative analysis of frequencies of different types of decisions and decisionmaking situations. (Level 4)	12 client-caregiver-nurse triads admitted for the first time to home health care agencies in suburban New England during 1994	None	Coalitions (two members of a triad acting together) form during triadic interactions; of 157 decisionmaking situations evaluated, coalitions formed in just 8 (5%). Decisions were organized into program decisions, operational decisions, and agenda decisions. Two of the roles (advocate and passive participant) that can be assumed by a third person were evident.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dalton 2003[128]	An understanding of triad interaction and how coalitions are formed in clinical settings may enhance the effectiveness of clinicians' communication with clients and family caregivers and facilitate positive client, caregiver, and nurse outcomes.	Systematic literature review (theory generation)	Literature review (Level 1) Theory generation (Level 4)	None	None	The theory of collaborative decision-making in nursing practice for a triad provides a framework for studying the effects of collaborative decision-making among nurses, family caregivers, and clients.
Davis 2004[76]	Telephone-based psycho-educational interventions may provide relief from the burden, distress, and depression suffered by caregivers who are not able to, or do not wish to, seek help from sources that require that they leave their home.	Three-group pretest and post-test (repeated measures design with randomization to treatment group)	Each of three groups of caregiver-recipient dyads received 12 weekly sessions of training by in-home contacts; training by telephone contacts; and friendly, socially supportive phone calls. (Level 2) Caregiver self-reported outcome measures: burden, distress, depression, social support, and life satisfaction. (Level 4)	71 caregiver-care recipient dyads were recruited from geriatric clinics and home care agencies in central Alabama, and were randomized into three groups.	Caregivers in telephone and in-home groups were trained in problem-solving, caregiver appraisal of behavior problems, written behavioral programs for managing specific problems, and strategies for handling affective responses to difficult caregiving strategies.	An unexpected reduction in caregiver burden and distress was observed in those receiving only friendly phone calls, possibly because the calls provided caregiver respite. Only the in-home training group experienced significant burden and caregiver distress reduction. Caregiver groups did not differ significantly on caregiver depression. Despite differences in contact time with the three different groups, they were all similar in satisfaction levels.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dunnion & Kelly 2005[24]	Improvements in planned discharge strategies (a multidisciplinary approach to developing referral guidelines, staff training, and dissemination of information) of elders from emergency room to home can lead to improved quality and continuity of care for the older person.	Cross-sectional (interviews) of 5 groups of health care professionals	Standardized questionnaires (Level 3) Quantitative data were analyzed with SPSS, and qualitative data were content analyzed. (Level 4)	Emergency department in a 320-bed rural general hospital in the Republic of Ireland. Purposeful sample (excluded psychiatric nurses, social workers, physiotherapists) of nursing and medical staff in the emergency room, totaling 222. 135 questionnaires were returned and 131 were analyzed.	None	Findings added support to others that found that in general, health professionals in the emergency department do not adequately determine the aftercare needs of older patients when they are being discharged. Effective discharge planning is impeded by gaps in communication between the hospital and community interface, such as illegible discharge summaries and delays in sending information to the general practice physician. There is a lack of synchrony between hospital and community nurses in relation to the level of communication between the two sectors. The liaison nurse role may help to improve communication links and channels between the primary and secondary interface. There is a clear need to develop referral criteria and guidelines, accurate documentation, and prompt referral to continuing care professionals.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Ferrell 1995[106]	Pain management can affect quality of life and caregiver burden.	Cross-sectional	Quasi-experimental (Level 3) Quality of life and caregiver burden; physical and psychological impact of family caregiving and pain management (Level 3)	50 family caregivers of patients experiencing cancer-related pain from two California medical centers	Pain education program: pain assessment, pharmacologic interventions, and nonpharmacologic interventions	The pain education program was effective in improving knowledge and attitudes regarding pain management. Pain management is a priority for nurses, and use of interventions such as structured pain education improves quality-of-life outcomes for patients and their caregivers.
Fortinsky 2001[130]	The quality of interaction in the health care triad is likely to influence health-related outcomes of family caregivers, persons with dementia, and primary care physicians. The consequences of dementia care communication and practice are most significant when dementia patients are entering or leaving a new health care setting.	Systematic literature review	Literature review (Level 1) Summarization of knowledge base (Level 4)	None	None	Interactions in medical encounters involving dementia care are not optimal from the perspectives of family caregivers or physicians. Physicians are willing to share ongoing management of dementia patients and their families with other organizations in the community. Older persons with dementia, even though physically present during triadic encounters, are unlikely to be involved as active participants in dialogs and decisionmaking regarding diagnosis and management of dementia symptoms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fulmer 2005[147]	Elder mistreatment is an enormous social problem, which emergency departments may help identify.	Cross-sectional	Older adults screened and recruited from emergency rooms (Level 3) Elder and caregiver cognitive status, functional status, depression level, health status; demographics; perceived social support; childhood support; personality. Relationship between measured variables and neglect-assessment team's diagnosis of neglect (Level 3)	165 subjects, 70 years or older, English/Spanish speaking, Mini-Mental Status Exam score of 18 or more, using a paid or unpaid caregiver 20 hours per week or more. Recruited from four urban emergency departments in New York and Tampa.	None	Older adults who are diagnosed as neglected are sicker, have fewer financial resources, and have less help in the home. There is a relationship between self-reported childhood trauma and later-life neglect, which may be considered normative by these elders. Personality traits may be indicators of neglect.
Gitlin 2001[100]	Upset family caregivers	Randomized controlled trial	Intervention RCT (Level 2) Behavioral problems, ADL, IADL, caregiver well-being, self-efficacy, and being upset (Level 4)	171 families of dementia patients; five 90-minute home visits by occupational therapists	Focusing on education and environmental modification every other week over 3 months; occupational therapists	Spouses reported reduced upset; women reported improved self-efficacy in managing behaviors; minority women reported improved self-efficacy in managing functional dependency.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Gitlin 2003[70]	Burden among dementia caregiver	Meta-analysis	Meta-analysis (Level 1) Pooled parameter estimates of nine active conditions compared with six control conditions of the Resources for Enhancing Alzheimer's Caregiver Research (REACH) project. Associations of caregiver characteristics and outcomes were examined statistically. (Level 3)	Homes of patients with dementia, multisite study	Consulting education, support, skill building, home visits, problem-solving; 6 months.	Active interventions are superior to control on caregiver burden. Active interventions superior to control for women, those with lower education. Family therapy and computer technology intervention impacted depression. Active better for Hispanics, nonspouses.
Gitlin 2005[107]	Negative behavior in patients with dementia	Randomized controlled trial	Randomized controlled trial (Level 2) Behavior problem checklist, Says ADL, task management affect (Level 4)	127 caregivers, 6 months	Skill building, education, problem-solving, and technical skills. Active—five 90-minute home visits and one phone session over 6 months. Maintenance—one home visit and three phone sessions over the next 6 months.	Decreased days assisting with ADLs at 6 months, no difference at 12 months. Decreased upset with memory-related behaviors at 6 months, no difference at 12 months. Improved affect at 6 months, none at 12 months. Decreased memory behavioral occurrences in patients at 6 and 12 months.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Glueckauf 2004[116]	Caregivers of persons with dementia typically experience emotional, physical, and psychosocial deterioration due to the extreme demands of providing home care without support.	Single-group pretest-post-test	Telephone interviews with caregivers to assess effects of the Positive Caregiving classes (Level 5) Survey instruments for dependent measures were: Steffen et al.'s Caregiver Self-Efficacy scale,[148] Parke et al.'s Stress-Related Growth Scale,[149] Lawton et al.'s Caregiver Appraisal Inventory[150] (Level 3)	21 caregivers of individuals with progressive dementia who had completed the AlzOnline's Positive Caregiving program	Series of six 45-minute interactive (PC- or telephone-based) Positive Caregiving sessions, every 2-3 weeks over a 16-week period	Moderate support was obtained for the effectiveness of AlzOnline's Positive Caregiving classes; significant increases in self-efficacy, concomitant decreases in subjective caregiving burden, little or no change in stress-related growth and positive caregiving appraisals, or perceptions of time burden in providing caregiving assistance.
Grant 2002[108]	Caregiver depression and burden	Randomized controlled trial	Randomized 3-group design (Level 2) Social problem-solving (Level 4)	45 stroke caregivers	Problem-solving: (1) 3-hour home visit with RN, (2) weekly phone calls by RN for 1 month, (3) phone calls by RN every 2 weeks for 1.5 months.	Improved problem-solving skills, preparedness, vitality, social functioning, mental health, and role limitations related to emotional problems. Less depression. No significant difference in burden.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Greenberger & Litwin 2003[124]	Caregiver burden "is liable to diminish the caregiver's ability to provide quality care."	Cross-sectional (interviews)	Structured in-home interview schedule (Level 3) Variables measured: background, personal and social resources, burden measures, feelings of caregiver competence, adherence facilitation, measured with multiple instruments (Level 3)	240 Jewish primary informal caregivers, randomly recruited using records of recently discharged dependent older patients, caring for recipients over the age of 65, who lacked at least one functional ability delineated by ADLs or assessing motor functions necessary for independence in IADLs, and with at least one chronic illness.	None (interaction only)	Operationalizes facilitation of care recipients' adherence to prescribed care regimens in informal caregiving. Shows positive association between caregiver burden and adherence facilitation; burdened caregivers can be successful informal caregivers; and efforts to bolster caregivers' self-esteem and social support may be more effective in assuring quality care than attempts to relieve their sense of burden.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Griffiths 2004[109]	Persons over 65 years old represent a significant percentage of medication-related admissions to hospitals. Community nurses can play a role in managing the administration of medicines and the monitoring of their effects on patients. Community nurses can play a unique role in the "medication team" (i.e., doctors, pharmacists, nurses, consumers) in a multidisciplinary approach to quality use of medicines.	Pretest-post-test with a cross-sectional survey	Survey (Level 3) Participants living at home and receiving community nursing care were assessed for knowledge of and ability to manage medication regimes. A nurse-initiated intervention was developed that included referral pathways to physicians and/or pharmacist medication review. (Level 3)	111 participants over age 65, taking oral medications and having regular community nursing visits, were surveyed. Recruited from case-load of Australian community nurses. A subgroup of 24 participants with diminished knowledge of medications were administered a followup in-depth survey.	Various interventions, including client education, referral paths to physicians and pharmacists, provision of administrative support systems.	After invention, participants showed improvement in their ability to manage medications (alteration in use of compliance aids) and demonstrated increased knowledge about their medications. Clients showed significant improvement in the ability to correctly name their medications and schedules correctly; clients did not experience reduction in the complexity of the regimes. Community nurses can successfully work within the boundaries of a multidisciplinary team to provide interventions within their professional scope of practice.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hallberg & Kristensson 2004[141]	Preventive case/care management interventions for community-dwelling frail older people may result in better quality of life, fewer emergency medical calls, and a reduction in hospital admissions.	Systematic literature review	Systematic review (Level 1) Three areas of outcome were targeted, though not at the same time: health care consumption, in some cases transformed into costs; quality of care; and patient's health and ability. (Level 4)	A literature review produced 26 papers that related to the topic. Articles discussing a particular group of diseases were excluded, as the focus was on the needs of frail older people with complex needs. Criterion for inclusion of older people in the programs was either having a chronic disease combined with receiving care from at least two professionals or nonprofessional caregivers and living independently in the community.	Case management interventions included traditional tasks (case finding, assessing, planning, implementation, coordination and monitoring, and evaluation of options); comprehensive (outreach, client assessment, advocacy, etc.); extensive (medication and symptom management, caregiver and family supportive counseling).	Case management includes a range of interventions, but the core of the intervention is a task-focused approach, with parallel functions added (interagency coordination, bereavement counseling) depending on the individual's situation. The effect of case management interventions studied showed a range of outcomes. The content of case management needs to be expanded and influenced more by a salutogenic, rehabilitative, and family-oriented health care approach. Nurses, preferably trained in gerontological nursing, have a key role in case management for frail older people. Nurses as case managers, along with a geriatric team, can solve difficult problems. Case management has not been standardized and usually does not take a deliberate preventive and/or rehabilitative approach, using psycho-educative interventions focusing on self-care activities, risk prevention, disease management, community involvement, and functional ability.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Heath 2005[151]	Assessment of prevalence of remediable health conditions from in-home geriatric assessments of referred adult protective services. Elder mistreatment has a significant impact on mortality of victims.	Retrospective cohort study	Assessments were conducted with referred elders by a nurse-practitioner-geriatric physician team, including a detailed medical and functional history, physical exam. (Level 5) Classifications of mistreatment (neglect, financial exploitation, abuse) were employed from the NJ State Dept. of Health and Senior Services as independent variables. Descriptive statistical analysis. (Level 3)	211 adult protective services referred to the Linking Geriatrics With Adult Protective Services program in central New Jersey.	None	The predominance of neglect among the subjects is consistent with the known national distribution of various forms of elder mistreatment. A high level of dementia and depression was also consistent with that found in neglected populations.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hellstrom 2004[152]	While health problems can reduce quality of life (QoL), dependency on others may also influence how people perceive their QoL. Understanding how living with health-related assistance at home affects peoples' lives can inform what nursing care should focus upon.	Cross-sectional (survey)	Survey (Level 3) Comparison of people 75 years and older, living at home and receiving help with daily living, with those without such help, with regard to sociodemographic data, self-reported illness, health problems, and QoL (Level 3)	1248 subjects (448 receiving help; 793 not receiving help; age stratified randomized sample) responded to a mailed survey in a southern Swedish municipality.	None	Although symptoms of health-related problems did determine QoL, it was specific symptoms and living conditions that predicted low QoL. Therefore, it is especially important to focus on these symptoms in nursing care. The transition from living independently to receiving help from others probably contributes to a change of values and attitudes about what is important in life. This indicates that an assessment of various symptoms and their importance for each individual is vital. There is a need for thorough assessment and monitoring, e.g. by a nurse, of older people who are living at home and who are restricted in their resources in handling daily living.
Heinrich 2003[25]	Support to caregivers of dementia patients; guidance from health personnel.	Non-comparative	Secondary analysis interviews (Level 4) Interview focus groups analysis (Level 3)	Interviews of 20 women who were caregivers and new data from 8 volunteers; 62 interviews total for analyses.	None	Wanted mutuality in decisionmaking with staff and partnership and empowerment. Community resources use was the experience they described. Struggled with personnel.

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Hepburn 2003[117]	Caregiver well-being, burden, emotional enmeshment	Changing practice projects	Training program descriptive field study (Level 6) Well-being, burden, goal setting. Burden CESD competence. (Level 4)	140 caregivers, 40% spouses, 47% adult, children	Manual, CD-ROM, workshops for caregivers	Improved reaction to caregiver behavior burden, emotional enmeshment changed, descriptive, increased skill, knowledge, confidence.
Houts 1996[81]	Establishment of a prescriptive problem-solving model for family members who care for patients at home can help caregivers develop and carry out orderly plans that address both medical and psychosocial problems and coordinate with care plans of health professionals.	Published guidelines	Proposal of a model for problem-solving in caregiving (Level 6) No outcome measures (Level 4)	None	None	The role of caregivers needs to be restructured to ensure they become effective members of the health care team. This requires educational materials and training programs.
Jang 2004[73]	Depression diminishes response to helping patient.	Randomized controlled trial	Spouse caregiver, AD patients, RCT (Level 2) Counseling, neuroticism, depression (Level 3)	160 in each group; caregivers, spouses caring for patient with dementia	Enhanced psychosocial care or usual care. Comprehensive, counseling sessions, counseling support and consultation (2), and family (4) sessions, then weekly groups 4 months later with ad hoc individual sessions as needed—usual care group.	Caregivers low in neuroticism responded with declining levels of depression, caregiver's height in neuroticism maintained baseline level of depression.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kozachik 2001[112]	With a shift to outpatient cancer care and increased responsibilities placed on family members, a greater potential exists for depressive symptoms to arise in a family caregiver.	Randomized controlled trial	Convenience sampling. Control dyads and experimental group that received Cancer Care intervention. (Level 2) Equivalence of groups at baseline; comparison of caregiver depression; impact of patient depression, patient symptoms, caregiver exposure to supportive nursing intervention on caregiver depression (Level 1)	120 caregiver/patient dyads. Caregivers of newly diagnosed cancer patients. Patients were from two Midwestern cancer treatment sites.	Nursing intervention of symptom monitoring/ management, education, emotional support, coordination of services, caregiver preparation to care.	Baseline caregiver depression and the number of patient symptoms at baseline were significant predictors of caregiver depression at 9 and 24 weeks. However, no main effect of the experimental condition existed on caregiver depression; a nonsignificant relationship was found between the number of interventions and depression scores for caregivers.

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Kurtz 1994[26]	Depression, health impact.	Cross-sectional studies	Descriptive interviews (Level 4) Issues addressed most frequently occurring symptoms, levels of symptom severity, immobility, dependences in ADLs, and depression variance. (Level 3)	Family caregiver experiences at different stages of patient illness, mean age 55, N = 208. Followed for 12 months.	None	Family caregiver variables of depression, impact on health, impact on schedule, and assistance with ADLs were correlated significantly with all patient variables. Family caregivers of elder patients were less depressed and perceived less impact of their schedules. As stage levels of depression progressed, there was a greater impact on caregivers' health and schedule, and increased involvement in assisting their patients with ADLs, closely mirroring the increasing progression with levels of the patient variables. As increased demands on the family caregiver occurred during the later stage of illness, physical and emotional support for the family caregiver did not occur.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mahoney 2003[75]	Caregiver bother and depression anxiety	Randomized controlled trial	Multisite randomized trial (Level 2) Bother, anxiety, depression mastery (Level 4)	100 AD caregivers, 50 in usual care and 49 in technology group	Year-long access to an automated interactive voice response system. Provided stress monitoring, counseling system, voice mail links to AD experts, voice mail telephone support group, and a distraction call for care recipients.	Improved caregiver bother and depression for those with lower mastery at baseline. Improved caregiver burden for wives. Affected bother, anxiety, and depression. Benefit from technology.
McCurry 2005[82]	Caregiver sleep	Randomized controlled trials (for caregiver)	Randomized trial (Level 2) 36 Community Developing CESD, Cornell Depression Scale. Problem checklist - Pittsburg Sleep Index (Level 3)	36 dyads who had a sleep problem	Sleep hygiene, daily walking, daily light exposure (over 3 weeks), written materials, principles of sleep hygiene, control group, general instructions	Improve percent sleep time and total sleep time, fewer waking periods per hour at post-test and 6 months, used actigraph. Effective, MR, control patients spent more time in bed.
McMillan 2006[83]	Mastery burden	Randomized controlled trial three-group design	Randomized controlled trial (Level 2) Coping burden mastery (Level 3)	354 family caregivers with patients with terminal cancer. Three interventions: (1) standard hospice care, (2) hospice care plus three supportive visits, (3) hospice care plus problem-solving training	Coping skills	Improved family coping. Improved caregiver QoL, reduced task burden.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mailey 2002[153]	The nurse's role of educating client's about their health care is an important component of quality care and can be key to successfully coping with a disastrous event.	Changing practice projects/ research	Theory application (Level 6) Neal Theory of Home Health Nursing (Level 4)	None	None	After determining which of Neal's stages (dependence, moderate dependence, autonomy, or collaborator) a nurse occupies, an agency can provide the appropriate resources (training, checklists, supervision, mentoring) the nurse needs (and can communicate to the caregiver) to function effectively in a disaster.
Miller 2006[85]	Caregivers' harmful behavior toward patients	Non-comparative	Descriptive (Level 5). Onetime measures; amount of care provided CO, depression (Level 3)	180 caregiver-care recipient dyads.	None	Compromised cognitive status in 39%; caregiver probably affects the quality of care.
Mittelman 2004[88]	Prevent negative responses to patients' troublesome behaviors	Randomized controlled trial	Randomized controlled trial (Level 2) Problem behavior checklist (Level 3)	406 spouses, caregivers.	Counseling and support and usual care counseling for 4 months, then support groups and ad hoc counseling.	Caregiver distress decreased over time from year 1 to year 4. RCT, effective

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mittelman 2004[89]	Fewer depressive symptoms	Randomized controlled trial	Randomized controlled trial (Level 2) Geriatric depression scale (Level 3)	406 spouses, caregivers of dementia patients.	Counseling sessions; individual (2) and family (4) sessions, then weekly groups 4 months later with ad hoc individual sessions as needed.	No difference in depression at 4 months, but significant differences at all other points up to 3 years after enrollment.
Metlay 2005[90]	In the outpatient setting, patients and their caregivers play a critical role in ensuring the safe use of medical therapies. Knowledge of the causes of medication errors can inform the design of medication-taking interventions.	Cross-sectional	Prospective cohort study (Level 4) Telephone interviews. Demographic characteristics of survey participants were compared to characteristics of nonparticipants in the PACE program. Five groups were identified for sampling by medication use. Interview responses to specific medication information and medication organization questions were compared across drug categories using chi-square tests (Level 3).	4,955 Pennsylvania Pharmacy Assistance Contract for the Elderly (PACE) members (65 years and older) who were taking warfarin, digoxin, and phenytoin (half of whom lived home alone)	None	Almost one-third of subjects reported not receiving any instructions on the use of their medications. Approximately 40% used no organizational system to adhere to medication regimens. A substantial proportion of older adults on high-risk medications do not recall receiving instructions for the use of their medications and do not take advantage of existing systems for organizing medication regimens.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Naylor 2000[154]	Identification of problems experienced by elders who were hospitalized and discharged to home.	Noncompara-tive	Content analysis of patient records by advanced practice nurses (Level 5) Problems encountered by discharged elders, interventions used by advanced practice nurses with patients, linkages between patient problems and advanced practice nurse interventions (Level 3)	Sample records obtained from 124 intervention group patients in a large randomized clinical trial.	None	Most problems experienced were either psychological in nature or related to health behaviors. The majority of interventions for both study groups could be linked to problems of circulation and discharge planning.
Naylor 2000[155]	An effective hospital discharge process can contribute to reduced costs and more positive care outcomes for caregivers and their patients at home.	Systematic literature review	Systematic review (Level 1) Development of a transitional care model (Level 6)	None	None	This program of research has increased an understanding of the differential effects of the model on elders with medical versus surgical cardiac conditions, the profile of elders at risk for poor outcomes, predictors of caregiver burden, the unique needs of elders and the contributions of advanced practice nurses in meeting these needs, and decisionmaking regarding home care referrals.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Naylor 2004[156]	Patients and caregivers report substantial numbers of unmet needs resulting from inadequate discharge procedures.	Randomized controlled trial	Two randomized groups (Level 2) Time to first rehospitalization or death, number of rehospitalizations, quality of life, functional status, costs, satisfaction with care (Level 3)	Six Philadelphia academic and community hospitals. 239 patients ages 65 and older and hospitalized with heart failure.	3-month advanced practice nurse-directed discharge planning and home followup protocol.	Time to first readmission or death was longer in intervention patients. For intervention patients, only short-term improvements were demonstrated in overall quality of life, physical dimension of quality of life, and patient satisfaction.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Ohman 2004[127]	Establishment of a close relationship between district nurses and people with serious chronic illness and their close relatives can increase the health personnel's possibility to alleviate and console those suffering illness, and can be useful for reflection of care interventions, in education and supervision of district nurses.	Non-comparative	Phenomenological hermeneutic (Level 5) Interviews with a narrative approach; interpretation of text in three phases: naïve understanding, structural analysis, interpretation of the text as a whole (Level 3)	Sweden. Purposive sample of 10 female district nurses, between ages 50 and 62 with work experience of 2–20 years.	None	The meaning of district nurses' (DNs) experiences of encounters with people with serious chronic illness and their close relatives at home can be understood as DNs being welcomed into the ill person's privacy, to share intimacy and their understanding of illness. This is expressed in three themes: being in a close relationship, sharing an understanding, weaving a web of protection. Listening was a prerequisite for being able to help and support people. A communicative process (interpretation of body language and verbal communication) has the function of establishing a common environment or shared world of meaning. It is difficult for DNs to escape the close relationship after it is established.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Pot 2005[157]	Elders receiving professional long-term care (vs. informal or no care) may experience increased stress and increased risk of depressive symptoms.	Time series (longitudinal)	Part of the Longitudinal Aging Study Amsterdam. Linear regression analysis (generalized estimating equations). (Level 4) Survey data gathered in 3,107 face-to-face interviews in respondents' homes, with followup interviews after 3 and 6 additional years. Independent variables used to evaluate the dependent variable of depression were (a) from no or informal care to professional home care, (b) from no or informal care to institutional care, (c) continuing professional home or institutional care, (d) from institutional or professional home care to no or informal care. (Level 3)	The Netherlands. Random, nationally representative age- and gender-stratified sample of adults 55–85 years old.	None	There was an association between professional care utilization and depressive symptoms over time, and between transitions in professional care and changes in depressive symptoms. Older adults with a transition to professional care reported considerably more depressive symptoms compared with those who did not receive professional care. Older adults who had a backward transition, from professional care to no or informal care only, did not show such change in depressive symptoms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rose 2000[17]	Combined knowledge of family caregivers and staff nurses can foster comprehensive and appropriate posthospital care.		Open-ended interviews with content analysis (Level 5) Nurses' perceptions of patients and family caregivers, family caregiver's perception of patients and themselves near admission and discharge from hospital (Level 4)	37 caregivers and 37 nurses who were present for discharge but not admission of patient.	None	Suggests a lack of agreement between staff nurses and family caregivers on health issues related to hospitalized older patients.
Roth 2005[77]	Caregiver depression	Randomized controlled trial	Randomized controlled trial (Level 2) Geriatric depression, satisfaction with social support (Level 3)	406 spouses, caregivers of dementia patients	Individual and family counseling; five 90-minute home visits focusing on education and environmental modification every other week over 3 months. Enhanced social support.	Improved number of support persons, satisfaction with support network, and support persons' assistance with caregiving. Increased satisfaction with social support network mediated a significant proportion of the intervention's impact on caregiver depression.
Schulz & Beach 1999[21]	Caregiving as a risk factor for mortality	Perspective population cohort study with 4.5 years of followup	Survey (Level 4) Morbidity, caregiver strain (Level 3)	Population based, community based	None	Caregivers who were providing care and experienced strain had risks 63% higher than noncaregiving controls. Mental or emotional strain is a risk factor for mortality among elderly spousal caregivers.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Schulz & Beach 1999[21]	Death of caregiver spouses	Prospective cohort	Survey. Prospective population-based cohort study with 4–5 year followup. (Level 4) Mortality, caregiver strain (Level 2)	392 caregivers and 427 noncaregivers, ages 66–96 living with spouses	None	Asked if they were experiencing caregiver strain after 4 years of followup, participants providing care who had strain reported mortality 63% higher than noncaregiving controls, and caregivers with no strain did not have elevated mortality rates.
Schumacher 1998[158]	Identification of concepts related to doing family caregiving well.	Systematic literature review	Systematic review (Level 1) Concepts organized into those referring to caregivers perceptions of how well they provide care and those that refer to professional assessment of the quality of care (Level 4)	None	None	Two issues that should be addressed to advance research are the perspective taken on doing caregiving well and change over time in doing caregiving well.
Silver 2004[159]	Core competence and care effectiveness	Noncompara-tive	Descriptive study (Level 5) Caregiver competence and effectiveness (Level 3)	Interviews of 30 family caregivers during first 3 months	None	Caregivers provided an average of 19 tasks per day. The tasks included functional, care management and technical, nutrition-related tasks. Low caregiver preparedness was associated with unmet training needs and low self-rated caregiver effectiveness.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sit 2004[143]	Family caregivers of stroke patients often do not have the requisite knowledge and skills to provide the extensive care needs of stroke survivors. The demands and stress of caring for the family member can result in the caregiver becoming a "second patient."	Cross-sectional (descriptive)	Family caregivers participated in face-to-face interviews 12 weeks after starting stroke caregiving role at home (Level 5). Interview guide consisted of four sections: demographics, assessment of stroke survivor's current health status, assessment of social support for the subject, caregiver's general health. Regression analysis applied to responses to open-ended questions (Level 3)	Hong Kong. 102 Mandarin or Cantonese-speaking subjects obtained from four rehabilitation hospitals with established stroke rehab units.	None	After 12 weeks, nearly half of the caregivers reported having somatic symptoms and fatigue to the extent that they needed to see a physician. Unmet social support needs were identified as tangible support, including provision of equipment, transportation, financial, respite; informational support, including guidance in health-related care task at home; structural support, including a network of people supplying support. Social support can have a positive impact on caregiver health, and nurses are in an excellent position to advance their practice by offering this professional support by extending nursing care beyond the hospital boundary. Nurses can mobilize supportive resources in the caregiver's natural network or provide a “created” network to supplement the insufficiency of the family caregiver's existing network during the period of stress and transition.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Smeenk 1998[160]	Patients with complex health care problems being cared for at home are often cared for by numerous professional caregivers. These caregivers may be providing "parallel" vs. "coherent" care, due to communication gaps, which can result in inadequate care for the patient.	Cross-sectional	Direct and professional caregivers of eligible subjects generated reports (Level 3) Costs and time spent providing care was recorded. Professional and direct caregivers completed a questionnaire after patient's demise, asking opinions on various aspects of intervention. (Level 5)	Terminal cancer patients in the Netherlands. Patients were followed until demise.	Transmural home care intervention program: a specialist nurse coordinator managed discharge from hospital and organized home care; 24-hour phone consultation; dossier maintained at home for various caregivers; specific care protocols established.	Patient, direct and professional caregivers showed that the specialist nurse coordinator and the 24-hour phone service were important components of the intervention. Most of time spent by specialist nurse coordinator was spent in contact with patients and families. Physicians were seen as having a limited role.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sorensen 2002[72]	Family caregivers of elderly persons with physical ailments and/or dementing illnesses often experience high levels of stress, which can lead to a lowered sense of well-being, feelings of being burdened, depression, compromised physical health, and even premature mortality.	Meta-analysis	A comprehensive literature review and the "ancestry method" (Level 1) Identified 78 eligible studies. Outcome measures were caregiver burden, self-rated depression, subjective well-being, uplifts, ability and knowledge, care receiver outcomes. (Level 4)	For eligible studies: number of intervention sessions ranged from 1 to 180; followups were conducted in 22% of cases; number of participants in the experimental intervention condition ranged from 4–2,268; mean age of caregiver was 62.3; caregivers had been providing care for an average of 4 years with 30 hours/week of care; most studies were conducted with heterogeneous disabilities samples; 60 studies were in North America, 11 in Europe, 7 in Australia.	Psycho-educational, supportive, respite/adult day care, psychotherapy, improvement of care receiver competence, multicomponent	Interventions are, on average, successful in alleviating burden and depression, increasing general subjective well-being, and increasing caregiving ability/knowledge. The majority of these effects persist after an average of 7 months after intervention. Providing psycho-educational interventions, psychotherapy, and a combination of several of these interventions is most effective for improving caregiver well-being in the short term. Individual interventions were more effective at improving caregiver well-being, whereas interventions in groups were more effective at improving care receiver symptoms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Steffen 2000[57]	Anger and hostility experienced by caregivers can impact psychosocial functioning.	Randomized controlled trial	Interviews of three groups: wait-list comparison, home-based viewing with weekly phone session, class-based viewing (Level 2) Demographics, self-reported anger intensity, depression, caregiving self-efficacy, telephone contacts (Level 3)	33 caregivers of Alzheimer's patients or other dementing disorder. Recruited through various methods. Provide 5 hours weekly of face-to-face direct care.	8-week psycho-educational video series for anger management, workbook.	Family caregivers may benefit from innovative anger management interventions based on cognitive/behavioral principles and techniques.
Teng 2003[162]	Early supported discharge programs may decrease hospital costs without having a negative effect on patient outcomes.	Randomized controlled trial	Two groups randomized to home intervention or usual care (Level 2) Interviews ascertained self-rated physical health; costs estimated for acute-care hospitalization, outpatient care, and in-home care; caregiver stress (Level 3)	Stroke patients who required rehabilitation services and had a caregiver at home.	4-week, tailor-made home program of rehabilitation and nursing services.	Providing care at home was no more (or less) expensive for those with greater functional limitations than for those with less. Caregivers in the early supported discharger group scored lower on the Burden Index than caregivers with usual care.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Toseland 2004[118]	Health education programs can help caregivers reduce depression, increase knowledge of community services and how to access them, change caregivers feelings of competence and how they respond to the caregiver situation.	Randomized controlled trial	Two-level randomized controlled trial (Level 2) General Health Questionnaire, Medical Outcome Short Form Health Survey, Social Provisions Scale, psychological well-being, perceived social support, subjective burden (Level 3)	Caregivers of spouse with chronic illness who was a member of a staff model HMO. Minimum score of 7 on Caregiver Strain Index. Care recipients with at least two impairments in ADLs. Total of 105 caregiver-care recipient dyads.	Multicomponent psycho-educational health education program. Consisted of 8 weekly sessions, followed by 10 monthly sessions.	Caregivers reported that by end of 1 year, they felt the health education program helped them learn about community resources and how to access them.
Travis 2000[12]	Improving understanding of how family caregivers deliver complex care can result in better care.	Noncompara-tive	Semistructured, face-to-face interviews (Level 5) Content analysis to capture the shared and idiosyncratic experiences of individuals responsible for all aspects of medication administration. Three categories of medication administration hassles were identified: scheduling logistics, administration procedures, and safety issues. (Level 3)	23 family caregivers providing 122 separate accounts.	None	Primary care providers must continually reevaluate and simplify medication regimens for dependent elderly persons in the care of family members, and the family caregivers must be given adequate training and access to ongoing information support systems to help them perform safe and effective medication administration responsibilities.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Visser-Meily 2005[74]	Identification of effectiveness of different types of intervention programs for caregivers of stroke patients.	Systematic literature review	Systematic review (Level 1) Four types of support groups identified: providing specialist services, psycho-educational, counseling, and social support by peers; various outcome measures (reduction of depression and burden, improvement of knowledge, satisfaction with care, family functioning, quality of life) (Level 5)	22 studies, a critical review	None	Could not identify sufficient evidence to confirm the efficacy of interventions, but counseling programs appeared to have the most positive outcome.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Ward-Griffin & McKeever 2000[140]	Quality of care delivered by informal caregiver, contingent upon communication and relationship with nurse	Cross-sectional	Critical ethnography—socialist-feminist perspective (Level 5) 38 in-depth focused interviews (average 75 min. in length) from 23 family caregiver-nurse dyads; data analysis through use of NUD*IST software (Level 3)	Dyads were acquainted 3 months–14 years; sample drawn from three nonprofit, publicly funded community nursing agencies in southwestern Ontario. Average age of nurses was 47 years (one male only); family caregivers' age was 33–82 years (all female); elder care recipients' age was 65–99 years.	None (interaction only)	Relationships between family and professional caregivers appear to be exploitive in nature (economic vs. humanitarian). Family caregivers were contributing more effort toward caring for recipients than nurses, and were not receiving adequate resources to assure minimization of risk to care recipients. Improved communication between formal and informal caregivers may lead to coalition building and collective lobbying for resources, but ultimately a "transformation of the broader political and economic conditions of home care is necessary" for an equitable sharing of caregiving responsibilities.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weuve 2000[139]	Outpatient geriatric evaluation and management (GEM) may alleviate caregiver burden, e.g., physical, psychological, social, and economic distress.	Randomized controlled study	Randomized controlled trial (Level 2) Assessed caregiver burden by telephone interview survey, using a Likert scale. Statistical analysis used to compare burden scores of control and treatment group. (Level 3)	568 high-risk older adults living in the community who were fee-for-service Medicare beneficiaries age 70 or older living in or near Ramsey County, Minnesota.	Participants in the control group received all health care from their usual providers; GEM participants were assigned to one of three clinical teams, each composed of a geriatrician, a nurse, a social worker, and a gerontological nurse practitioner for 6 months. GEM participants (outpatient) received counseling from the team until it was determined that the participant had attained GEM goals or was adhering to a comprehensive plan of care. Caregivers were assessed for burden at baseline and 1 year later. Caregivers did not receive a standard intervention, although they received resource referrals.	GEM and control caregivers were similar at baseline. During the 1-year observation period, mean burden scores of GEM caregiver group tended to decline, while mean scores of control tended to increase or decline less substantially. Assignment to GEM was associated with a reduction in the amount of time caregivers devoted to assisting recipients in some specific tasks. Caregivers who were less experienced and less closely related to their care recipients tended to benefit more from GEM.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Williamson & Shaffer 2001[163]	Potentially harmful behaviors to patients	Non-comparative	Descriptive interviews (Level 5) Caregiver depression (Level 3)	142 caregivers—98 wives, 44 husbands—interviewed	None	Depressed caregivers are more likely to treat spouses in hurtful ways. Premorbid relationships were directly related. If perceived as rewarding, less depression and less harmful behaviors.
Zarit 1998[79]	Family caregivers of dementia patients can suffer overwhelming and uncontrollable stress that can take a toll on emotional health and well-being. Programs can be developed to relieve these negative effects.	Non-randomized trials	Quasi-experimental comparing two groups of primary family caregivers who enrolled relatives in adult day care (Level 3) Caregivers were interviewed at three intervals over 1 year.	Treatment group comprised of caregivers in New Jersey with relatives enrolled in day care; control group was from another state and relatives were not in day care.	Caregivers in treatment group used substantial amounts of day care services.	Use of adult day care by caregivers of dementia patients results in lower levels of caregiving-related stress and better psychological well-being when compared to that of controls.
Zarit 1986[164]	Caregiver burden can affect quality of life and decisions to institutionalize.	Time series	Interviews (Level 5) Caregiver burden, severity of impairment, social support, quality of relationship, placement decision factors (Level 3)	64 caregivers for a spouse with senile dementia, recruited from a clinic offering counseling and support to caregivers, and membership lists from an Alzheimer's disease advocacy group.	None	Severity of the patient's symptoms did not differentiate caregivers who placed relatives from those who did not.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design and Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding(s)
Zwygart-Stauffacher 2000[134]	It appears that there is a discrepancy between the perceived needs of stroke survivors and their caregivers and those of health professionals. Stroke survivors' and caregivers' perspectives as to their needs are critical if professionals are to identify unmet needs and deliver health care that is truly high quality and client centered.	Cross-sectional	Phase I: Twelve focus group and individual interviews, with 47 stroke survivors, caregivers, and professionals from the community (Level 5) Asked caregiver to rate importance of needs and degree to which need had been met. Factor analysis done on needs of survivors and caregivers. (Level 3)	281 stroke survivors and 223 caregivers completed the mailed survey.	None	For both caregivers and survivors, the most highly rated domain for importance was the need for information. Both survivors and caregivers identified the importance of clear information about medications, tests, and treatments, as well as wanting time for questions to be answered and resources. The nurse is pivotal in activating discharge services and facilitating smooth transition of care across health care settings. The nurse can provide caregivers more information on what they can expect through written, verbal, and electronic means.

Chapter 15. Pediatric Safety and Quality

Susan Lacey, Janis B. Smith, Karen Cox

Background

Pediatric inpatient safety and quality of care are dynamic and complex phenomena. Our intent is to inform the reader about efforts underway by pediatric stakeholders and specialty groups and to understand where credible information can be accessed pertaining to patient safety and quality in the provision of care for the hospitalized child. Over the past several years, pediatric groups have partnered to improve general understanding, reporting, process improvement methodologies, and quality of pediatric inpatient care. These collaborations have created a robust program of projects, benchmarking efforts, and research.

This chapter discusses general findings about safety and quality; major initiatives by agencies, groups, and collaborations; a guide to synthesis documents surrounding quality care and evidence-based practice for specific areas of pediatric care; and recommendations about how we can move pediatric safety and quality forward in practice and in the policy arena.

Patient safety literature and associated findings on adverse events for pediatric patients have been widely disseminated.[1–9] Much of the focus has centered on medication errors—the most frequently reported adverse event for both adult and pediatric patients. Indeed, the Institute of Medicine (IOM) reported that medication errors are the most common, yet preventable, type of harm that can occur within the pediatric population,[10] and Bates[11] reported that when pediatric medication errors occur, these patients have a higher rate of death associated with the error than adult patients.

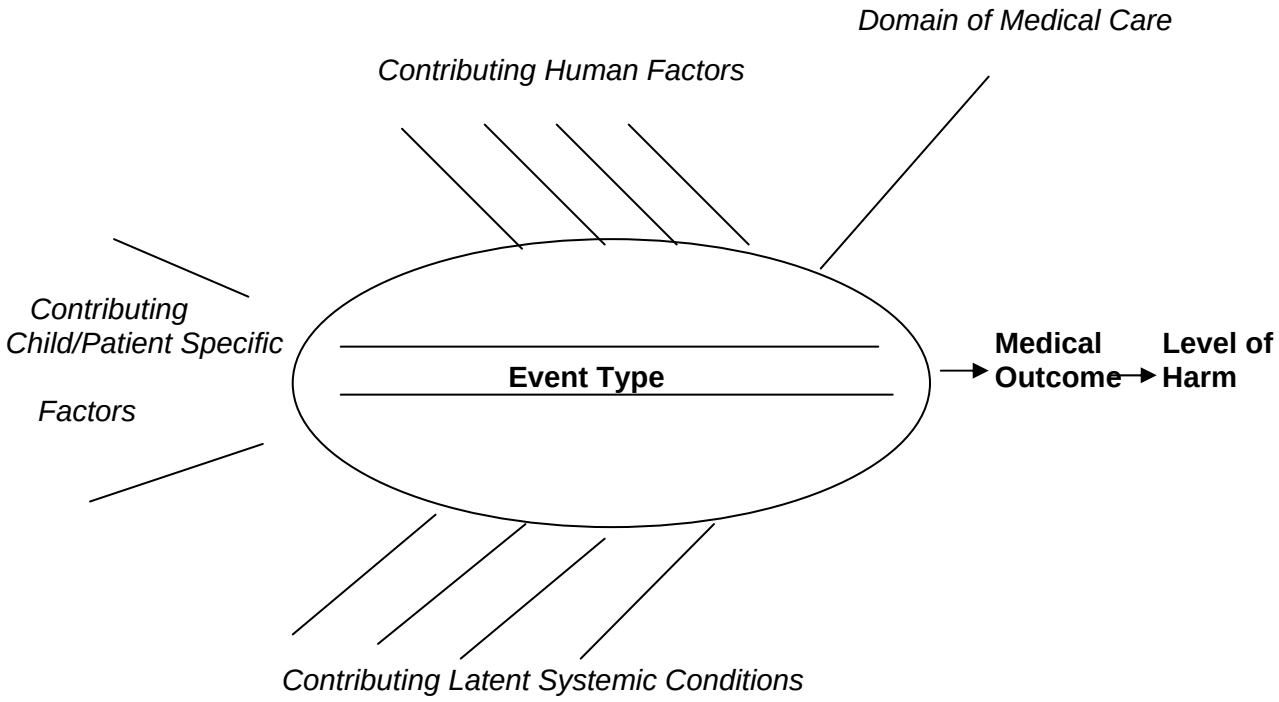
Medication errors, however, are only one potential adverse event for hospitalized children. Slonim and colleagues[4] found 1.86–2.96 medical errors per 100 discharges of hospitalized children. Four distinct challenges confront those conducting research and caring for children.[12] These four related issues are each problematic, but in concert they create a high-risk environment for hospitalized children. Following are the four issues for pediatric patients, summarized from Beal and colleagues:[12]

- Development: As children mature both cognitively and physically, their needs as consumers of health care goods and services change. Therefore, planning a unified approach to pediatric safety and quality is affected by the fluid nature of childhood development.
- Dependency: Hospitalized children, especially those who are very young and/or nonverbal, are dependent on caregivers, parents, or other surrogates to convey key information associated with patient encounters. Even when children can accurately express their needs, they are unlikely to receive the same acknowledgment accorded adult patients. In addition, because children are dependent on their caregivers, their care must be approved by parents or surrogates during all encounters.
- Different epidemiology: Most hospitalized children require acute episodic care, not care for chronic conditions as with adult patients. Planning safety and quality initiatives within a framework of “wellness, interrupted by acute conditions or exacerbations,” presents distinct challenges and requires a new way of thinking.

- Demographics: Children are more likely than other groups to live in poverty and experience racial and ethnic disparities in health care. Children are more dependent on public insurance, such as State Children's Health Insurance Program (SCHIP) and Medicaid.

All quality research is challenged to standardize frameworks and language under which all care providers operate. Each population has unique language and focused areas with no current common language across all specialty areas. Pediatric safety and quality efforts are further challenged as most of the work on patient safety to date has focused on adult patients. There is no standard nomenclature for pediatric patient safety that is widely used. However, a standard framework for classifying pediatric adverse events that offers flexibility has been introduced.[13] The model, seen in Figure 1, allows for analysis and depicts the relationships and interactions of the elements of an event.

Figure 1. Conceptual Model of a Patient Safety Taxonomy



Standardization provides consistency between interdisciplinary teams and can facilitate multisite studies. If these large-scale studies are conducted, the findings could generate large-scale intervention studies conducted with a faster life cycle. More rapid acceptance of efficacious improvement strategies should result.

Leaders in Pediatric Safety and Quality

Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is the Federal authority for patient safety and quality of care. AHRQ has been a leader in funding safety and quality improvement efforts, synthesizing and disseminating findings to clinicians and the public for more than two decades to stimulate both scientific and policy dialogue. AHRQ has been a leader in pediatric quality and safety. Within the agency, the Children's Health Advisory Group is a resource for AHRQ's senior leaders that helps focus work in key topic areas as the state of the science changes. A focus of AHRQ funding is translational research, which moves scientific findings to health care settings across the care continuum. Projects funded by AHRQ help determine where gaps in safety and quality exist.[14]

AHRQ also sponsors the Health Cost and Utilization Project (HCUP), a family of databases supported by a Federal-State-industry partnership. One of the databases is the Kids Inpatient Database (KID). HCUP is the largest information source of patient encounters in both inpatient and outpatient settings. All HCUP databases contain more than 100 variables linked to patient care, including both clinical and charge data. All patient identifiers are removed to protect patients' confidentiality. The HCUP databases are used by clinicians and health services researchers to investigate care delivery and discover trends in outcomes and costs. They are also used internally at AHRQ for special projects, such as the development of pediatric indicators outlined in the next section.

The initial AHRQ work on pediatric patient safety was conducted by investigators from Johns Hopkins, using the KID database for the year 1997.[4] However, Miller, Elixhauser, and Zhan[5] conducted a more recent review of potential pediatric safety issues by using the previously defined adult indicators. They found that hospitalized children who experienced a patient safety incident, compared with those who did not, had

- Length of stay 2- to 6-fold longer
- Hospital mortality 2- to 18-fold greater
- Hospital charges 2- to 20-fold higher

Another key finding in this initial work demonstrated that severity of illness and type of hospital are directly associated with patient safety incidents, except for birth trauma. Birth trauma was directly associated with African American and Hispanic race, but not type of hospital.

Subsequently, AHRQ sought to develop pediatric quality indicators with the goal to "highlight areas of quality concern and to target areas for further analysis."[15] Nominated peer reviewers from 44 professional clinical organizations joined this effort. Each had to spend the majority of his or her time in direct clinical practice. Development of the PedQIs is the result of Phase I of this work. The complete report, *Measures of Patient Safety Based on Administrative Data: The Patient Safety Indicators*, was published in February 2006.

After rigorous review, 18 pediatric quality indicators were recommended for inclusion in the AHRQ quality measure modules, based on expert input, risk adjustment, and other considerations. Thirteen inpatient indicators are recommended for use at the hospital level, and five are designated area indicators. Inpatient indicators are treatments or conditions with the greatest potential of an adverse event for hospitalized children. Area-level indicators are intended

to measure access to care and have the potential to reduce hospitalization and subsequent untoward events. Table 1 presents the AHRQ pediatric quality indicators.

Table 1. Pediatric and Area-Level Indicators

Pediatric Quality Indicators **Provider-Level Indicators**	**Area-Level Indicators**
Accidental puncture or laceration	Asthma admission rate
Decubitus ulcer	Diabetes short-term complication rate
Foreign body left during procedure	Gastroenteritis admission rate
Iatrogenic pneumothorax in neonates at risk	Perforated appendix admission rate
Iatrogenic pneumothorax in nonneonates	Urinary tract admission rate
Pediatric heart surgery mortality	
Pediatric heart surgery volume	
Postoperative hemorrhage or hematoma	
Postoperative respiratory failure	
Postoperative sepsis	
Postoperative wound dehiscence	
Selected infections due to medical care	

Source: Agency for Healthcare Research and Quality—www.qualityindicators.ahrq.gov.

Phase II of this project will extend the work to include indicators of neonatal care quality. In addition, methodological issues associated with risk adjustment require refinement to reduce variation in coding patient care for future comparison studies. Possible additions to the dataset will address the patient's condition on admission and increase the understanding of how laboratory and pharmacy utilization impact patient outcomes. AHRQ will continue to work with health care providers to refine the area-level indicators to improve outcomes for children receiving outpatient care and reduce the incidence of hospitalization for those defined conditions.

The findings of AHRQ-funded research provide Congress with critical information about patient safety and quality of care for the American people. This work will influence Federal funding for projects related to improving health care safety and quality for children. (See AHRQs' Web site, www.ahrq.gov, for more information.)

National Guideline Clearinghouse and National Quality Measures Clearinghouse

The National Guideline Clearinghouse is a public resource for evidence-based clinical practice guidelines, while the National Quality Measures Clearinghouse is a repository of evidence-based practice measures and measure sets. These entities, both initiatives of AHRQ, offer consumers and clinicians the most recent information about the continuum of care and best practices for all health care recipients. Those which involve the provision of care to children are relevant to this chapter. Although both sources offer comprehensive guides for numerous diseases and disorders for children, there are also specific reports and documents pertinent to pediatric inpatient care. In addition, users are able to search both sites with a high level of specificity; the search for articles can be narrowed to those that are peer reviewed, by authors, by dates, etc.[16, 17]

Collaborations for Pediatric Safety and Quality

Numerous groups are actively engaged in improving pediatric care, quality and safety. Each of these groups has a unique mission and membership. Several recent efforts have these groups

working on joint projects to move things forward within their respective spheres of influence. Table 2 details these groups' missions and how to access their Web sites.

Table 2. Key Web Sites

Organization	Mission	Web Site
The National Association of Children's Hospitals & Related Institutions	Clinical care, research, training, and advocacy	www.childrenshospitals.net
Child Health Corporation of America	Business strategies, safety & quality	www.chca.com
National Initiative for Children's Healthcare Quality	Education and research	www.nichq.org
Neonatal Intensive Care/Quality & Vermont Oxford Network	Quality improvement, safety & cost effectiveness for newborns & families	www.nicq.org
Children's Oncology Group	Cures for childhood cancers, family support	www.childrensoncologygroup.org
Initiative for Pediatric Palliative Care	Education, research & quality improvement	www.ippcweb.org
End-of-Life Nursing Education Consortium	End-of-life education & support	www.aacn.nche.edu/elnec

The National Association of Children's Hospitals and Related Institutions

The National Association of Children's Hospitals and Related Institutions (NACHRI) is a not-for-profit organization of 160 member institutions in the United States, Australia, Canada, Italy, Mexico, and Puerto Rico. It supports and promotes children's health issues through clinical care, research, training, and advocacy. NACHRI works through collaborative efforts to help build measures for inpatient pediatric outcomes and is a key stakeholder in these efforts. In addition, NACHRI staff have led national focus groups to facilitate the understanding of barriers to pediatric patient safety and quality of care. The Web site can be searched for information on improvement efforts either completed or underway.[18]

Child Health Corporation of America

Child Health Corporation of America (CHCA) is a for-profit organization with membership of free-standing pediatric hospitals across the United States. Its mission is to support its membership through improved business strategies, and also through improved safety and quality of care. In fact, CHCA was the lead on the development and adoption of the pediatric core asthma measures, described below, included in the National Quality Forum work.[19]

The National Initiative for Children's Healthcare Quality

As a not-for-profit organization, the National Initiative for Children's Healthcare Quality focuses on education and research and is dedicated solely to improving the quality of health care provided to children. Founded in 1999, the National Initiative's mission is to eliminate the gap between what is and what can be in health care for all children.[20]

The Neonatal Intensive Care/Quality and Vermont Oxford Network

The Neonatal Intensive Care/Quality is a multicenter collaborative working with members of the Vermont Oxford Network, a not-for-profit organization that has as its mission to improve the quality and safety of care for newborn infants and their families through a coordinated program

of research, education, and quality improvement projects.[21] Currently, the Neonatal Intensive Care/Quality collaborative has three primary goals:

1. Achieve measurable improvements in the quality, safety, and efficiency of neonatal intensive care.
2. Develop new resources, tools, and knowledge for quality improvement in neonatal intensive care units.
3. Disseminate this improvement knowledge to the neonatal community.

Children's Oncology Group

The Children's Oncology Group is an international research organization supported in large part by the National Cancer Institute.[22] The National Cancer Institute founded the pediatric cooperative group in 1955. Since then, cure rates for children and adolescents with cancer have risen dramatically, from 10 percent to 70 percent. The Children's Oncology Group includes 500 pediatric cancer specialists from 240 pediatric institutions in the United States, Canada, and Australia. Currently more than 40,000 children, adolescents, and young adults in the United States are treated according to research protocols. A multidisciplinary approach is used, and both curative and supportive care are constantly under investigation. They way in which the Children's Oncology Group collaborates is considered the gold standard for cooperative clinical research because of its ability to pool scientific ideas, research skills, and data. Member institutions can obtain rapid answers to clinical questions of interest and pursue optimal care for pediatric patients diagnosed with cancer.

100,000 Lives Campaign

CHCA, NACHRI, and the National Initiative for Children's Healthcare Quality are partnering to bring resources to the children's health care community as part of the Institute for Healthcare Improvement 100,000 Lives Campaign. The Pediatric Node of the 100,000 Lives Campaign was launched in December 2004.[23] The objective of the campaign was to save 100,000 pediatric lives within 18 months by improving strategies in key areas of care: preventing surgical site and central line infections, preventing ventilator-associated pneumonia, deploying rapid response teams for inpatient settings, and medication reconciliation. A target of 1,600 participating institutions was set, and as of April 2006 there were more than 2,200 organizations engaged in this work.

Pediatric Intensive Care Measures

The Pediatric Intensive Care Measures collaborative is a joint effort of NACHRI; Medical Management Planning, a benchmarking service; and CHCA to develop pediatric core measures.[24] In February 2004, the Pediatric Intensive Care Measures collaborative issued a national call for measures from hospitals and received 51 measures from a variety of sources. An expert panel was created representing a variety of expertise and care models, with panelists from all parts of the Nation. The panel's charge was to rigorously review the measures submitted and determine which should move forward for consideration as standard measures for generalized use.

A key issue that arose immediately was the need for a standardized risk-adjustment methodology that would meet the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) requirement to be in the public domain, but that also had been validated in the United States pediatric population. The panel did not identify any single tool to meet these criteria, but noted that risk adjustment was a critical component of any core measure set for pediatric intensive care units (PICUs).

After several months of work by the expert panel, by additional experts who worked in subgroups, and after voting by the children's hospitals, the following potential PICU core measures were identified:

- PICU standardized mortality ratio
- PICU severity-adjusted length of stay
- PICU unplanned readmission rate and review of unplanned readmissions
- PICU pain assessment on admission and PICU periodic pain assessment
- PICU medication safety practice adoption
- PICU central line infection prevention practice adoption

Next steps are continued discussions with all stakeholders to pilot test these measures in a respectable number of PICU settings followed by modification of these measures, if necessary. Because the Joint Commission uses only measures endorsed by the National Quality Forum, discussed in other chapters and below, advocates will seek this endorsement. Ultimately, PICUs would embed these measures in their overall quality improvement programs with institutional improvement strategies.

The National Quality Forum

The mission of the National Quality Forum is to improve the lives of patients by building consensus for quality measurement and reporting. The majority of this work has been done with adult patients. A vigorous collaboration with NACHRI and CHCA was launched to create pediatric measures. This partnership has identified the Children's Asthma Core, which is made up of the following core measures for asthma patients:[25]

1. Return to hospital (i.e., emergency department, observation status, or inpatient admission) with same asthma diagnosis within 7 days following inpatient discharge
2. Return to hospital with same asthma diagnosis within 30 days following inpatient discharge
3. Return to hospital with same asthma diagnosis within 7 days following emergency department or observation stay
4. Use of relievers (drugs used to control exacerbations) for inpatient asthma
5. Use of systemic corticosteroids for inpatient asthma
6. Risk-adjusted length of stay
7. Home management plan of care discussed with patient/caregiver

Development and national pilot testing of these children's asthma core measures was conducted and, as of October 2007, three were selected for inclusion as performance measures for accreditation by the Joint Commission: use of relievers, use of systemic corticosteroids, and home management plan of care.

Resources and dedication are needed to conduct and sustain this level of inquiry. Hospitals are committed to this level of disease-specific investigation and reporting. However, the Joint

Commission's involvement adds an additional level of organizational commitment to provide the necessary resources to collect and report this information consistently over time.

This work is aligned with the National Heart, Lung, and Blood Institute's and the American Academy of Pediatrics's most recent recommendations for pediatric asthma guidelines, which are now under revision. These guidelines include information on best practices with asthma medications as related to symptoms, prevention, and monitoring and controlling asthma.[26] All of this work is an iterative process, and organizations and regulatory bodies continue to modify and revise this work.

Palliative Care

Over the last few decades, a significant body of research has contributed to the science of palliative care. Two key groups have developed best practices and guidelines for individuals and institutions that provide care to dying children: the Initiative for Pediatric Palliative Care (IPPC) and the End-of-Life Nursing Education Consortium.[27, 28]

IPPC is both an education and a quality improvement effort, aimed at enhancing family-centered care for children living with life-threatening conditions. IPPC's comprehensive, interdisciplinary curriculum addresses knowledge, attitudes, and skills that health care professionals need to better serve children and families.

IPPC is a project of the Center for Applied Ethics and Professional Practice, a division of Education Development Center, Inc. The Education Development Center is a nonprofit organization with more than 600 professional staff, working on 300 educational projects throughout the United States and in 27 other countries. Education Development Center is the lead organization in this initiative, working in close collaboration with NACHRI, the Society of Pediatric Nurses (SPN), the Association of Medical Schools Pediatric Department Chairs, and the New York Academy of Medicine.

The IPPC team is composed of nationally renowned educators and clinicians with expertise in pediatric palliative care. IPPC is a broad-based collaborative effort that includes children's hospitals, pediatric units in general hospitals, and hospice or home care programs that serve children living with life-threatening conditions and their families.

The End-of-Life Nursing Education Consortium project is a national education initiative to improve end-of-life care in the United States. The project provides undergraduate and graduate nursing faculty, continuing education providers, staff development educators, pediatric and oncology specialty nurses, and other nurses with training in end-of-life care so they can teach this essential information to nursing students and practicing nurses.

Nurse Staffing and Pediatric Outcomes

An established body of literature links nurse staffing and hours worked with patient outcomes. While the number of nurses providing patient care is recognized as an inadequate measure of nursing care quality, there is hard evidence that nurse staffing is directly related to patient outcomes. Patient death, nosocomial infections, cardiac arrest, and pressure ulcers are linked to inadequate nurse-to-patient ratios.[29, 30] Heavy workloads, nurses' perception that they are unable to carry out their professional role, conflict and other difficult relationships, and unsupportive leadership are identified by the IOM as related to increased risk of errors and accidents, as well as to substance abuse, conflict, increased use of sick time, and workplace

violence.[31] However, most of the research linking nursing workload and outcomes for either patients or nurses has been conducted with adult patients and the nurses who care for them. The following section covers only pediatric patients and nurses.

National Database of Nursing Quality Indicators

The American Nurses Association's National Center for Nursing Quality collects data about nursing care quality reported by nursing units to the National Database of Nursing Quality Indicators.[32] The database provides a data repository for hospitals participating in a national effort to address nursing care safety and quality. The National Database of Nursing Quality Indicators has collected data about nursing care quality for adult patients since 1998. Indicators of pediatric nursing care quality were developed and pilot tested in 2004. Since the fourth quarter of 2004, data about the pain assessment, intervention, and reassessment cycle and peripheral intravenous infiltration have been collected from a national sample of pediatric units and children's hospitals.

These two indicators of pediatric nursing care quality are *sensitive* measures of nursing care. That is, the presence or absence of registered nurses (RNs) impacts the outcome for pediatric patients requiring pain management and/or peripheral administration of intravenous fluids and/or medications. Professional nurses play a key role in successful pain management, especially among pediatric patients unable to verbally describe pain. Astute assessment skills are required to intervene successfully and relieve discomfort.[33] Maintenance of a patient's intravenous access is a clear nursing responsibility. Pediatric patients are at increased risk for intravenous infiltration and for significant complications of infiltration, should it occur.[34, 35]

The characteristics of effective indicators of pediatric nursing care quality include the following:

- Scalable. The indicators are applicable to pediatric patients across a broad range of units and hospitals, in both intensive care and general care settings.
- Feasible. Data collection does not pose undue burden on staff of participating units as the data is available from existing sources, such as the medical record or a quality improvement database, and can be collected in real time.
- Valid and reliable. Indicator measurement within and across participating sites is accurate and consistent over time.

In 2003, Stratton[36] studied the link between pediatric outcomes of interest and nurse staffing. She used administrative data from seven academic, not-for-profit children's hospitals, which included 17 medical/surgical, 5 oncology, and 12 intensive care units, to analyze the correlation between staffing and 5 indicators of quality care identified in the literature as nurse sensitive. Stratton controlled for unit type and patient characteristics. The five indicators were medication administration errors, central line infections, bloodstream infections, intravenous infiltrates, and parent/family complaints. Key findings supported a strong inverse relationship between the proportion of hours of pediatric nursing care delivered on patient care units by RNs and the rate of occurrence of central line and bloodstream infections. Other significant findings included the following:

- A higher percentage of nursing overtime hours was associated with lower parent/family complaint rates.
- A higher percentage of nursing overtime hours and a lower percentage of hours of care from float/agency/traveler RNs were associated with lower bloodstream infection rates.

This work applies nurse staffing to outcomes among pediatric patients and also expands the context of nurse staffing to include "float/travel/agency" nurses and the complex issue of overtime into the research questions. Since maximizing the capability of the nursing workforce is a strategy employed in high-reliability organizations, this work makes an important contribution to pediatric nursing.

The California Nursing Outcomes Coalition Database Project

The California Nursing Outcomes Coalition Database Project, the statewide database that links patient outcomes and nurse staffing, is actively conducting data collection and unit-based benchmarking for pediatric units across the State (N. Donaldson, co-principal investigator, Carolyn Aydin, co-investigator, California Nursing Outcomes Coalition Pediatric Pilot Project, personal communication, July 2006).To date, 66 diverse pediatric units have joined this database. No formal reports have been generated, as this work is in process.

Evidence-Based Pediatric Practice

Evidence-based practice is defined as a systematic approach to clinical decisionmaking to provide the most consistent and best possible care to patients.[37] Evidence-based practices can also be applied to organizational structure and processes. As individuals and organizations seek to provide safe, high-quality care for hospitalized children, tactics to reduce hospital errors are an important beginning point. McFadden, Towell, and Stock[38] systematically reviewed the literature on patient safety and derived a list of seven "critical strategies" for dealing with the challenges of reducing errors and improving patient safety, as well as both internal and external barriers to error-reduction strategies. Following are the evidence-based recommendations for improvement:

1. Create a partnership for safety with all stakeholders—doctors, nurses, administrators, trustees, and patients. Care of children in hospitals necessitates the inclusion of parents or other surrogates among the safety stakeholders.
2. Develop a system for reporting errors that is free of blame. An effective reporting system encourages reporting by being confidential and impartial, and assuring that no retribution for reporting occurs.
3. Foster open discussion of errors and near misses at all levels of the organization to identify risks, define goals, and measure progress in an environment where individuals feel comfortable discussing problems and sharing information and knowledge.
4. Create an organizational culture where patient safety is the top priority and there is an ongoing commitment to address patient safety issues.
5. Provide staff education and training in error-reduction strategies.
6. Systematically analyze the data collected on errors to understand the complex relationships and interactions that are often related to health care errors.
7. Redesign hospital systems and processes (the workplace and the work) to mitigate error so that it is difficult or impossible to make a mistake.

Barriers to the adoption of evidence-based strategies to reduce errors were also identified from the literature. Examples of organizational factors that may function as barriers include lack of support from top administrators, lack of knowledge or understanding of errors, and lack of resources. External barriers to reporting errors include threat of malpractice suits and media

attention to errors. Cost-containment efforts resulting from managed care may reduce staffing to dangerous levels, divert resources from error prevention, or both.[38]

Hospitals are making progress toward adopting strategies that improve patient safety, McFadden, Stock, and Gowen report.[39] Though continued progress is needed, most U.S. hospitals have begun to implement some of the evidence-based practices that research has demonstrated are efficacious in reducing hospital errors.

Challenges in Pediatric Evidence-Based Practice

Nurses caring for hospitalized children face similar challenges as nurses in all hospital settings. There is a substantial gap between evidence and practice, as many nurses do not understand or value research and have had little training that helps them find evidence on which to base their practice.[36, 40] Most nurses practice based on what they learned in nursing school and from their subsequent experiences with patient care.[41] When practice questions arise, nurses are most likely to ask peers for information and advice.[37]

Common challenges to nurses learning about and putting into practice guidelines based on the systematic identification and synthesis of the best available scientific evidence persist in all settings. For example, nurses' knowledge and competence with the recommended technique for endotracheal suctioning is inadequate, especially with regard to the instillation of normal saline.[42, 43] Bridging the gap between scientific evidence for practice and the application of the evidence in the clinical care of patients continues to challenge practicing nurses, nursing educators, nurse experts, and nursing administrators.

The following personal and organizational barriers to the use of research and the implementation of evidence-based practices among nurses have been identified:[37, 40, 41, 44–46]

- Perceived low usefulness of research in clinical decisionmaking
- Lack of time to access, read, and evaluate research
- Lack of access to the tools needed to search for evidence
- Inadequate skills to conduct information searches
- Real or perceived lack of assistance with information seeking
- Difficulty understanding research articles
- Belief that change will produce minimal benefits
- Perceived lack of authority
- Low management and staff support
- Lack of physician collaboration and buy-in
- Costs of resourcing the development of evidence-based practices

Unique challenges in nursing care for children. Some authors suggest that pediatric nursing, rooted deeply in tradition and ritual, is particularly resistant to evidence-based practice changes.[47, 48] Pain management in infants and children is an example of the influence of tradition, personal bias, the persistence of myths, and resistance to change.[48] However, it is important to note that SPN has recognized that evidence-based practice represents a shift in clinical decisionmaking and provides a more complete and comprehensive understanding of "best" clinical practice. Its position and recommendations are as follows:[49]

1. SPN endorses clinical practice based on "best evidence" from evidence-based practice sources and patient and family preferences.

2. SPN supports clinically based nurses who use an evidence-based practice approach to maximize clinical outcomes for pediatric patients and their families.
3. SPN supports advanced practice nurses in the roles of evidence-based practice mentors for clinically based nurses.
4. SPN supports nursing research that generates new knowledge of best practice based on measurable, improved patient outcomes.
5. The SPN Listserv provides an opportunity for best practice discussions among its members.
6. SPN supports nursing higher education that trains all levels of nurses in the application and dissemination of evidence-based practice.
7. SPN supports institutions' efforts to create a culture and resource infrastructure that incorporates evidence-based practice in all aspects of patient care delivery, including collaboration and sharing of ideas and information among other nursing institutions and agencies.

The *Journal of Pediatric Nursing* includes an evidence-based practice section in each issue, focusing on the search for and critique of the best evidence to answer challenging clinical questions so that the highest quality, up-to-date care can be provided children and their families. The American Academy of Pediatrics Steering Committee on Quality Improvement and Management develops and classifies clinical practice guidelines "intended to improve clinical care by reducing inappropriate variations, producing optimal outcomes for patients, minimizing harm, and promoting cost-effective practices"[50] (p. 874). The committee uses a three-step process in developing clinical practice guidelines:

1. Determination of the quality of the evidence in support of a proposed practice recommendation
2. Evaluation of the anticipated balance between benefits and harm when the recommendation is carried out
3. Designation of the recommendation's strength (*strong recommendation, recommendation, option*, or *no recommendation*).

Clearly, leadership exists for overcoming barriers to implementing evidence-based pediatric practice.

The challenges of family-centered care. Family-centered nursing of children places the concerns, needs, strengths, and capabilities of the family at the center of a hospitalized child's care. Rush and Harr[48] suggest family-centered care and evidence-based practices might be at odds at the bedside and recommend a "marriage" of the two to assure that the best care is achieved. More recent definitions of evidence-based practice include patient preference, but pediatric nurses will have an opportunity to lead efforts to include existing evidence-based strategies for family-centered care, as well as lead the further development of practice guidelines that include the perspective of the family in care. Several examples of evidence-based, family-centered care follow.

Nearly two decades ago, Martha Curley demonstrated that the nursing mutual-participation model of care diminished distress for parents of children in the pediatric intensive care unit.[51, 52] When nurses assisted parents of critically ill children to continue specific parenting activities with their children in the intensive care unit, parents reported less stress.

Bernadette Melnyk and colleagues[53–55] tested the effects of the Creating Opportunities for Parent Empowerment program with mothers of young children in the pediatric intensive care unit. Study participants were provided written and audiotaped information describing young

children's typical responses to critical illness and intensive care and parental-role information, which suggested strategies the parents could use to facilitate their children's adjustment. These parents, compared to the control group, reported less negative mood and parental stress, provided more support to their children during intrusive procedures, participated more in their children's care, and reported fewer posttraumatic stress symptoms after discharge.

A strategy to prepare parents for their child's transfer from the pediatric intensive care unit was tested for its impact on parental anxiety.[56] Study parents received written information explaining the transfer procedure and the level of care on the general pediatric unit, reinforcing the positive aspects of their child's transfer. The information was provided 24 to 48 hours prior to the transfer. Findings indicated that experimental group parents had lower levels of anxiety following transfer.

In 2004, Melnyk, Small, and Carno[57] critically appraised these five studies of parent-focused interventions aimed at improving coping and mental health outcomes for children and their parents. Despite what is known about the potential adverse effects of critical illness and intensive care for children and their families, interventions with proven effectiveness are not in place in pediatric critical care units across the United States. Clinical practice guidelines that incorporate evidence-based interventions are needed if they are to become the standard of care.

IPPC[27] is a consortium of seven academic children's hospitals, Education Development Center, NACHRI, the New York Academy of Medicine, SPN, and the Association of Medical School Pediatric Department Chairs. The group has both education and quality improvement objectives that address the growing empirical evidence that U.S. health care systems fail to meet the needs of children with life-threatening conditions and their families.

A commitment to culturally respectful, family-centered care of children with life-threatening conditions is evidenced as support of the family unit and involvement of the child and family in communication. Decisionmaking and care planning are two of six quality domains in the program. Evidence-based practice guides discovering what matters to families and incorporating the perspectives of children and families in care planning and implementation.[58]

The American Heart Association issued guidelines in 2000 that recommended, for the first time, that family members be given the option to be with their loved ones during resuscitation efforts, whenever possible.[59] Pediatric Advanced Life Support guidelines also endorse family presence during resuscitation of children.[60] However, clinicians in many settings have resisted following the guidelines, citing the belief that the family will suffer undue trauma and may not understand what is happening to their loved one, and concern that family presence may lead to litigation.[61] A literature review for evidence-based practice guideline development at the Children's Hospital, Denver, found that families want to have a choice about being present during resuscitation efforts, refuting previous beliefs that family presence is detrimental to family members or institutions. The review led to development of an evidence-based practice policy that may guide others to provide compassionate, family-centered care that respects family choice and supports their presence during resuscitation efforts.[62]

Evidence-Based Clinical Practice Guidelines: Exemplars

The development of guidelines for practice is vital to the implementation of evidence-based practices and the quality outcomes anticipated as a consequence of reducing unnecessary variation, enhancing benefit, minimizing harm, and promoting cost effectiveness. The gap between establishing evidence for practice and implementing evidence-based practice, however,

is significant. In fact, the IOM identifies it as a "quality chasm."[63] In July 2003, the National Quality Forum released 30 safe practices for better health care, calling it a road map for safety. The practices identified are supported by "evidence so clear that if they were universally implemented, they would significantly improve the situation with regards to medical errors and patient safety"[64] (p. 12). More than two-thirds of the 30 safe practices are related to Joint Commission national patient safety goals or other Joint Commission initiatives, and they are applicable to the care of hospitalized children. In addition, pediatric quality indicators proposed by AHRQ and those proposed by the IOM inform and direct efforts to improve the safety and quality of care for hospitalized children. The section that follows presents progress toward evidence-based clinical practice guidelines for pediatric care addressing national patient safety and quality objectives.

Pressure Ulcer Prevention

Pressure ulcers do occur in acutely ill children. However, there are differences among pediatric patients, such as between premature neonates and older infants or children; between all pediatric patients and those in at-risk groups, such as those with spina bifida and those who are critically ill; and in the distribution of pressure ulcers between infants, children, and adults.

Risk factors for pressure ulcer development are not different among pediatric patients or between children and adults. The factors include (1) decreased mobility, activity, and sensory perception; (2) increased moisture, friction, and shear forces; and (3) intrinsic factors that influence tissue tolerance associated with age, nutrition, and tissue perfusion.

The incidence of pressure ulcers among hospitalized children is consistent across studies. There is a 17 percent incidence in children in the intensive care unit following cardiac surgery,[65] 19 percent among infants in a neonatal intensive care unit,[66] 26 percent among children in a multidisciplinary pediatric intensive care unit,[67] 27 percent in a prospective, multicenter study of pediatric intensive care unit patients,[68, 69] and 23 percent in a recently reported study that included pediatric intensive care and general pediatric care patients.[70]

Prevention of skin breakdown begins with accurate prediction of pressure ulcer risk. The Braden Skin Risk Scale score, the gold standard for predicting pressure ulcer risk in adult patients, has been adapted for use with pediatric patients to reflect the unique needs of children.[71] A multicenter study of the Braden Q Scale demonstrated that its performance is similar in a pediatric intensive care population and in adult patients. The modified Braden Q, which is shorter, is comparable.[68] The Starkid Skin Scale used the Braden Q as the basis for developing a shorter, simpler tool to measure risk of skin breakdown. While it has high interrater reliability and high specificity, the initial study of its use found its sensitivity low.[70] It is, however, the only tool evaluated in general pediatric patient care.

Risk factors for the development of pressure ulcers include white race; younger age; diarrhea; use of medical devices, especially mechanical ventilation; and higher severity of illness, hallmarked by hypotension and prescription of vasoactive medication infusions. Lower Braden Q or Starkid Scale scores were predictive of risk for skin breakdown.

The location of pressure ulcers in pediatric patients is different than it is in adults. The most common location in pediatric intensive care patients was the head (occiput and ears). Acutely ill pediatric patients in the intensive care unit also developed lower-body pressure ulcers, with their heels most frequently affected.[68] In general care pediatrics, skin breakdown on the buttocks or perineum is most commonly related to diaper dermatitis.[70]

Most children in all studies had Stage I pressure ulcers and developed them early in hospitalization—likely when they were most ill. Prevention and treatment strategies have not been studied in children, but those recommended in the AHRQ evidence-based review of practices known to prevent pressure-related injury are logically applicable in pediatric patients. Evidence supports the use of pressure-reducing devices to distribute weight over a larger surface area, head-of-bed elevation to the lowest degree consistent with the patient's condition to minimize sheer-related injuries, elevation of the heels off the bed, and a turning schedule to provide pressure relief.[72] In addition, injuries from medical devices such as oximeter probes, endotracheal and tracheostomy tubes, BiPAP masks, catheters, and splints—which were not included in pressure ulcer data in the studies—warrant efforts at prevention from vigilant pediatric care providers. "Excellent skin care is a hallmark of quality nursing care."[70]

Catheter-Related Bloodstream Infection Prevention

Catheter-related bloodstream infection (CRBSI) is associated with increased morbidity, mortality, and health care costs.[73] While securing and maintaining reliable venous access is essential in acute care of hospitalized infants and children, use of central venous catheters carries a number of risks. Included are local infection, CRBSI, septic thrombophlebitis, endocarditis, metastatic infections (brain abscess, lung abscess, osteomyelitis), and mechanical complications during insertion.[74] Children are at greater risk than some adults for CRBSI. In pooled pediatric intensive care unit data reported by the Centers for Disease Control and Prevention (CDC) National Nosocomial Infection Surveillance System in 2003, the rate of CRBSI was 7.3 per 1,000 catheter days.[75] Bloodstream infection is the most common nosocomial infection in pediatric critical care units, followed by ventilator-associated pneumonia.[75, 76] Length of stay increases dramatically in the face of bloodstream infection, as do associated hospital costs.[77]

Strategies to reduce risk of CRBSI. Measures to minimize the risk for infection related to intravenous therapy have important implications for nursing care of acutely ill pediatric patients. Evaluation of the risk-reduction measures has, most often, been undertaken in studies with adult patients. Most, however, apply to the care of hospitalized infants and children.[74, 78] Important differences are noted. Factors over which nurses have direct influence are discussed.

Site selection. The presence of phlebitis and the density of skin flora at the catheter insertion site are risk factors for infection. For adults, lower-extremity insertion sites, including those in the femoral vein, are associated with a higher risk of deep vein thrombosis[79] and have been demonstrated to have relatively high bacterial colonization rates.[80] In children, femoral catheters have a low incidence of mechanical complication and may have an infection rate equivalent to catheters in alternative locations.[81–83]

Hand hygiene and aseptic technique. Hand hygiene with an antibacterial soap and water or with waterless alcohol-based gels or foams contributes significantly to reducing risk of CRBSI.[74, 84] Hand hygiene is recommended before and after palpating potential catheter insertion sites, and before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter.[74] During central venous cannulation, the CDC recommends maximal barrier protection (cap, mask, sterile gown, gloves, and drape). Skin asepsis with 2 percent aqueous chlorhexidine is recommended. Providone iodine, which has been the most widely used antiseptic for cleansing intravascular insertion sites, is acceptable if it is allowed to remain on the skin for at least 2 minutes, or until dry, prior to catheter insertion.[75]

Catheter site dressing changes. Recommendations for catheter site dressing changes are extrapolated to pediatrics from adult studies.[78] Central catheter dressings should be either sterile gauze or sterile, transparent, semipermeable dressing that covers the insertion site. The choice of dressing is a matter of preference, as no differences for CRBSI have been found between the two.[85] Gauze may be preferred in patients who are diaphoretic or who have oozing or bleeding at the insertion site. Dressings should be changed using aseptic technique at least weekly or if the dressing becomes damp, loosened, or visibly soiled.[75]

The longstanding practice of intermittent application of topical antibiotic ointment to the catheter insertion site is no longer endorsed by the CDC.[75] Application of antibiotic ointment increases the rate of catheter colonization with Candida species, promotes emergence of resistant bacteria, may compromise the integrity of the catheter, and has not consistently been shown to decrease the rate of CRBSI.

Replacement of intravenous administration sets. The optimal interval for routine replacement of administration sets has been well studied. Data reveal that replacing administration sets no more frequently than every 72 hours is safe and cost effective.[86, 87] Data from a more recent study demonstrated that phlebitis rates were no different when administration sets were left in place for 96 hours compared with 72 hours.[88] Data from an additional recent study with adults support delaying replacement of administration sets up to 7 days if the patient is not receiving total parenteral nutrition, blood transfusion, or interleukin-2 via the intravenous tubing.[89]

Implementing the recommendations. Multifaceted interventions are necessary to assure that evidence-based infection control guidelines to prevent CRBSI are followed. In a recent study in an adult surgical intensive care unit, CRBSI was nearly eliminated when five interventions were put in place to improve adherence with infection control guidelines during central venous catheter insertion.[90] The interventions were as follows:

1. An educational intervention to increase provider awareness of evidence-based infection control practices
2. Creation of a central catheter insertion cart to assure that needed equipment and supplies to provide asepsis during central venous catheter insertion or exchange were accessible in one location
3. Asking providers daily in interdisciplinary rounds about removal of central catheters to reduce risk from prolonged, but unnecessary exposure
4. Implementation of a checklist of items that assure compliance with evidence-based infection control guidelines, completed by the bedside nurse during central venous catheter insertion or exchange
5. Nurse empowerment to stop procedures if guidelines are not followed

The study authors report sustained improvement years following the initial implementation of the five interventions. Between January 2003 and April 2004, there were two CRBSIs in this surgical intensive care unit or 0.54/1,000 catheter days. No infections had occurred in more than 9 months. By their estimate, 43 CRBSIs and eight deaths may be prevented per year, saving nearly $2 million in additional costs annually.

The authors report the following important lessons learned from this initiative: (1) relatively simple and inexpensive interventions produced significant improvement; (2) processes that reduce steps in workflow are more likely to succeed than those that require more steps; (3) creating redundancy through the use of a checklist, as in aviation, is an effective technique to improve patient care safety; and (4) a culture of safety requires teamwork and collaboration.

Improving Communication and Collaboration

Health care errors and poor quality of care are consequences of a variety of workplace systems and processes. Care of hospitalized patients across the lifespan is provided in complex environments where limited time, parallel tasking, interdependence, and the need for decisionmaking despite uncertainty create unique demands. The importance of effective communication with patients and their families as well as between interdisciplinary teams is recognized as key to reducing errors and improving quality in a number of industries. Analysis of 2,455 sentinel events reported to the Joint Commission revealed that the primary root cause in more than 70 percent was communication failure. The seriousness of these failures is evident: approximately 75 percent of these patients died.[91]

Relational coordination. The concept of relational coordination was developed and validated in the commercial aviation business.[92] When team members and team relationships are well coordinated, there is frequent, timely, accurate communication, as well as problem-solving, shared goals, shared knowledge, and mutual respect. The impact of team relationships on outcomes for patients has been demonstrated in a number of studies.

The impact of relational coordination in health care was tested in a study of orthopedic surgery patients undergoing total joint replacement at nine hospitals in three U.S. cities.[93] Quality of care, postoperative pain and functioning, and length of stay were the outcome measures for this study. Patients evaluated the quality of care by completing a questionnaire that measured the patients' reported confidence and trust in their physicians, nurses, physical therapists, or case managers; knowledge of the identity of the physician, nurse, physical therapist, or case manager in charge of their care; belief that providers were aware of their medical history; belief that providers were aware of their condition and needs; belief that their providers supplied consistent information; belief that their providers worked well together; belief that they were treated with respect and dignity; satisfaction with their overall care; and finally, intent to recommend the hospital to others. Providers, including physicians, nurses, physical therapists, social workers, and case managers, assessed four communication dimensions (frequent, timely, accurate, and problem-solving communication) and relationship dimensions (shared goals, shared knowledge, and mutual respect) between each respondent and each of the five core disciplines involved in the care of joint replacement patients.

The study found that relational coordination varied significantly between the hospital sites. Quality of care was significantly improved by relational coordination and each of its dimensions. Postoperative pain was significantly reduced by relational coordination, whereas postoperative functioning was significantly improved by several dimensions of relational coordination, including the frequency of communication, the strength of shared goals, and the degree of mutual respect among care providers. Length of stay was significantly shortened by relational coordination and each of its dimensions.

Improving communication and teamwork. The Kaiser Permanente health care system has adopted standardized tools and behaviors from commercial aviation and has demonstrated their effectiveness in enhancing teamwork and reducing risk of patient harm.[94] Crew resource management training was provided to team members from a variety of clinical domains, including the operating room, the intensive care unit, obstetrics and perinatal care, and a cardiac treadmill unit. The teams each worked on a clinical project in which crew resource management techniques could be applied to improve the quality and safety of patient care, supported with site visits and educational sessions. The tools and behaviors to improve communication effectiveness

in this study were briefings using the SBAR (situation, background, assessment, recommendation) format, appropriate assertion, clear language, situational awareness, and debriefing. This work is explicated in the section on communication of this book.

Briefings. Brief, concise communication of critically important information transmitted in a predictable format has been adopted in the perinatal unit by nurses, midwives, and physicians to improve the team response to fetal distress. A common language is used to optimize problem recognition. Simple and effective rules are activated when a problem is recognized: the identifying person has 1 minute to look at it independently, 2 minutes to look at it with a colleague, and by minute 3 should be physically correcting the problem.

Perioperative briefings by surgical teams have virtually eliminated wrong-site surgeries and improved nursing turnover in the operating room by 16 percent. Employee satisfaction has risen; perception of safety in the operating room is judged "outstanding"; and significant improvements in teamwork, communication, responsibility for patient safety, and handling errors have been measured.[94]

Appropriate assertion and critical language. Creating environments where people will express their concerns and speak up is a key factor in safety. The hierarchy of caregivers in hospitals and differences in communication styles between nurses, physicians, and others often interfere with adequate communication. The common practice of indirect communication between nurses and physicians is risky. In assertive communication there is a series of steps to clearly communicate what is needed and reach a decision:

1. Get the person's attention.
2. Express concern.
3. State the problem.
4. Propose action.
5. Reach a decision.

Nurses have license to say "I need you to come now and see this patient." They need not provide an objective argument to convince a physician to see a patient. It is acceptable for nurses to say "Something is wrong, I'm not sure what it is, but I need you here now." Recently, emergency medical teams from Australia demonstrated that in-hospital cardiac arrests were reduced 65 percent by early intervention.[95] The number one criterion to call for help was a staff member who "was worried" about a patient.

Sharing goals. Patients in the intensive care unit at Johns Hopkins University Medical Center are cared for by intensivist-led teams, which include the intensive care unit attending physician, critical care fellows, anesthesia and surgery residents, nurse practitioners, nurses, respiratory therapists, and a pharmacist. During daily rounds, the intensive care unit team develops a plan of care for the day, spending 20 to 25 minutes at each patient's bedside. One attending physician questioned that rounds failed to clarify explicit patient care goals, prompting the team to measure their impact on team communication.[96]

When measured, less than 10 percent of residents and nurses understood the goals of care for the day. To improve communication among providers, the team developed and implemented a daily goals form, based on crew resource management principles, which outlines the tasks to be completed, the plan of care, and the plan for communication with the patient and family members. The following are discussed in rounds and noted:

1. What needs to be done for the patient to be discharged from the intensive care unit?
2. What is this patient's greatest safety risk? How can we reduce that risk?
3. Pain and sedation management

4. Cardiac/volume status
5. Pulmonary/ventilator management
6. Mobilization
7. Infection, cultures, drug levels
8. GI/nutrition status
9. Medication changes (Can any be discontinued?)
10. Tests and procedures
11. Scheduled labs, morning labs, chest x-ray
12. Consultations
13. Communication with primary service
14. Family communication
15. Can lines/catheters/tubes be removed?
16. Is this patient receiving DVT/peptic ulcer disease prophylaxis?

The daily goals form is completed for each patient during rounds, signed by the fellow or attending physician, and handed to each patient's nurse. The goals are reviewed at least three times each day by all providers, who initial the form to indicate their review. The form is updated if the goals of care change.

To evaluate the impact of the daily goals form on patient outcomes, intensive care unit length of stay was measured for 1 year following pilot testing, revision, and implementation. After implementing the goals form, the percentage of residents and nurses who understood their patient's daily goals increased to more than 95 percent. Intensive care unit length of stay decreased significantly from a mean of 2.2 days to 1.1 days. With a decrease in length of stay, the intensive care unit was able to admit 670 additional patients in the study year. In addition, the use of the goals form may have prevented complications such as CRBSI (by prompting removal of central venous catheters when no longer needed for therapy) and ventilator-associated pneumonia (by assuring head-of-bed elevation, peptic ulcer disease prophylaxis, and assuring patients were assessed for readiness for extubation).

The team learned that using an interdisciplinary communication tool is more important than the specific statements on the form. As its use has spread to other intensive care units in the Johns Hopkins system and to other hospitals, the structure and content of the form have changed. Other hospitals are invited to modify the form to meet their needs and are cautioned to expect frequent revisions in the beginning.

Interdisciplinary collaboration. Nurse-physician relationships have been characterized negatively for more than a century. The "doctor-nurse game," first described in 1967, is a stereotypical pattern of interaction in which nurses learn to show initiative and offer advice, while appearing to passively defer to physicians' authority.[97] The game has been replayed and revisited in the decades since, though a recent literature review suggests that this pattern of interaction is decreasing in frequency in contemporary health care settings.[98] The importance of managing the doctor-nurse game is illustrated in an analysis of nurse-physician collaboration in pain management practices and underscores the need to draw on nursing practice and knowledge to effectively challenge issues of power and status.[99]

Patient outcomes are linked to healthy professional relationships. A descriptive study with nurses at 14 hospitals that had achieved Magnet status (see section on the Magnet Recognition Program below) suggests that collaborative relationships between nurses and physicians contributes to lower mortality at magnet hospitals, compared with mortality at hospitals without the designation.[100] Nurses participating in the study described relationships with physicians along

a scale of collegial, collaborative, student-teacher, neutral, or negative. Collegial and collaborative relationships were differentiated based on the power base characterizing interactions. In collegial relationships, the power base is equal, although it may be different. Nurses respect physicians for their education, while physicians respect nurses for their knowledge and extended contact with patients. In collaborative relationships power is mutual, but not equal. In both, mutual dependence and willing cooperation are characteristic.

Subsequently, direct care nurses, nurse managers, and physicians at 44 clinical units in 5 hospitals where extensive collegial and collaborative relationships were identified have participated in interviews to identify structures that enable their positive relationships.[101, 102] Goals of the multisite initiative are to identify evidence-based management practices and suggestions for attaining high-level, productive, and beneficial nurse-physician relationships.

Improving team structure and heightening communication have been tested in a 5-year study with nurses and physicians caring for general surgery patients at a tertiary care hospital.[103] Well-defined patient care teams (physicians, case managers, and charge nurses) with clear role responsibilities were developed, and a formal, regular schedule of daily team meetings was initiated. Following the intervention, mean length of stay for surgical patients was decreased and patient volume increased, while a high level of patient satisfaction was maintained.

Differences in education and socialization may make collaboration difficult. Interdisciplinary learning opportunities have been effective in developing collaborative skills among those new to their professions.[104, 105] The registered nurse-resident physician preceptor program at the University of Kentucky pairs new residents with a registered nurse for an 8-hour orientation shift.[106] Physicians directly encounter the nurse's unique functions, perspectives, knowledge, and contributions.

A recent systematic review of evidence for the effectiveness of interdisciplinary education as a strategy to build collaborative relationships found no definitive outcomes, as studies had wide inclusion criteria, methodology, and outcomes.[107] The absence of evidence does not mean that interdisciplinary education is ineffective; it may simply mean that it has not yet been rigorously evaluated.

The same review examined evidence of the effectiveness of interdisciplinary collaboration interventions. Although the review found a heterogeneous sample of intervention studies, which prevented meta-analysis, clinical improvements in patient care were related to interventions that target improving interdisciplinary collaboration.[107] The authors have a funded randomized controlled trial to evaluate the impact of both an interdisciplinary education intervention and an interdisciplinary collaboration intervention with 20 general medicine units in four Toronto hospitals. Evaluation lasting 12 months of some 30,000 patient admissions is anticipated. Information about patient outcomes; patient and family satisfaction; readmission rates; evidence-based discharge prescriptions; length of stay; staff turnover; and interdisciplinary satisfaction and trust among nurses, physicians, and allied professionals will be collected. It is anticipated that the study will add rigor to the body of evidence for interdisciplinary collaboration.

Culture change is at the heart of improving communication, teamwork, and collaboration. Care complexity in today's hospital systems demands care coordination that is unparalleled. Individual provider excellence alone is insufficient; the team and its coordinated efforts must be excellent. Improving communication is evidence-based care that benefits patient safety and care quality.

Infant Position in Neonates Receiving Mechanical Ventilation

Mechanical ventilation is often required when treating critically ill newborns, especially those who are preterm. A systematic review of randomized controlled trials that compared the impact of several body positions during mechanical ventilation of sick newborns was conducted by the Cochrane Collaboration and reported in 2003.[108] Ten trials involving 164 infants were included in the review. The trials compared several positions: prone versus supine, prone versus lateral right, lateral right versus supine, lateral left versus supine, lateral right versus lateral left, and good lung dependent versus good lung uppermost. In all the trials, stable infants were selected for the intervention.

Only the prone position was more efficacious than supine positioning. Placing infants prone for short periods of time improved oxygenation. However, evidence that prone positioning produces sustained improvements in oxygenation was not reported.

None of the trials reported complications of repositioning infants who were receiving mechanical ventilation. However, accidents such as inadvertent extubation or umbilical catheter dislodgement are easily imagined. Infants who require prolonged mechanical ventilation may be at risk for the development of pressure ulcers if maintained in one position and would benefit from repositioning.

The review suggests that large controlled clinical trials are needed to determine the various benefits or problems from different positions. Studies that look at medium and long-term outcomes—duration of mechanical ventilation, skin integrity, hospital length of stay, and mortality—are necessary. In addition, reexamination of positioning interventions with infants who are less stable may help to clarify whether there are subgroups of infants with different disease severity who may benefit. Finally, questions about the effects of lateral positioning, especially in infants with asymmetrical pulmonary pathology, still need answers.

Smoking Cessation

Smoking and other tobacco-product use by adolescents is a major public health problem recognized by the World Health Organization (WHO). Data from 1999–2005 found that nearly 20 percent of adolescents report current tobacco use.[109] Tobacco cessation programs must address this significant public health problem. In addition, both adolescents and younger children may be exposed to second-hand smoke. Nurses who care for pediatric patients have an opportunity to address the health risks of smoking with both pediatric patients and their families. The Joint Commission recommends that smoking cessation advice be given to pediatric patients who are hospitalized with community-acquired pneumonia or asthma and their families. Indeed, Turner-Henson and colleagues[110] have urged nurses to consider assessment of smoking status as part of taking vital signs for all pediatric admissions and in outpatient settings.

A recent meta-analysis of the effects of nursing-delivered smoking cessation interventions with adults found nursing efforts to modestly increase the odds of quitting.[111] There was evidence that interventions were most effective for patients hospitalized with cardiovascular disease, and interventions with nonhospitalized adults were also beneficial. Studies of smoking cessation efforts with adolescents and during pregnancy were not included in the meta-analysis. However, it is not unreasonable to generalize from the findings that smoking cessation interventions with hospitalized patients were most effective. Patients in the hospital may be more

amenable to the intervention. Certainly, the opportunity to offer cessation advice and resources to pediatric or family tobacco users should not be missed.

A study of adolescent smokers' attitudes toward quitting and their beliefs about their parents' opinion about smoking included more than 4,500 U.S. high school students who had smoked within the previous 30 days.[111] All adolescent smokers were asked, "Have you ever seriously thought about quitting smoking?" Those who had seriously considered quitting were questioned about past attempts and how recent their last attempt was. Those who had not seriously thought about quitting were asked if they thought they would ever want to quit. Regardless of whether their parents smoked, adolescents who placed value on their parents' opinions were more likely to think seriously about quitting and to have tried to quit in the past 6 months. Recalling a parent's expressed desire that their child not smoke was associated with significant increases in the likelihood of seriously thinking about quitting, even among those adolescents whose parents smoked. Agreeing with the statement, "When I'm older, my parents won't mind that I smoke," was significantly associated with decreased odds of seriously thinking about quitting and recently attempting to quit. This study demonstrates that parents, both those who smoke and those who do not, may have a significant role in influencing young smokers' desire to quit smoking. Nurses need to exploit this information with families of adolescent patients.

A recent randomized clinical trial compared an Internet-based smoking cessation intervention (Stomp Out Smokes—SOS) developed at the University of Wisconsin with brief individual counseling sessions for adolescent smokers.[113] The smoking abstinence rate for teens who received individual counseling was twice that of those who accessed the Internet-based intervention at 30 days, 24 weeks, and 36 weeks. In fact, the SOS intervention participants accessed the site an average of only 7 days and 11 total logins. Likely, they did not have an adequate "dose" of treatment. More structured, personal, and proactive patient education delivered in person or by telephone or e-mail is recommended for intervention with adolescent smokers.

This section has presented a sample of the evidence-based practices that have implications for national safety and quality aims and the care of infants and children in hospitals. Nurses who care for pediatric patients must be actively involved in the development, testing, implementation, and evaluation of evidence-guided best practices.

Other Issues for Pediatric Care

Although this chapter has focused on pediatric inpatient care, most care for children takes place in outpatient settings. There are critical issues for children requiring outpatient care that impact their health and well-being and, therefore, the illnesses seen in hospitalized children and their potential to experience an adverse event. We must address these issues with the same vigor as the movement toward inpatient evidence-based practices. Otherwise, the overall health of children will deteriorate with lifelong consequences that will impact their quality of life and the cost of health care, as well as limit their opportunities to contribute to society in positive ways.

Poverty and Disparity

Poverty and disparities in health care, two overarching issues for children in this country, impact their care within the community and the inpatient setting. In most cases they are inextricably intertwined. In 2003, an estimated 35.9 million Americans (12.9 percent) lived in

poverty, 4.3 million newly poor since 2000. Approximately 733,000 American children lived in poverty.[114] This is a fluid statistic as third-party payers for children's health care are often public programs, which fill the gaps created by reductions in employer-based health plans. These State and Federal programs are subject to review and reduction at any time, when other financial issues or crises take priority.

Childhood Obesity

Childhood obesity is at epidemic proportions. One in every six children in the United States is obese or overweight.[115] Obesity is not only an adverse social stigma and a threat to quality of life; significant health issues are associated with it. Obese individuals are at greater risk for diabetes, cardiovascular diseases, and poor mental health than persons who are not obese. Children are not an exception. These chronic conditions increase the cost of care over a lifetime and can lead to serious disability.[114]

Poverty, disparities in health care, and childhood obesity present unique challenges for the health care system at large. Long-range planning must address these issues and tangential issues for our children to live healthy, productive lives.

Unique Issues in Adolescent Health

Adolescents (children ages 13–20 years) have unique health care needs, distinct from those of younger children and nonelderly adults. Their physiologic and social characteristics differ from those of younger children and adults. Adolescents require reproductive health care; care for sexually transmitted diseases; mental health care for depression, substance abuse, and other disorders; trauma care; and care for chronic diseases—asthma being the most common.[116]

Recent data reveal unique patient safety problems when adolescents are hospitalized. The incidence of adverse events in the Colorado and Utah Medical Practice Study found 2.74 percent more adverse events among adolescents than younger children.[117] In this study, more than three-quarters of adverse events for hospitalized adolescents occurred with diagnostic, medication, and pregnancy and delivery-related services.

There are racial disparities in the incidence of asthma, a leading cause of chronic illness in children and adolescents. African Americans have a higher prevalence of asthma and are four times more likely to be hospitalized and five times more likely to die of asthma than non-African Americans.[118, 119] Despite much attention on improving asthma care and asthma disparities, a 2003 IOM report still identified the quality of asthma treatment as one of 20 priority areas for national action.[120] Priorities in research to reduce asthma disparities were published by the National Heart, Lung, and Blood Institute in 2002.[121]

The Role of Nurse Scientists

Pediatric nurse scientists have actively engaged in scientific inquiry from the bench to the bedside for many decades. There have been rich contributions associated with nurse-patient interactions that focus on the patient in a holistic manner. Recommendations from Sue Thomas Hegyvary, editor of the *Journal for Nursing Scholarship,* might frame the future of pediatric nursing research. She proposed research that will

1. Attend to morbidity, mortality, and contributing factors at the micro and macro levels of society.
2. Support programs of study that are longitudinal, sequential, and comparative and that continue to examine phenomena from small to larger contexts.
3. Move from reviews of the literature, concept analyses, and proposals for investigation toward new knowledge in the field.
4. Focus on the interventions and outcomes of a study, rather than debate superior or inferior methodologies.
5. Synthesize the aforementioned recommendations to generate research beyond the theoretical and small-scale application.
6. Draw evidence-based conclusions based on scientific findings. In other words, only conclusions based on empirical findings should be promulgated as nursing science.[122]

Benchmarking, Funding, and Federal Data

Participation in national benchmarking and quality work can pose a significant expense for involved institutions. It is difficult, therefore, for some organizations to participate in this valuable work. Institutions should not face economic barriers to participation. Perhaps organizations that demonstrate need could be federally funded to join these efforts.

Funding for scientific work in pediatrics must be increased. However, appropriation discussions for Federal funding are highly competitive. Children are disadvantaged as they are not voting members of society. Although there are strong advocates for funding children's research, their voices can be muted by other specialty groups with voting power. It is critical that nurses, health care providers, and other pediatric stakeholders continue their efforts to speak for children in the halls of Congress.

A well-funded national strategy for organizing, analyzing, and reporting patient safety and quality data would accelerate progress in pediatric safety and quality improvement. The KID HCUP, the Kids Inpatient Database developed as part of the Healthcare Cost and Utilization Project, forms a sound basis for this work; however, not all States report these data, as participation is voluntary. No mandate for participation appears likely. Currently, 36 States report discharge data to AHRQ for inclusion in the KID HCUP database. Even when States do report, missing data can be a significant problem. For instance, reporting race is still optional. Lack of consistency in reporting makes it difficult to control for confounding variables when analyzing the data to answer research questions.

Despite its imperfections, the KID HCUP database is a rich source for health services researchers and practitioners to mine. It would be an even stronger tool if all States reported data and if uniformity and consistency were assured.

National Institute of Nursing Research. The National Institute of Nursing Research (www.ninr.nih.gov), established in 1993, began as the National Center for Nursing Research in 1985. It has been a leader in funding for nursing research in key areas (see Table 3). Part of the National Institute of Nursing Research mission is to identify and fund research in areas of science unique to nursing and vulnerable patients, including children. A full complement of funding is available, from intramural awards that support onsite education and training to develop young investigators, to extramural funding for investigator-initiated research and for centers that conduct and disseminate research for special populations.

Table 3. National Institute of Nursing Research—Extramural Areas of Science

Chronic illness & long-term care	Health promotion & risk reduction in adults	Cardiopulmonary health & critical care
Neurofunction & sensory conditions	Immune responses & oncology	Reproductive health & child health promotion
End-of-life & environmental contexts		

Other funding sources. The American Nurses Foundation (www.nursingworld.org/anf) and Sigma Theta Tau (www.nursingsociety.org) are two additional organizations that support nursing research. In addition, many specialty organizations have grant funds available on a competitive basis. A search on each organization's Web site can yield information about the availability of grants and their application process. All typically support both quantitative and qualitative research that can help launch an investigator's pilot work, in advance of funding for more comprehensive studies.

Positive Momentum for Nursing Practice: The Magnet Recognition Program

In the past decade, the Magnet Recognition Program, the seal of approval for professional nursing practice environments, has gained considerable momentum across the country. One of the hallmarks of this prestigious certification is that direct care nurses have clinical experts who help create an environment of scientific inquiry. Practice based on evidence is critical to both a culture that contributes to nursing satisfaction and to quality care for patients. Magnet momentum (www.nursingworld.org/ancc/magnet) continues to grow each year and can only advance the use of evidence-based nursing practices. Children and their families will reap the benefits of professional nursing practice driven by science, not tradition—valuable and worthy goals for us all.

Conclusions

Pediatric care is complex due to developmental and dependency issues associated with children. How these factors impact the specific processes of care is an area of science in which little is known. We are only beginning to understand the relationship between nurse staffing and adverse events in hospitalized children; effects that may be compounded by inadequate numbers of pediatric nurses. Throughout health care providing safe and high quality patient care continues to provide significant challenges. Efforts to improve the safety and quality of care are resource intensive and take continued commitment not only by those who deliver care, but by agencies and foundations that fund this work. Advocates for children's health care must be at the table when key policy and regulatory issues are discussed. Only then will the voice of our most vulnerable groups of health care consumers be heard.

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Chapter 16. Prevention—Safety and Quality

Carol Loveland-Cherry

Background

To date, the preponderance of research on patient safety and the transformation of the work environment has focused on inpatient, acute care settings. Institute of Medicine (IOM) reports[1, 2] clearly recommend that work be done on "studies and development of methods to better describe, both qualitatively and quantitatively, the work nurses perform in different care settings"[2] (p. 325). Specifically, the recommendation is that research on patient safety needs to be addressed across care settings. Preventive services, primary care, and ambulatory care settings are areas in which there is a more limited body of work related to patient safety. Yet, these nonacute care settings constitute growing loci of health care services. This chapter will review the extant research on patient safety in preventive services, primary care, and ambulatory care settings. Preventive services, broadly defined, include screening, counseling, and chemoprophylaxis. This chapter will not focus on prevention of adverse events in ambulatory care or inpatient settings.

The Surgeon General's report[3] and subsequent plans for ensuring the health of the nation[4, 5] emphasize the role of prevention in addressing the leading causes of morbidity and mortality. Clinicians play important roles in both primary and secondary prevention.[6] Primary prevention is directed at measures to avoid or prevent the onset of disease or adverse condition. Secondary prevention focuses on the identification and treatment of asymptomatic individuals who have identified risk factors to prevent the development of active disease and/or reduce morbidity and mortality. Preventive services encompass health care provided in primary care settings, such as office-based practices and clinics, and in community-based settings. Preventive services are less regulated and controlled than health care services provided in institutions such as hospitals, long-term care facilities, and nursing homes. Not only have preventive services increased and become a central component of primary health care, these services also have become a focus of scrutiny in terms of quality and safety[6] (p. 13). Screening, counseling, preventive medications, skill building, and behavioral change strategies comprise the major foci of preventive services.

Two national task forces have been charged with the evaluation of preventive services. The Agency for Healthcare Research and Quality (AHRQ) convened the United States Preventive Services Task Force (USPSTF), an independent body of experts, to evaluate and make recommendations for clinical preventive services. The Centers for Disease Control and Prevention (CDC) established the Community Task Force to evaluate public health prevention programs.[7] Both task forces focus on establishing the efficacy of prevention strategies and also consider the relative harms and benefits of preventive services. The recommendations of these two task forces are available in print and online (http://www.ahrq.gov/clinic/prevenix.htm; http://www.thecommunityguide.org/) and will not be reviewed in this chapter.

Several IOM reports have emphasized the need to address not only the efficacy and effectiveness of health care strategies, but also patient safety.[8] The report *To Err is Human: Building a Safer Health System*[8] defines important terms. Safety is defined as "freedom from accidental injury" (p. 4) and error as "failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (p. 28). Error can occur in either the planning or

execution of health care services. In preventive services, the challenges are defining and tracking safety issues or adverse events. Thus, identification of literature related to patient safety and quality of care in preventive services is difficult. Further, with few exceptions, the studies are of medical errors. The studies of medical errors and adverse events cover doctors and other primary health care providers, such as nurse practitioners.

The research evidence for patient safety in preventive services falls into five distinct groups: identification and classification of errors in primary care, harms of screening, harms of information technology, errors arising from language in preventive services, and potential interventions to prevent errors and adverse events. The evidence in each of the first four groups will be summarized and assessed in this chapter; the potential interventions will be included within each of the relevant categories.

Research Evidence

Errors in Preventive Services/Primary Care

In the United States, the literature on patient safety has focused primarily on the inpatient, acute care setting. In contrast, a growing literature in the United Kingdom focuses on identifying, tracking, and assessing errors in primary care. Seven manuscripts describe some aspect of errors in preventive services, primary care, or ambulatory services. The first priority for promoting patient safety in primary care was to identify the most common errors that occur in primary care.[9]

Researchers have used several different methodologies to identify errors in primary care. The approaches include observational prospective studies,[10, 11] review of malpractice claims,[12] reports from physicians,[13, 14] and interviews with adult patients.[15] One systematic review has summarized literature in this area published between 1965 and 2001.[16] The different methodologies, including study length and modes of data collection, make it difficult to compare rates of errors or adverse events. The number of events reported were

- 117 errors for 15 physicians in 83 visits across 7 offices over 3 half-day sessions[11]
- 221 incidents from interviews with 38 patients asking them to recall events that occurred at any time in the past[15]
- 344 incidents from 42 physicians over 20 weeks[13]
- 940 incidents over 2 weeks across 10 practices[14]
- 805 incidents occurring between October 1993 and June 1995 from 324 physicians[10]
- 5,921 incidents from claims data for over a 15-year period[12]
- 1,223 incidents from 4 articles published 1995-2002[16]

Regardless of the methodology, similar categories of errors and events were identified and patterns emerged that provided the basis for development of classification systems. Dovey and colleagues[13] developed a taxonomy based on the identified types of errors and sources of errors. The most general groupings of errors resulted in two major categories: process errors, and knowledge and skills errors. Each of the two categories had three additional levels of specificity. For example, a process error in investigating a patient's condition, specifically in the process of laboratory investigations, might involve a wrong test being ordered or a test not ordered when appropriate. Bhasale and colleagues[10] classified incidents as pharmacological (e.g., inappropriate drug), nonpharmacological (e.g., treatment omitted/delayed), diagnostic (e.g., missed), or equipment (e.g., malfunction/ineffective). Preventable harms identified by patients were

classified as psychological (e.g., personal worth), physical (e.g., pain) or economic/other (e.g., avoidable personal medical expense).[15] Elder and colleagues[11] described office administration errors (i.e., charting, general office administration), physician-related errors, patient communication errors, and preventable adverse events. Rubin and colleagues[14] noted six categories of errors: prescriptions, communication, equipment, appointments, clinical, and others. Elder and Dovey[16] identified three categories: diagnosis—related to symptoms or prevention with either missed or delayed diagnosis; treatment—either drug or nondrug as incorrect/inappropriate, delayed or omitted; and preventive services—inappropriate, delayed, omitted, or procedural complication. In addition to classifying types of errors, Elder and Dovey identified related factors, such as clinician factors (clinical judgment and procedural skills error), communication factors (clinician–patient, clinician–clinician/health care system personnel), administration factors (clinician, pharmacy, ancillary providers, office setting), and blunt-end factors (personal and family issues of clinicians and staff, insurance company regulations, government regulations, funding and employers, physical size and location of practice, general health care system).[16] Kuzel and colleagues[15] offered a similar list of access breakdown, communication breakdown, relationship breakdown, technical error, and inefficiency of care.

Bhasale and colleagues[10] also identified differences in individuals involved in preventable incidents. The incidents involved slightly more females (58 percent) than males and more older individuals 25 years and older (around 85 percent) than younger ones. Overall, infants and females older than 75 years were overrepresented in the incidents. The same study described factors that mitigated the outcomes of adverse events: early intervention by reporting physician, patients, patient's relative, another provider; plain good fortune; patient's good physical or psychological condition; prior experience or training; reliability of professional backup; skilled assistant; high awareness via quality assurance activities; and reliability of equipment.

The data from this group of studies, regardless of the methodology, provide both identification of errors or adverse events in preventive services or primary or ambulatory care and direction for interventions. Dovey and colleagues'[13] major classifications of process and knowledge and skills errors provide major conceptual groupings within which to examine the specific error identified in the schema. Combined with Bhasale and colleagues'[10] identification of mitigating factors, this group of studies provides direction for both identifying errors and adverse events and for proposing interventions to address them. The findings specific to preventive services imply that errors or adverse events result from screening, counseling, or chemoprophylaxis being inappropriate, delayed, or omitted, or involve procedural complications. These errors or adverse events may arise from either process errors or knowledge and skill errors. Process errors are defined as resulting from some aspect of care delivery systems.[13] Examples of process errors include care that was provided but not documented in the patient's chart (e.g., a mammogram performed but not recorded) or a medication not being dispensed as ordered. Knowledge and skill errors are related to providers' clinical skills and knowledge (e.g., a wrong or missed diagnosis or a wrong treatment based on lack of clinician knowledge).

The next section examines two groups of studies that represent specific instances of areas with potential harms: medication errors and screening activities.

Adverse Drug Events in Preventive Services/ Primary Care/Ambulatory Care

Twelve studies[17–28] examined adverse drug events in primary or ambulatory care. None of these studies were specific to chemoprophylaxis. Rather, the foci were similar to those in acute care or inpatient care, but occurred in ambulatory or primary care settings. Thus, this group of studies was not included in this review as adverse drug events are covered in other chapters in this book.

Potential Harms Related to Screening in Preventive Services

Screening is a major intervention in preventive services. Although a number of benefits have been associated with screening activities in preventive services, risks have also been identified. Potential risks of screening include misunderstanding test results, misdiagnosis, mislabeling, stigmatization, and decreased psychological well-being.[28] Three major reviews[30–32] and 10 studies[33–42] examined the benefits, risks, and harms associated with screening activities. The most common screening tests reported were for breast, cervical, prostate, and colorectal cancers.

Screening mammography is recommended for women ages 40 years and older, but there is limited evidence for the upper age for screening. There are potential harms associated with mammography. The incidence of ductal carcinoma in situ (DCIS) increases in elderly women. The risk of death from DCIS progressing to invasive breast cancer is very low; therefore, the risks of surgery to treat DCIS outweigh the benefits. Three studies found that approximately 8 percent of women ages 70 years and older had an abnormal result from mammography, and 85 percent to 92 percent of those with an abnormal result did not have cancer.[31, 33, 35] A slightly lower percentage of clinical breast examinations (3.9 percent) resulted in abnormal results, but a higher percentage of these women (97 percent) did not have cancer on followup.[33] Thus, potential harms of screening mammography or clinical breast examination include unnecessary biopsy and the stress and worry related to the possibility have having cancer.[20]

Similarly, overdiagnosis and overtreatment in 40 percent of women[34] are potential harms of cervical cancer screening. Results of a cohort study of Pap smear results in postmenopausal women 44–79 years of age[37, 31] demonstrated a high incidence of false positive results (all but 1 of 110 abnormal Pap smears). Other harms of Pap smear screening include identification and treatment of inconsequential disease, high anxiety, low self-esteem, and disrupted partner relationships.[31]

In addition to the potential harms of psychological distress and false-positive results, perforation, bleeding, stroke, myocardial infarctions, Fournier gangrene and thrombophlebitis, and treatment of inconsequential disease are harms associated with colonoscopy in 3 of 1,000 screenings.[31] Woolf [36] identified potential harms of PSA testing for men without disease and for those with prostate cancer. False-positive results cause unnecessary followup procedures and anxiety. Treatment of inconsequential disease results in unnecessary procedures and potential complications.

These potential harms of cancer screening are especially important in decisionmaking for elderly individuals, as there are fewer studies and evidence for this segment of the population. Based on analysis of all-cause and cancer-specific mortality from the National Center for Health Statistics and Surveillance Epidemiology and End Results Survey (SEER), Rich and Black[38] concluded that potential harms may outweigh the small benefit of screening for breast cancer,

colon cancer, and cervical cancer in elderly individuals. Volk and colleagues[39] evaluated a patient-educational approach to shared decisionmaking for prostate cancer screening that included both potential benefits and harms of screening. The results of the randomized clinical trial indicated positive outcomes in terms of increased knowledge and more informed decisions regarding prostate cancer screening. Walter and Covinsky[40] advocated including potential harms in their framework for individual decisionmaking in cancer screening in elderly individuals.

In summary, harms of various cancer screening procedures have been identified. However, it is important to evaluate the potential harms for each procedure relative to the benefits for specific age groups and other individual considerations. Thus, the USPSTF recommends routine screening mammography for women ages 40 years and older; routine screening for cervical cancer in women who have been sexually active and have a cervix, but against routine screening for women older than 65; and routine colorectal cancer screening for men and women 50 years and older. However, the USPSTF is currently updating recommendations for screening for colorectal, cervical, and breast cancer. The USPSTF currently recommends against routine screening for pancreatic cancer or ovarian cancer. The task force concluded that there was insufficient evidence to recommend for or against routine screening for prostate cancer, skin cancer, oral cancer, or lung cancer.

Errors and Adverse Events Related to Language in Preventive Services

A small but interesting group of studies[41, 42] and one review[43] examined the role of language either as a barrier to receiving care or as a factor in adverse events. This area of study is particularly relevant given the growth of ethnic populations in the United States. Nearly 20 percent of U.S. citizens over the age of 5 years speak a language other than English at home.[41] However, it is estimated that "more than 50 percent of adults over the age of 18 who speak a language other than English at home speak English 'very well'"[41] (p. 254). Lack of proficiency in English may result in communication problems with health care providers and decreased utilization of care, and it may reflect cultural values and beliefs.[42] Results of two studies supported the potential for harm resulting from women not receiving preventive services[42] and infants of parents whose primary language is not English not receiving recommended preventive care.[41] Using data from a cross-sectional survey of 22,448 women completing the 1990 Ontario Health Survey, logistic regression calculated odds ratios for receiving breast examinations, mammograms, and Pap tests for women who reported a language other than English as spoken at home versus those who reported English as the primary language, adjusting for socioeconomic factors, contact with the health care system, and cultural measures.[42] Results indicated that women who reported a language other than English spoken at home were less likely to receive important preventive services than those who spoke English at home. These findings persisted after adjusting for the confounding variables. French-speaking women were less likely to receive breast examinations or mammograms, and women speaking other languages were less likely to receive Pap tests.

In a retrospective cohort study of 38,793 year-old infants enrolled in Medicaid, relative risk of receiving appropriate and timely preventive care was estimated using multivariate regression.[41] Primary language of parents, race and ethnicity, rural residence, and managed-care plan were independent variables. Results indicated that "fewer than one in six infants enrolled in Medicaid in their first year of life received recommended preventive care as defined by the

[American Academy of Pediatrics]"[41] (p. 257). Further, infants whose parents reported that English was not their primary language were half as likely to receive recommended preventive care. When confounding factors were considered, results indicated that Asian-American infants were less likely to experience disparities in preventive care associated with primary language than White, Hispanic, and African-American infants.

While the evidence is limited, the results of these two studies support the potential for adverse events resulting from language barriers. An obvious strategy would be to reduce the language barriers. A systematic review of the impact of medical interpreter services on the quality of health care[43] indicated that health care was compromised for patients not proficient in English; they were less likely to receive preventive screening, more likely to have a greater number of tests done at higher costs; and were less satisfied with care. Additionally, the quality of care is further compromised when untrained or ad hoc interpreters, especially children, are used. However, availability of trained interpreters was positively associated with obtaining preventive screening, such as mammograms. In light of the changing demographics and diversity of the U.S. population, this small but growing body of literature on language as a barrier or factor in adverse events in preventive services provides another challenge for the health care systems.

Errors and Adverse Events Related to Information Technology in Preventive Services

A final group of studies explored the impact of the growing use of information technology (IT) in health care. IT in health care has been examined from several perspectives. There is a literature on the use of e-mail and the Internet by consumers, another on the adoption of IT by health care systems, and a third on the unintended consequences of the use of IT in health care.

Although reports of the extent of use of the Internet and e-mail for health care vary from 35 percent to 80 percent of adults in the United States,[44] the actual and potential impact of IT in health care is significant. A survey of a nationally representative sample of 8,935 (69.4 percent of a random sample of 12,878) adults age 21 years and over, individuals age 50 and older, and veterans identified four frequent uses of the Internet and e-mail.[44] The most common use of the Internet (reported by 40 percent of respondents) was for information or advice about health or health care. This was followed by use of e-mail or the Internet to communicate with family or friends about health, use of e-mail or the Internet to communicate with a health care professional, and use of these technologies to communicate with other people with similar health conditions. However, use of the Internet for health care was a relatively infrequent activity (every 2 to 3 months or less frequently). Individuals younger than 75 years old and women were more likely to use the Internet and e-mail for health. Results also indicated that e-mail and the Internet were used most often to gain health-related information and had little effect on the number of contacts with health care providers or to obtain a prescription drug.

IT has been more developed and adopted for financial management than for quality and safety purposes.[45] Results from a study of IT use in a variety of health care settings in the Boston and Denver areas indicate that physician practices (the most common site of preventive services), which are generally run as "small independent practices"[46] (p. 6), use IT primarily to manage billing and schedule patients. Poon and colleagues[46] propose that the limited use of electronic health records in these practices is related to the perception of limited proven benefits relative to the required financial and time commitments needed.

Based on results from separate qualitative studies, Ash, Berg, and Coiera[47] presented evidence that implementation of electronic patient care information systems (PCISs) in many instances appears to promote rather than limit errors. They argued that factors, including the complexity of PCISs and the physical space and other system characteristics, contributed to the occurrence of "unintended consequences"[47] (p. 104). The authors identified errors in two general areas: process of entering and retrieving information, and communication and coordination processes. They attributed errors in entry and retrieval of information to the high level of interruption and "cognitive overload" related to practice environments. Further, the authors proposed that errors in communication and coordination were related to the assumptions of a linear workflow and communication as information transfer. They advocated for educating health care providers to have a critical approach to PCISs, that developers and vendors of PCISs be clearer about the limitations of the systems, and that clinicians be supported in continuing interactions that are part of monitoring the safety of clinical systems.

Research that evaluates the ability of IT systems to promote patient safety and reduce errors is limited but growing,[45] especially in preventive services. Five studies[48–52] examined the use of an electronic health record system to generate physician, telephone, and letter reminders for patients to obtain preventive services. Results indicated that all three types of reminders were effective. There is evidence supporting the reduction of medication errors and adverse events through the use of computerized physician order entry and online decision support.[53] Bakken and colleagues[54] advocated the use of informatics to address errors associated with impaired access to information through the use of personal digital assistants, to address communication failures associated with adverse events, to promote the use of standardized practice patterns, and to provide automated surveillance to detect and prevent real-time errors. The proposed approaches have direct application in preventive care settings.

Evidence-Based Practice Implications

The evidence on errors and adverse events in preventive care provides preliminary direction for practice. Few if any studies proposed or evaluated approaches to avoid or reduce errors and adverse events in prevention. However, a growing number of studies have evaluated strategies to reduce errors and adverse events in acute, inpatient, ambulatory, primary, and home care, and they provide potential direction for prevention as the field matures. Leape's[55] directives—identify what works, ensure that the patient receives it, and deliver it flawlessly—are relevant for ensuring safety in prevention. At this point, perhaps the most viable approach to assure patient safety in prevention practice is use of the guidelines of the USPSTF, AHRQ, the Community Task Force, and CDC.

Research Implications

The greatest challenge in patient safety and quality in preventive care is the lack of a strong body of evidence on which to base our understanding of errors and adverse events in prevention and, more broadly, in ambulatory and primary care settings. Research in preventive care is limited relative to that in acute care, inpatient settings, and home care. The focus has been on research evaluating the efficacy of preventive services, which includes an evaluation of the potential and actual harms of the services in order to determine the net benefit. While there is a growing body of evidence for safety and quality in health care in primary and ambulatory

settings, there is very limited literature on harms or adverse events in preventive care and how to avoid them. Additionally, much of the research is observational and descriptive, with few interventions being tested. The research on identifying and describing errors in primary and ambulatory care has relevance for preventive care. However, there is a need for research directed at explicating errors and adverse events in preventive care.

Once the types of errors and adverse events have been identified and described, then research describing the factors associated with these events is needed. Further, there is limited evidence on basic questions, such as when to begin or discontinue screening, chemoprophylaxis, or counseling and implications for adverse events or potential harms. Only then can nurses and other health care professionals develop and test strategies to reduce risk related to preventive services. For example, the evaluation of the use of IT to decrease risks and adverse events is a major focus in acute care, ambulatory care, and primary care settings. Would the use of IT approaches be appropriate in preventive services? How can the human factor principles of standardization, simplification, and use of protocols and checklists[55] be facilitated by the use of IT in prevention? Finally, the difficulties inherent in research on preventive services present significant challenges, including timing of services and consideration of contextual factors (age, culture, race/ethnicity, gender, setting, etc.).

Thus far, the evidence presented attempts to answer the following: (1) How do errors and adverse events in prevention differ from those for other types of health care services? (2) How do contextual factors contribute to potential errors and adverse events in prevention? and (3) What are potential areas of research for nursing that would contribute to addressing patient safety in prevention? The following areas are the critical research gaps:

- Descriptive data on errors and adverse events in preventive services
- Data on factors related to errors and adverse events in preventive services
- Evaluation of interventions to reduce errors and adverse events in preventive services.

Conclusion

The limited body of evidence on errors and adverse events in preventive services, especially from a nursing perspective, supports the need for additional research to move ahead in the area of patient safety. It is likely that some of the evidence from studies in ambulatory and primary care will provide direction for research and subsequent evidence-based practice in preventive care. However, there may be unique errors and adverse events associated with preventive services. It is clear that there is potential for errors and adverse events in preventive services, but additional evidence is needed to explicate what they are. The evidence that is available is largely from either descriptive studies or from randomized controlled trials (RCTs) examining the efficacy of preventive services, specifically in cancer screening. There is less systematic evaluation of counseling interventions for prevention. The nature of preventive services and their outcomes and where they are delivered increase the complexity of both establishing an evidence base and implications for practice. The continued evaluation of using information technology to address risks and adverse events is a promising area for study and practice.

The focus in safety and quality research in health care has been on preventable events rather than on preventive services. Screening, counseling, and chemoprophylaxis are the key elements of preventive services. The evidence base on errors and adverse events in preventive services is limited and needs to be developed to provide direction for practice.

Search Strategy

A search of the CINAHL®, Ovid MEDLINE®, Cochrane Database of Systematic Reviews electronic databases, and the AHRQ Web site from 1990 to 2006 was conducted using the following search terms: patient safety, safety, quality, preventive services. The search was further limited to research studies and reviews. A total of 115 references were identified and the abstracts reviewed. The criteria for inclusion in the review for this chapter were (1) systematic review of published research; (2) nonsystematic review of published research; and (3) published research that used randomized control, comparison, and pretest–post-test no control designs. Based on the review of the abstracts using these criteria, 6 reviews, 10 commentary or background articles, and 32 studies were selected for inclusion in the review.

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Evidence Table. Prevention—safety and quality

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Ash 2004[46]	Patient care information system-related (PCISs) errors	Literature review, nonsystematic, and series of qualitative studies	Qualitative studies (5) impact of PCISs in health care and unintended outcomes (2).	Health care delivery settings and interviews with professionals in the United States, Netherlands, and Australia	None	Types of errors: Process of entering and retrieving information – juxtaposition error, orders entered for or on behalf of the wrong person, cognitive overload, communication and coordination process – inflexibility, urgency, work-arounds, transfers, loss of communication, loss of feedback, decisions support overload, catching errors, multidisciplinary qualitative research.
Baker 2003[44]	Use of Internet and e-mail for health care information	Cross-sectional study	National survey of Internet use for health care and prevalence of e-mail use for health care (5). Use of Internet and e-mail for health care and effects on knowledge of health care and use of health care system (3).	4,764 individuals ages 21 years and older who were self-reported Internet users drawn from a research panel of more than 60,000 U.S. households	Internet and e-mail use	~40 percent of respondents with Internet access used Internet to look for advice or information about health or health care; 6 percent used e-mail to contact a health care professional; ~1/3 using Internet for health reported it affected a health or health care decision; little effect on health care utilization – 94 percent reported no effect on number of visits and 93 percent no effect on number of telephone contacts; 5 percent reported use of Internet to obtain prescriptions or pharmaceutical products.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Bakken 2004[54]	Use of informatics to promote patient safety and enable evidence-based practice	Literature review, nonsystematic	Literature review, nonsystematic (6). Patient safety and evidence-based practice (3).	Review of literature on informatics infrastructure for patient safety and evidence-based practice	None	Examples of how components of informatics infrastructure can be integrated to achieve evidence-based practice and patient safety objectives in four areas: improving information access, automated surveillance for real-time error detection and prevention, facilitating communication among members of the health care team, and standardization of practice patterns.
Barratt 2002[56]	Harms of screening mammography	Systematic literature review	Decision-analytic, cost-effectiveness models; quality of life and life expectancy	Australian women 70 years and older	None	Five models met inclusion criteria; two included quality of life. Life-expectancy benefit of screening mammography diminishes with increasing age: 70–79 years, 40–72 percent without quality of life adjustment, 18–62 percent with it. 9,600 of 10,000 will be told they do not have breast cancer, ~400 will have further tests; ~70–112 will undergo breast biopsy and 19–80 cancers detected; ~ 15–20 percent will be DCIS; quality-adjusted life-year = $8,119–$27,751. Relatively cost-effective. Not studied: anxiety, mortality from mastectomy, post-op morbidity.
Barton 2005[57]	Risk factors for breast cancer	Literature review, nonsystematic/ narrative	Accepted screening methods and new technologies	Women in the United States	None	False-positive approach 50 percent after 10 screens; discovery of DCIS with transformation 14–60 percent; MRI more sensitive but led to >three times the number of biopsies with no cancer; high costs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Bhasale 1998[10]	Incident monitoring of potential harm in general practice	Noncomparative study	Observational study (5). Reports of number and type of incidents, contributing factors, mitigating factors, additional resource use (Level 1).	324 general practitioners (GPs) from nonrandom sample of Australian GPs 10/93–6/95	None	805 incidents reported: 76 percent preventable, 27 percent potential for severe harm, no long-term harm for 66 percent, related to pharmacological management, nonpharmacological management, diagnosis, or equipment; most common contributory factors poor communication between patients and health care professionals, actions of others, and errors in judgment.
Brawley 2005[30]	Biases, harms, accuracy of cancer screening	Literature review, nonsystematic/ narrative	Nonsystematic literature review (6). Harms of screening (2).	Review of screening modalities for specific cancers, including potential harms and accuracy of screening	None	Biases – selection, lead-time, length; harms – complications of treating true-positives and false-positives, labeling, mental anguish; accuracy – sensitivity, specificity positive predictive value, negative predictive value; breast cancer false-positives – repeat mammogram, ultrasound, biopsy; ovarian – additional, invasive evaluation; prostate – missed cases, clinically insignificant cases.
Brown 2006[20]	Pharmacist-physician relationship in detecting ambulatory medication errors	Noncomparative study	Observational study without controls (5). Data pharmacist's role, responsibilities, and expectations to inform physicians about medication errors (3).	Focus groups with 30 pharmacists and 31 patients in community pharmacies in Mississippi	None	Ambulatory pharmacist is common link between physician and patient, multiple physicians; pharmacist is patient educator, pharmacist is interceptor in detecting medication errors; hesitancy to contact physicians, physician accessibility barriers.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Cohen 2006[41]	Disparities in pediatric preventive care associated with primary language of parent	Retrospective cohort study	Review of Medicaid data (5). Appropriate and timely receipt of six preventive care visits in first year of life (2).	Review of records for 38,793 Medicaid - enrolled 1-year-old infants in Washington State	Primary language of parent	Infants of parents whose primary language was not English were half as likely to receive recommended preventive care; disparity evident for white, Hispanic, and African-American but not Asian-American infants.
De Smet 2004[28]	Repeat prescribing	Systematic literature review	Repeat prescribing in ambulatory care patients: definition and scale of repeat prescribing; problems with repeat prescribing and areas for improvement; characteristics and results of intervention studies; conclusions and recommendations for future research (3).	Ambulatory care patients	Review of medications by pharmacist; feedback to patient and physician; home inventory of medications; monthly dispensing with protocol led to check on drug-related problems; chart review; written feedback by physician	Repeat prescriptions range from 29 percent to 75 percent; much by GPs without direct doctor-patient contact; overall interventions helped resolve pharmaceutical care issues – compliance; effects on health-related quality-of-life, death rate, health care consumption or total health care cost not observed; real clinical improvements – adverse effects score, lipid values, reduced inappropriate prescribing in elderly outpatients receiving polypharmacy; some showed positive effect on number of medications, medication units, and medication cost.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Dovey 2002[13]	Medical errors in family practice	Noncomparative study	Observational study without controls (5); "error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim"; "safety is defined as freedom from accidental injury"; "anything that happened in your own practice that should not have happened, that was not anticipated, and that makes you say 'that should not happen in my practice and I don't want it to happen again'" (1).	42 family physicians from the National Network for Family Practice and Primary Care Research	Preliminary taxonomy of medical errors in family practice	330 error reports resulting in four-layered taxonomy: Process errors and knowledge and skills errors; knowledge and skills – receptionist failing to make urgent appointment, physicians decided to discharge patients before able to function well at home; process – treatment delivery problems, miscommunication; consequences – none, care delayed/extended, financial and time costs to patients, physicians, system, patient upset or lost trust in physician, became ill, did not regain health, admitted to hospital, or died.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Elder 2002[16]	Errors and preventable adverse event from medical care in outpatient primary care settings	Systematic literature review	Systematic review of original research (7 studies); process errors and preventable adverse events (1).	Seven studies from family practice, ambulatory care, primary health care	Classification of preventable adverse events (PAE) and process errors in primary care	Limited number of small studies; classification of three main categories of PAEs – diagnosis (misdiagnosis related to symptoms or prevention) treatment (drug or nondrug), and preventive services (inappropriate, delayed, omitted, procedural complications); attributable to four groups of process errors: clinician factors (clinical judgment, procedural skills error), communication factors (clinician-patient, clinician-clinician, or health care system personnel), administration factors (clinician, pharmacy, ancillary providers, office setting), blunt-end factors (personal and family issues of clinicians and staff, insurance company regulations, government regulations, funding and employers, physical size and location of practice, general health care system).
Elder 2004[11]	Errors and preventable adverse events by family physicians in outpatient visits	Noncomparative study	Observational study without controls (5). Errors and preventable adverse events, patient harm (1).	15 family physicians in 7 practices in Cincinnati area	None	117 errors or preventable adverse events; most common were administration errors (charting, general office administration); physician-related errors; patient communication errors. Harms: actual minor physical discomfort, mild adverse drug reaction, moderate physical injury from a procedure, progression of disease; most common emotional distress and wasted time for the patient; potential harms development of preventable disease, pain or physical distress, progression of disease, drug-drug interactions, infection, and poor outcomes from procedure.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Field 2004[24]	Strategies for identifying adverse drug events (ADEs)	Prospective cohort study	Observational study without controls (5); drug/drug-related incidents (1).	31,757 Medicare enrollees in large multispecialty group practice in New England over 12 months	None	1,523 ADEs, 28 percent considered preventable; positive predictive values for sources – 54 percent, highest provider reports but accounted for only 11 percent of ADEs and 6 percent of preventable ADEs, hospital discharge summaries very low PPV, computer-generated signals accounted for 31 percent of ADEs and 37 percent of preventable ADEs, electronic notes accounted for 35 percent of ADEs and 29 percent of preventable ADEs; little overlap in ADES identified across all sources; electronic strategies identify more ADEs than other sources; use multiple sources.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Flores 2005[43]	Effect of medical interpreter services on health care quality	Systematic review	Systematic review of 36 studies (RCT, descriptive, qualitative, survey) on LEP (limited in English proficiency) (1). Quality of health care and errors related to use of interpreters; communication issues; patient satisfaction with care; and processes, outcomes, complications, and use of health services (2).	Urban emergency department, hospitals, physician offices	None	Lack of interpreters results in poor self-reported understanding of diagnosis and treatment plan. Ad hoc interpreters misinterpret or omit up to half of all physicians' questions, are more likely to commit errors with potential clinical consequences, have a higher risk of not mentioning medication side effects, and ignore embarrassing issues when children are ad hoc interpreters. Lack of interpreters affects communication and quality of psychiatric encounters, including positive effects of bilingual providers and an adverse impact of ad hoc and no interpreters. Bilingual providers and telephone interpreters yield highest levels for satisfaction. Interpreters resulted in increase of preventive screening and reduced disparities in LEP and EP patients: with interpreters, greater increase in office visits, number of prescriptions written and filled, but none in number of phone contacts, urgent care phone calls, or urgent care visits. Controversy on duration of visits. LEP with no or ad hoc interpreter have more medical tests, higher test costs, more frequent intravenous hydration, and higher risk of hospitalization.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Gandhi 2003[19]	Adverse drug events in primary care	Prospective cohort study	Observational study without controls (5). Adverse drug events (1).	Survey of 661patients who received at least one prescription during a 4-week period (55 percent response rate) and chart review at four adult primary care practices in Boston (two hospital based and two community based)	None	25 percent (n = 162) had a total of 181 adverse drug events;13 percent (24) serious, 28 percent (51) ameliorable, 11 percent (20) preventable. Of 51 ameliorable 63 percent attributed to physician's failure to respond to medication-related symptoms, and 37 percent to patient's failure to inform physician of symptoms; most frequent medication classes – selective serontonin-reuptake inhibitors (10 percent), beta-blockers (9 percent), angiotensin-convertying-enzyme inhibitors (8 percent), nonsteroidal anti-inflammatory agents (8 percent). Multivariate analysis – only number of medications taken significantly associated with adverse events.
Gandhi 2005[26]	Outpatient prescribing errors	Prospective cohort study	Observational study without controls (5). Adverse drug events (1).	Outpatients over age 18 who received a prescription from 24 participating physicians in 4 adult primary care practices in Boston using prescription review, patient survey, and chart review	None	Screened 1,879 prescriptions from 1,202 patients and 661 surveys (55 percent response rate); 143 prescriptions contained a prescribing error, 3 errors led to preventable ADEs, and 62 had potential for patient injury. 1 (2 percent) was potentially life threatening and 15 (24 percent) were serious. Rates of medication errors and potential ADEs not significantly different at basic computerized prescribing sites vs. handwritten sites; advanced checks could have prevented 95 percent of potential ADEs; prescribing errors in 7.6 percent of outpatient prescriptions.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Glassman 2006[27]	Effects of automated drug alerts on clinicians' knowledge and perceptions	Pretest and post-test study	Observational study with controls (4). Increased recognition of selected interacting dug pairs and perceptions of computerized order entry (3).	97 clinicians (82 physicians and 15 nurse practitioners/physician asst) in ambulatory settings in Southern California Veterans Affairs Healthcare System	Interval (~2 years) exposure to automated drug alerts via computerized patient record system (CPRS)	Clinicians recognize seven interacting and/or contraindicated drug-drug pairs at both time periods; recognition of three contraindicated drug-drug pairs moderately improved; more clinicians preferred order entry at followup vs. baseline (63 percent vs. 45 percent); most common barrier to use of order entry system was "poor signal to noise" ratio or too may nonrelevant alerts.
Gurwitz 2003[17]	Adverse drug events among older person in ambulatory setting	Retrospective cohort study	Observational study without controls (5). Adverse drug events (1).	Medicare enrollees cared for by multispecialty group practice during a 12-month period	None	1,523 adverse drug events – 27.6 percent (421) considered avoidable; 578 (38 percent) categorized as serious, life threatening, or fatal; overall rate of 50.1 adverse drug events/1,000 person-years; rate of 13.8 preventable adverse drug events/1,000person-years. Errors occurred most often at stages of prescribing (58.4 percent) and monitoring (60.8 percent); 21.1 percent of errors involved patient adherence. Most common medication categories were cardiovascular (24.5 percent), diuretics (22.1 percent), nonopioid analgesics (15.4 percent), hypoglycemics (10.9 percent), anticoagulants (10.2 percent).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Hibbard 2005[58]	Medical errors	Cross-sectional	Assess the effectiveness of 12 recommendation actions form AHRQ's 20 tips; respond to scenarios of 29 different possible medical errors; response to terms patient safety and medical errors; how effected are recommended actions; how likely are consumers to engage in actions.	195 consumers of medical care recruited from University of Oregon classified staff, mean age 42, 71 percent female, 81.5 percent Caucasian, 12 percent high school graduates, 55.4 percent college graduates, 14 percent listed health as fair or poor, 44 percent reported they or family member had experienced a medical error.	None	Patient safety (27 percent not a serious problem) perceived as less of a problem than medical errors (23 percent not a serious problem); more likely to engage in older established recommended actions (4.6) than newer recommended ones (2.9) or those actions requiring questioning (2.6). Self-efficacy and effectiveness of action related to likelihood to engage in recommended actions.
Hicks 2006[25]	Medication errors in children	Retrospective cohort study	Observational study without controls (5). Harmful medication errors in children (1).	Data from voluntary medication error reporting system (MEDMARX®) over 5 years for individuals <17 years old	None	816 harmful outcomes involving 242 medications; 11 medications accounted for 34.5 percent of errors; wrong dosing and omission errors common; associated with opioid analgesics (11 percent), antimicrobials (7.5 percent), antidiabetic agents (4.5 percent), fluids and electrolytes (4.4 percent).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Kerlikowske 1999[35]	Cost effectiveness and impact on life expectancy of mammography screening in women 70–79 years	Noncomparative study	Decision analysis and cost-effectiveness analysis using a Markov model (4). Deaths due to breast cancer averted, life expectancy, cost effectiveness (2).	General population of women 65 and older	Outcomes of screening mammography based on three screening strategies	Continuing screening to age 79 with bone mineral density in top 3 quartiles prevent 9.4 deaths and add ~2.1 days to life expectancy with incremental cost of $66,773 /year of life saved; continuing screening in all women to age 79 prevents 1.4 additional breast cancer deaths and adds 7.2 hours to life expectancy with incremental cost of $117,689/year of life saved. Goal is to prevent deaths from breast cancer at reasonable cost and minimize harms of screening healthy women. Incidence of DCIS increases with age with 25 percent of cancer being DCIS in elderly women; increases rate of surgical treatment of insignificant lesions; 8 percent of women ages 70 and older will have abnormal result; 85 percent–92 percent with abnormal result do not have cancer; worry and anxiety.
Koshy 2005[53]	Medical errors and patient safety	Literature review, nonsystematic/ narrative	Review of literature (5). Computer solutions to medical errors and patient safety (2).	Biometrics data base; biometrics – fingerprints, CPOE (computerized physician order entry), DSSs (decision support systems)	None	Proposed Patient Care Information System – integrated, seamless, with access to real-time patient information (biometrics, CPOE. electronic medical records, etc.). Recommendations: existing error-prevention strategies are not adequate to reduce errors and assure safe health-care deliver; proposes layout of linked data systems from hospital medical information system to regional database to central database

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Kralewski 2005[22]	Influence of structure and culture of medical group practices on prescription drug errors	Retrospective cohort study	Observational study without controls (5). Influence of structure and culture of medical group practices (3).	Care Plus claims data, prescription drug error rates at enrollee level aggregated for 78 group practices in upper Midwest, ambulatory care	None	30 percent of 250,024 prescriptions written flagged as potential errors; ~half of errors were for over- or underdoses; predictors of drug errors – physician workload, use of outpatient case managers related to lower error rates; coordinating care in rural areas related to higher error rates; urban group practices lower error rates; value of physician autonomy lower error rates; financial incentive use of electronic information systems not associated with lower error rates; structure and culture variable explain 52 percent of variance.
Kuzel 2004[15]	Medical errors in primary care	Noncomparative study	Observational study without controls (5). Stories of preventable problems with primary care that led to physical or psychological harm (1).	38 in-depth anonymous interviews with adults from rural, suburban, and urban locales in Virginia and Ohio	None	221 problematic incidents reported; 37 percent (n = 82) involved breakdowns in clinician-patient relationship; 29 percent (n = 63) involved breakdown in access to clinicians; several reports of perceived racism; incidents linked to 170 reported harms (psychological – 70 percent, physical – 23 percent).
Mandelblatt 2003[32]	Cost effectiveness of screening mammography beyond age 65 and potential harms	Systematic literature review	Systematic review (1). Cost-benefit analysis, cost effectiveness, life-years gained, and costs per person of biennial screening after age 65 (2).	Women 65 years and older; cost-effectiveness articles published between January 1989 and March 2002	None	115 studies – 10 met inclusion criteria; Incremental costs of ~$34,00 to $88,000 per life-year saved after age 65; cost effective to screen if had not been regularly screened before age 65; potential harms not fully captured in any study; potential harms include anxiety associated with false-positive results, misdiagnosis, and previous knowledge of cancer or living longer with consequences of treatment, quality of life, operative mortality.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Mayo 2004[18]	Nurses' perceptions of medication errors made by nurses	Noncomparative study	Observational study without controls (5). Perceptions of medication errors (1).	Random sample of 983 acute care nurses in Southern California; self-report survey	None	Causes of drug errors – physician's writing is difficult to read or illegible, nurses are distracted on the unit, nurses are tired and exhausted, confusion between two drugs with similar names, nurse miscalculates the dose, physician prescribes the wrong dose, nurse fails to check patient's name band with the medication administration record, nurse sets up or adjusts an infusion device incorrectly, medication labels/packaging are of poor quality or damaged, nurses are confused by different types and functions of infusion devices. 45.6 percent of nurse believed all drug errors are reported; reasons for not reporting include fear of manager and peer reactions.
McDowell 1986[51]	Comparison of methods for recalling patients for influenza	Randomized clinical trial	Randomized clinical trial comparing three methods of reminding patient to receive influenza vaccination (2). Influenza vaccination rates (3).	939 patients ages 65 years and older in four family practices in Canada	Personal reminder by physician vs. telephone reminder by nurse vs. reminder by letter vs. no reminder	Vaccination rates – 22.9 percent for physician reminder, 37 percent for nurse reminder, 35.1 percent for letter reminder, 9.8 percent for no reminder; reminders automatically generated from a computerized medical record system.
McDowell 1989[49]	Computerized reminders for cervical screening	Randomized clinical trial	Randomized clinical trial (2). Cervical screening rates (3).	1,587 women ages 18–35 overdue for a screening test in family medicine center in Canada	Personal reminder by physician vs. telephone reminder by nurse vs. reminder by letter vs. no reminder	Screening rates – 16.1 percent for physician reminder, 25.9 percent for letter reminder, 20 percent for nurse reminder, 13.7 percent for no reminder; reminders automatically generated from a computerized medical record.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
McDowell 1989[48]	Computerized reminders of blood pressure screening in primary care	Randomized clinical trial	Randomized clinical trial (2). Blood pressure screening rates (3).	8,298 patients ages 18 and older who had not had a blood pressure measurement during the previous year, from large family practice in Canada	Computer-generated reminder to physician to check blood pressure during visit vs. telephone reminder by nurse vs. reminder by letter vs. normal care control	Screening rates – 30.7 percent for physician reminder, 35.7 percent for letter reminder, 24.1 percent for nurse reminder, 21.1 percent for no reminder; reminders automatically generated from a computerized medical record.
Metlay 2005[23]	Medication-taking practices on high-risk medications in home-based older adults	Noncomparative study	Observational study without controls (Level 4).	Telephone survey of 4,955 community-dwelling older adults in Pennsylvania in PACE (a State insurance program) program	None	32 percent had not received any specific instructions about medications; 35 percent received instructions from primary care provider and 46 percent from pharmacist; 54 percent used pillbox to organize meds; those prescribed warfarin more likely to report receiving instructions than those with digoxin or phenytoin.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Phillips 2004[12]	Malpractice claims in primary care	Retrospective cohort	Observational study without controls (4). Review of malpractice claims data 1985–2000 from Physician Insurers Association of America (4).	49,345 primary care claims; 26,126 peer reviewed, 5,921 assessed as negligent	None	No single condition accounted for >5 percent, internists and family practice/general practitioners more common than general pediatricians. Diagnostic error, failure to supervise or monitor case, improper performance, medication errors, failure/delay in referral, not performed, performed when not indicated, no medical misadventure, delay in performance, failure/delay in admission to hospital, failure to recognize a complication of treatment. Causes – problems with records, content issue; premature discharge from institution, x-ray error, vicarious liability, communication between providers, others; similar to the United Kingdom.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Poon 2006[46]	Health care information technology (HIT) adoption	Multisite qualitative study	Multisite qualitative study; survey of electronic results review, CPOE, EHR (electronic health record), claims and eligibility checking, patient-doctor electronic communication, provider to provider electronic communication. Modified Delphi approach to obtain national estimates (5), adoption of HIT in two markets: Boston and Denver (4).	Key informants from stakeholder groups in each city	None	52 of 119 potential informants (44 percent) agreed to interview; functionalities to support financial reimbursement were better developed than those to support safety and quality clinical care; national estimate similar to those from Boston and Denver; major barriers; HIT adoption is limited.
Quaid 1993[29]	Psychological and ethical considerations in screening for disease	Literature review, nonsystematic	Nonsystematic review (6). Potential harms of screening (2).	Nonsystematic literature review of potential risks of screening for disease	None	Risks include misunderstanding of test results, misdiagnosis, labeling, stigmatization, and decreased psychological well-being; results may be misused by industry or insurance companies; screening should not be implemented until certain safeguards in place; clinicians and public should be educated about potential risks and benefits; use accurate, reliable, valid, and sensitive screening tests; obtain informed consent; followup surveillance; procedures to protect right to privacy should be implemented.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Rich 2000[38]	Screening for breast, cervical, and colon cancer	Cross-sectional study	Model days of life lost by stopping screening at various ages using SEER data (5). Days of life lost by stopping screening at various ages (1).	Randomized trial data, model using life tables to calculate life expectancy at various ages for stopping screen and for continuing until death for breast, cervical, and colon cancer	Stopping screening at various ages	Start age of 50 years, maximum potential life expectancy benefit of 43 days for breast cancer, 28 days for colon cancer. Start at age 20, maximum potential benefit of 47 days; 80 percent of benefit is achieved before age 75 for breast cancer, 80 years for colon cancer, and 65 years for cervical cancer. Small benefit may be outweighed by harms of anxiety, additional testing, and unnecessary treatment.
Rosser 1991[52]	Reminders for preventive procedures	Prospective randomized controlled study	Prospective randomized controlled study (2). Completion of preventive procedures (2).	8,502 patients 15 years or older not in a hospital or institution; 5,883 randomly assigned by family to a control, physician reminder, or telephone or letter reminder group; 2,619 not assigned to group but monitored	During 1 year patients in active reminder groups received a telephone or letter reminder of any overdue preventive procedures,and those in passive groups received a physician reminder vs. no reminder	All three reminder systems improved delivery of preventive services completion rates – 42 percent for letter reminder, 33.7 percent for physician reminder, 14.1 percent in control group; reminders were computer generated.
Rosser 1992[50]	Reminders of tetanus booster vaccination	Prospective randomized controlled study	Prospective randomized controlled study (2). Proportion of patients receiving tetanus toxoid during study year or had claim of vaccination in previous 10 years (2).	8,069 patients 20 years or older not in a hospital or institution – 5,589 randomly assigned to control, physician reminder, telephone reminder, or letter reminder group; 2,480 patients not randomized but monitored	No reminder vs. physician reminder at office visit vs. telephone reminder vs. letter reminder	Rates of recorded tetanus vaccination – 3.2 percent for control no reminder, 19.6 percent for physician reminder, 20.8 percent for telephone reminder, 27.4 percent for letter reminder; all three reminder systems were computer generated and increased the rate of tetanus vaccination, but all fell sort of achieving complete population coverage.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Rubin 2003[14]	Errors in general practice	Noncomparative study	Observational study without controls (5). Staff reported errors – classification and frequency (1).	5 physicians, 1 nurse, 1 pharmacist, and 11 administrative staff from 19 practices in UK general practice, North East of England	Error classification	940 errors in prescriptions, communication, equipment, appointment, clinical, other; 75.6/1,000 appointments; most were administrative relating to prescriptions or communication; 13 percent related to computers.
Shekelle 2006[47]	Costs and benefits of health information technology (HIT)	Systematic review of studies related to HIT systems in all care settings	Systematic review of studies (meta-analysis, systematic review, original research) (1). Costs and benefits of HIT for pediatric care; ability of one aspect of HIT – the electronic health record (EHR); costs and cost effectiveness of implementing EHR; effect of HIT on making care more patient centered (2).	256 articles of 855 screened from electronic search of articles published 1995 to January 2004	None	156 studies about decision support, 84 assessed EHR, and 30 on computerized physician order entry (CPOE); 124 in outpatient or ambulatory setting, 82 in the hospital or inpatient setting; 97 used a randomized design; 11 controlled clinical trials, 33 pre/post-test design, 20 time series, 17 case studies with concurrent control; 211 hypothesis-testing studies, 81 had at least some cost data. Clinical decision support systems (CDSS) reduce medication dosing error; CPOE plus CDSS reduce incidence of harmful medication errors in inpatient pediatric and neonatal intensive care settings; evidence for HIT cost savings in pediatrics is limited but promising; current use of EHR systems is limited. Added guidelines show decrease in orders for overused tests and increase in orders for underused tests; costly – 3–13 years to break even. Limited evidence on patient-centered care. Barriers to HIT implementation – situational, cognitive and/or physical, liability, and knowledge and attitude. Potential to dramatically alter health care, but limited experimental evidence.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Sawaya 2000[37]	Positive predictive value of cervical smears in previously screened women	Randomized controlled study	Prospective cohort study and randomized double-blind, placebo-controlled trial (2). Positive predictive value of cervical smears and the effect of oral estrogen plus progestin on incident cervical cytologic abnormalities (1).	2,561 women with a uterus and normal cytologic characteristics at baseline in 20 U.S. outpatient and community clinical centers	Annual smear; oral conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, or identical placebo	Incidence of new cytologic abnormalities 2 years after a normal smear was 110/person-years. In 103 women with known histologic diagnoses, 1 had mild to moderate dysplasia; positive predictive value of any smear abnormality 1 year after normal smear was 0 percent, 2 years was 0.9 percent. Conclusion – cervical smear should not be warranted within 2 years of normal cytologic results in postmenopausal women.
Tabar 2004[33]	Efficacy of breast cancer screening by age	Randomized controlled trial	Clinical trial of breast cancer screening (2). Mortality (1).	133,065 Swedish women ages 40–74 with 13-year followup of 2,467 cancers	Breast cancer screening	30 percent reduction in mortality associated with screening in women 40–74 after 13 years, 34 percent in women 50–74, and 13 percent for women 40–49; reduced effect on mortality in women 40–49 due to prognostic factors of tumor size, lymph node status, and histologic type.
Triller 2005[21]	Prevalence of risk factors for adverse drug events (ADEs)	Retrospective cohort study	Observational study without controls (5). Risk factors for ADEs (2).	Data on 10 risk characteristics of patients at point of discharge discharged in 2000 to home health care, self-care, long-term care	None	Data on 4,250 discharges; risk characteristics varied across three groups: home health care – highest prevalence of heart failure, cardiovascular medication use, and poly pharmacy; long-term care – highest prevalence of hypoalbuminemia, cognitive impairment, and psychiatric drug use.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Volk 1999[39]	Shared decisionmaking for prostate cancer screening	Randomized controlled trial	RCT with pre-office visit assessment and 2-week followup (2). Patients' core knowledge of prostate cancer, reported preferences for PSA testing, and ratings of videotape (3).	160 men ages 45–70 with no history of prostate cancer or treatment, from university-based family practice center	Patient-educational approach to shared decisionmaking for prostate cancer – PSA videotape	Significant change in knowledge about prostate cancer knowledge – mortality, performance of PSA testing, treatment complications and disadvantages of PSA testing; significant decrease in patient preferences for PSA.
Walter 2005[31]	Extrapolation to older person of efficacious screening tests for cancer, harms	Literature review, nonsystematic	Nonsystematic literature review (6). Surrogate outcomes (2).	Review of evidence-based literature	None	Few screening trials include person >70; questions to ask when deciding to extrapolate results of cancer screening trials to older individuals: Are there differences in the behavior of cancers in older people that reduce the benefit of early detection/treatment? Are there differences in the accuracy of screening tests in older people that make tests more likely to miss cancer? Are there differences in individual characteristics of older people that: Reduce the likelihood of benefit from screening? Increase the likelihood of benefit from screening? Potential complications of screening identified (e.g., physical complications, psychological distress, followup procedures, high anxiety). Screening in older persons is individual and requires weighing potential benefits and harms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Walter 2001[40]	Framework for individualized decisionmaking for cancer screening	Cross-sectional study	Description of development of framework (6). Potential benefits and harms of screening (1).	Elderly individuals (50–90 years old); use of life expectancy tables and published data	Development of framework for individualized decisionmaking	Potential benefits presented as number needed to screen to prevent one cancer-specific death; variability in potential benefit for patients of similar ages with varying life expectancies; with <5 years unlikely to derive a survival benefit. Potential harms – greatest occur by detecting cancers that would never be clinically significant; burdens due to screening; individualized decisionmaking with consideration of patient's values and preferences.
Woloshin 1997[42]	Main spoken language as barrier to preventive services	Cross-sectional survey	Self-report of breast examination, mammogram, and Pap test (20).	22,448 women completing 1990 Ontario Health Survey, population-based random sample of households	Language spoken	French-speaking women or those who spoke a language other than English were less likely to receive important preventive services.

Chapter 17. Improving the Quality of Care Through Pain Assessment and Management

Nancy Wells, Chris Pasero, Margo McCaffery

Background

At some point in life, virtually everyone experiences some type of pain. Pain is often classified as acute or chronic. Acute pain, such as postoperative pain, subsides as healing takes place. Chronic pain is persistent and is subdivided into cancer-related pain and nonmalignant pain, such as arthritis, low-back pain, and peripheral neuropathy. These authors will draw from the body of knowledge related to chronic pain; however, this chapter will focus on the evidence supporting management of acute pain experienced by hospitalized adults.

Scope of the Problem

Almost 35 million patients were discharged from U.S. hospitals in 2004; of these patients, 46 percent had a surgical procedure and 16 percent had one or more diagnostic procedures.[1] Pain is common, and expected, after surgery. Recent data suggest 80 percent of patients experience pain postoperatively[2] with between 11 and 20 percent experiencing severe pain.[2, 3] Despite the availability of analgesics—particularly opioids—and national guidelines to manage pain, the incidence of postoperative pain has remained stable over the past decade.[4] Thus, acute pain associated with surgical and diagnostic procedures is a common occurrence in U.S. hospitals and remains inadequately managed for many patients.

Importance of Controlling Pain

Inadequately managed pain can lead to adverse physical and psychological patient outcomes for individual patients and their families. Continuous, unrelieved pain activates the pituitary-adrenal axis, which can suppress the immune system and result in postsurgical infection and poor wound healing. Sympathetic activation can have negative effects on the cardiovascular, gastrointestinal, and renal systems, predisposing patients to adverse events such as cardiac ischemia and ileus. Of particular importance to nursing care, unrelieved pain reduces patient mobility, resulting in complications such as deep vein thrombosis, pulmonary embolus, and pneumonia. Postsurgical complications related to inadequate pain management negatively affect the patient's welfare and the hospital performance because of extended lengths of stay and readmissions, both of which increase the cost of care.

Continuous, unrelieved pain also affects the psychological state of the patient and family members. Common psychological responses to pain include anxiety and depression. The inability to escape from pain may create a sense of helplessness and even hopelessness, which may predispose the patient to a more chronic depression. Patients who have experienced inadequate pain management may be reluctant to seek medical care for other health problems. (For more detail, go to the section, "Harmful Effects of Unrelieved Pain," below.)

Poorly managing pain may put clinicians at risk for legal action. Current standards for pain management, such as the national standards outlined by the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations, JCAHO),[5] require that pain is promptly addressed and managed. Having standards of care in place increases the risk of legal action against clinicians and institutions for poor pain management,[6] and there are instances of law suits filed for poor pain management by physicians.[7] Nurses, as part of the collaborative team responsible for managing pain during hospitalization, also may be liable for legal action.

Hospitals stand to lose reputation as well as profit if pain is poorly managed. Patient satisfaction with care is strongly tied to their experiences with pain during hospitalization. Evidence indicates that higher levels of pain and depression are linked to poor satisfaction with care in ambulatory settings.[8] With the advent of transparent health care, report cards for hospitals are becoming more prevalent, and performance on pain management is likely to be one of the indicators reported.

Undertreatment of Pain

The undertreatment of pain was first documented in a landmark study by Marks and Sachar in 1973.[9] These researchers found that 73 percent of hospitalized medical patients had moderate to severe pain. The undertreatment of pain continues. Thirty years later in 2003, Apfelbaum and others[2] found that 80 percent of surgical patients experienced acute pain after surgery, and 86 percent of those had moderate to extreme pain. Of 1,308 outpatients with metastatic cancer from 54 cancer treatment centers, 67 percent reported pain.[10] Of those who had pain, 62 percent had pain severe enough to impair their ability to function, and 42 percent were not given adequate analgesic therapy. It is estimated that 45 percent to 80 percent of elderly patients in nursing homes have substantial pain that is undertreated.[11] These studies and others suggested that when patients had moderate to severe pain, they had only about a 50 percent chance of obtaining adequate pain relief.[12]

Harmful Effects of Unrelieved Pain

Patients suffer from pain in many ways. Pain robs patients of their lives. Patients may become depressed or anxious and want to end their lives. Patients are sometimes unable to do many of the things they did without pain, and this state of living in pain affects their relationships with others and sometimes their ability to maintain employment.

What is often overlooked is that pain has physically harmful effects. It is often actually physiologically unsafe to have pain.[13] The effects of pain on the endocrine and metabolic system, cardiovascular system, gastrointestinal system, and immune system—and the potential for future pain—are but a few of examples of how unsafe unrelieved pain may be.[13]

Pain causes stress. The endocrine system reacts by releasing an excessive amount of hormones, ultimately resulting in carbohydrate, protein, and fat catabolism (destruction); poor glucose use; and other harmful effects. This reaction combined with inflammatory processes can produce weight loss, tachycardia, increased respiratory rate, fever, shock, and death.[14] Unrelieved pain prolongs the stress response, adversely affecting the patient's recovery.[13]

The cardiovascular system responds to stress of pain by activating the sympathetic nervous system, which produces a variety of unwanted effects. In the postoperative period, these include hypercoagulation and increased heart rate, blood pressure, cardiac work load, and oxygen

demand. Aggressive pain control is required to reduce these effects and prevent thromboembolic complications. Cardiac morbidity is the primary cause of death after anesthesia and surgery.[13, 15]

Since the stress response causes an increase in sympathetic nervous system activity, intestinal secretions and smooth muscle sphincter tone increase, and gastric emptying and intestinal motility decrease. This response can cause temporary impairment of gastrointestinal function and increase the risk of ileus.[13, 15]

Unrelieved pain may be especially harmful for patients with metastatic cancers. Stress and pain can suppress immune functions, including the natural killer (NK) cells that play a role in preventing tumor growth and controlling metastasis.[13, 16] Further, management of perioperative pain is probably a critical factor in preventing surgery-induced decrease in resistance against metastasis.[17]

Unrelieved acute pain can result in chronic pain at a later date. Thus, pain now can cause pain later. If acute shingles pain is not treated aggressively, it is believed to increase the risk of postherpetic neuralgia.[18, 19] A survey of patients having undergone surgery found a high prevalence of chronic postsurgical pain in patients whose acute postsurgical pain was inadequately managed.[20]

Assessment of Pain

Assessment of pain is a critical step to providing good pain management. In a sample of physicians and nurses, Anderson and colleagues[21] found lack of pain assessment was one of the most problematic barriers to achieving good pain control. There are many recommendations and guidelines for what constitutes an adequate pain assessment; however, many recommendations seem impractical in acute care practice. Nurses working with hospitalized patients with acute pain must select the appropriate elements of assessment for the current clinical situation. The most critical aspect of pain assessment is that it is done on a regular basis (e.g., once a shift, every 2 hours) using a standard format.[5] The assessment parameters should be explicitly directed by hospital or unit policies and procedures.[5, 22, 23] To meet the patients' needs, pain should be reassessed after each intervention to evaluate the effect and determine whether modification is needed. The time frame for reassessment also should be directed by hospital or unit policies and procedures.[5]

An early *Clinical Practice Guideline on Acute Pain Management* released by the Agency for Health Care Policy and Research addressed assessment and management of acute pain.[22] This guideline outlines a comprehensive pain evaluation that would be most useful when obtained prior to the surgical procedure. In the pain history, the nurse identifies the patient's attitudes, beliefs, level of knowledge, and previous experiences with pain. Expectations of patient and family members for pain control postsurgically will uncover unrealistic expectations that can be addressed before surgery. This comprehensive pain history lays the foundation for the plan for pain management following surgery, which is completed collaboratively by the clinicians (physician and nurse), the patient, and his or her family.

Pain History

The pain history should include the following:

- Significant previous and/or ongoing instances of pain and its effect on the patient

- Previously used methods for pain control that the patient has found either helpful or unhelpful
- The patient's attitude toward and use of opioids, anxiolytics, or other medications, including any history of substance abuse
- The patient's typical coping response for stress or pain, including the presence or absence of psychiatric disorders such as depression, anxiety, or psychosis
- Family expectations and beliefs concerning pain, stress, and postoperative course
- Ways the patient describes or shows pain
- The patient's knowledge of, expectations about, and preferences for pain management methods and for receiving information about pain management[22] (p. 7–8)

Pain Assessment Tools

During the postsurgical period, pain assessment must be brief and simple to complete.[22] Because choice of intervention, including type of analgesic and dosing, is made based upon intensity, every pain assessment should include this type of measure. Numerous pain intensity measures have been developed and validated. Several tools provide a numeric rating of pain intensity (e.g., visual analogue scale, numeric rating scale (NRS)). Simpler tools such as the verbal rating scale, which classifies pain as mild, moderate or severe, also are commonly used. For patients with limited cognitive ability, scales with drawings or pictures are available (e.g., the Wong-Baker FACES scale). Patients with advanced dementia require behavioral observation to determine the presence of pain; tools such as the PAIN-AD are available for this patient population. (For more detail, go to section “Tools to Assess Pain Intensity in Cognitively Intact and Impaired Adults,” below.)

The Joint Commission developed pain standards for assessment and treatment based upon the recommendations in the *Acute Pain Clinical Practice Guideline.* The Joint Commission requires that hospitals select and use the same pain assessment tools across all departments. This standard suggests providing options among scales such as the NRS, the Wong-Baker FACES scale, and a verbal descriptor scale.

Selecting the pain assessment tool should be a collaborative decision between patient and health care provider. When this is done during the preoperative period, it ensures the patient is familiar with the scale. If the nurse selects the tool, he or she should consider the age of the patient; his or her physical, emotional, and cognitive status; and preference.[22] We tend to think of these intensity scales as verbal, but patients who are alert but unable to talk (e.g., intubated, aphasic) may be able to point to a number or a face to report their pain. The pain tool selected should be used on a regular basis to assess pain and the effect of interventions. It should not, however, be used as the sole measure of pain perception.[24]

Location and quality of pain are additional assessment elements useful in selecting interventions to manage pain. Since patients may experience pain in areas other than the surgical site, location of pain using a body drawing or verbal report provides useful information. The pain experienced may be chronic (e.g., headache, low-back pain) or it may be related to the positioning and padding used during the procedure. The quality of pain varies depending upon the underlying etiology. Instruments such as the McGill Pain Questionnaire[25, 26] contain a variety of verbal descriptors that help to distinguish between musculoskeletal and nerve-related pain. Typically, patients describe deep tissue pain as dull, aching, and cramping, while nerve-related pain tends to be more sporadic, shooting, or burning.[27, 28]

Pain interferes with many daily activities, and one of the goals of acute pain management is to reduce the affect of pain on patient function and quality of life.[24] The ability to resume activity, maintain a positive affect or mood, and sleep are relevant functions for patients following surgery. The Brief Pain Inventory[10, 29] includes four items that may be useful in assessing this aspect of the pain experience. Using an NRS format, assessment of interference with ability to walk, general activity, mood, and sleep during the recovery period will assist in selecting interventions to enhance function and quality of life.

The final elements of pain perceptions involve determining current aggravating and alleviating factors.[22, 24] Aggravating factors may be as simple as patient position, a full bladder, or temperature of the room. Alleviating factors include the interventions used (e.g., analgesics) and cognitive strategies used to control pain. Examples of such strategies are distraction, positive self-talk, and pleasant imagery. The pain history will provide insight into the coping strategies previously used by the patient and their effectiveness with previous painful episodes.

In addition to self-reported pain perceptions, a comprehensive assessment of pain following surgery includes both physiological responses and behavioral responses to pain[22] (p. 11). Physiological responses of sympathetic activation (tachycardia, increased respiratory rate, and hypertension) may indicate pain is present. Behaviors that may indicate pain include splinting, grimacing, moaning or grunting, distorted posture, and reluctance to move. While these nonverbal methods of assessment provide useful information, self-report of pain is the most accurate. A lack of physiological responses or an absence of behaviors indicating pain may not mean the patient is not experiencing pain. (Go to section “Tools to Assess Pain Intensity in the Cognitively Impaired,” below, for more detail.)

Adequate pain management requires an interdisciplinary approach.[22, 24] Documentation of pain assessment and the effect of interventions are essential to allow communication among clinicians about the current status of the patient’s pain and responses to the plan of care. The Joint Commission requires documentation of pain to facilitate reassessment and followup. The American Pain Society suggests that pain be the fifth vital sign as a means of prompting nurses to reassess and document pain whenever vital signs are obtained.[30] Documentation also is important as a means of monitoring the quality of pain management within the institution.

Monitoring the Quality of Pain Management

Establishing and maintaining an institutional pain performance improvement plan is a Joint Commission requirement.[5] Institutions should develop interdisciplinary approaches to acute pain management with clear lines of responsibility for achieving good acute pain control.[5, 22, 24] This interdisciplinary approach includes an individualized plan of care for pain control, developed in collaboration with the patient and family. Systems should be in place to monitor pain management that alerts the clinician when pain is poorly managed. For example, in an institution with a computerized documentation system, an alert may pop up when a patient’s pain exceeds a threshold. The threshold may be set individually by patient and clinician or institutionally. A reasonable threshold might be moderate to severe pain, which means a pain score of greater than 4 on a 0–10 scale.[31] The plan of care provides the basis for monitoring the quality of acute pain management provided.

American Pain Society Current Guidelines

One of the first quality improvement programs was developed by the American Pain Society.[23] The quality improvement guideline was refined and expanded in 2005[24] (p. 1576) based upon a systematic review of pain quality improvement studies conducted over the past 10 years.[32] The emphasis has shifted from processes to outcomes.

- Recognize and treat pain promptly.
- Involve patients and families in pain management plan.
- Improve treatment patterns.
- Reassess and adjust pain management plan as needed.
- Monitor processes and outcomes of pain management.

The goal of pain management after surgery is to prevent and control pain. Postsurgical pain, like cancer pain, is expected to be present continuously with spikes of increased pain with movement, deep breathing and coughing, and ambulation during the fist 24–48 hours after surgery. Around-the-clock dosing is recommended during this early postsurgical period to prevent severe pain and control continuous pain.

Quality Indicators[24] (p. 1578)

Quality indicators for pain management focus on appropriate use of analgesics and outcomes.

- Intensity of pain is documented using a numeric (0–10) or descriptive (mild, moderate, severe) rating scale.
- Pain intensity is documented at frequent intervals.
- Pain is treated by route other than intramuscular.
- Pain is treated with regularly administered analgesics, and, when possible, multimodal approach is used. (Multimodal approach includes a combination of pain control strategies, such as opioids, nonsteroidal anti-inflammatory drugs, nonpharmacological interventions.)
- Pain is prevented and controlled to a degree that facilitates function and quality of life.
- Patients are adequately informed and knowledgeable about pain management.

To efficiently monitor quality indicators, patient records should contain documentation of

- Pain intensity (0–10 or mild, moderate, severe)
- Analgesics prescribed and administered, including drug, route, and dosing
- Impact of pain on function and quality of life (e.g., ability to walk, general activity, mood, sleep)
- Pain education for patient and family member(s)

Patient Satisfaction

Although satisfaction with pain management currently is used as a measure of institutional quality, satisfaction with pain management is no longer recommended as a quality indicator for pain control.[24, 32] This is because patient satisfaction findings are difficult to interpret. In their review of 20 quality improvement studies conducted between 1992 and 2001, Gordon and colleagues[32] noted 15 studies reported high satisfaction with pain management despite many

patients experiencing moderate to severe pain during hospitalization. Thus, patient satisfaction data should be cautiously interpreted and, if used, used in conjunction with other quality indicators. Because of the current focus on report cards for health care organizations, patient satisfaction data are routinely collected and easily obtained for review.

Many institutions use commercial patient satisfaction surveys to monitor satisfaction with care. Most of these surveys have at least one item on satisfaction with pain management. Institutions also may use generic health status or quality of life surveys, such as the Medical Outcomes Study Short From-36, to monitor patient outcomes; most of these surveys include one or more questions on pain experienced. Regular review of these patient satisfaction data can be used as a quick measure of quality of pain care. If satisfaction scores on pain management dip, a more thorough investigation of pain management processes is warranted.

Use of an interdisciplinary team to monitor current pain practice, identify areas for improvement, and oversee quality improvement plans is consistently recommended in the guidelines.[5, 22, 24] To effectively monitor pain practice within a hospital, electronic systems are needed to capture and collate data on the indicators in a readily available form. One method of changing clinician behavior is through the use of feedback on performance; thus the reports generated for interdisciplinary committee review also may be used to assist clinicians to review and adjust their performance.

Current Guidelines

Many State and professional organizations have developed clinical practice guidelines to direct health care providers in adequate management of acute pain. The 1992 *Acute Pain Clinical Practice Guideline*[22] lays the foundation for the more current guidelines. Listed below is a sample of current guidelines available from the National Guideline Clearing House.

- Pain management guideline; developed by the Health Care Association of New Jersey; released July 2006. This guideline includes definitions of pain (acute and chronic); clear direction for assessment and treatment with pharmacological and nonpharmacological interventions (including physical and occupational therapy); policies for pain education for staff, patients, and families; and direction for quality monitoring. The guideline is applicable to pain management in acute care and long-term care nursing facilities. Web site: http://www.guidelines.gov/summary/summary.aspx?doc_id=5526&nbr=003757&string=pain+and+assessment+and+nursing
- "Pain Management"; written for the 2nd edition of *Geriatric Nursing Protocols for Best Practice*; published in 2003. This guideline addresses pain in the elderly, assessment strategies, and nursing interventions to control pain. Pharmacological and nonpharmacological interventions are included in the guideline. Web site: http://www.guidelines.gov/summary/summary.aspx?doc_id=3514&nbr=002740&string=pain+and+assessment+and+nursing
- *ASPAN Pain and Comfort Clinical Guideline*; developed by American Society of Perianesthesia Nurses; released August 2003. This guideline provides direction for assessment, interventions, and expected outcomes for the preoperative and postoperative phases of treatment. Use of pharmacological and nonpharmacological interventions is endorsed. Web site: http://www.guidelines.gov/summary/summary.aspx?doc_id=5526&nbr=003757&string=pain+and+assessment+and+nursing

- *Clinical Practice Guideline for the Management of Postoperative Pain*; developed by the Veterans Health Administration; released May 2002. This guideline is organized into two main algorithms, one for the preoperative phase and the other for the postoperative phase. The pain management plan is set within the context of comprehensive pre- and postsurgical care and includes discharge planning. A patient-focused objective is provided for each step of the pain management plan. Emphasis is placed upon reassessment and modification of the treatment plan. Clear descriptions of common opioid side effects and interventions to reduce them are included in the guideline. Web site: http://www.guidelines.gov/summary/summary.aspx?doc_id=3284&nbr=002510&string=pain+and+assessment+and+nursing
- The American Society of Pain Management Nursing has published two position statements on pain management issues that pose difficulty ethically and in practice. Practice recommendations based upon research and clinical expertise are included in both position statements.
  - Herr et al. Pain assessment in the nonverbal patient: Position statement with clinical practice recommendations. *Pain Management Nursing* 2006;7(2):44-52.
  - American Society for Pain Management Nursing. ASPMN position statement: pain management in patients with addictive disease. *Journal of Vascular Nursing* 2004;17(3):99-101.
- With the implementation of the Joint Commission standards for pain management, the requirements for "as needed" (PRN) orders were altered. The American Society of Pain Management Nursing and the American Pain Society developed a consensus statement on the use of PRN range orders to guide nursing practice.
  - Gordon et al. Use of "as needed" range orders for opioid analgesics in the management of acute pain. *Home Healthcare Nurse*, 2005;23(6):388-96.

Research Evidence

Analgesics, particularly opioids, are the primary treatment for acute pain. It is estimated that up to 90 percent of cancer pain can be adequately managed with analgesics using the World Health Organization (WHO) analgesic ladder.[33, 34] Although no evidence exists to estimate the likelihood of adequately managing acute pain, it is reasonable to infer that the vast majority of postsurgical pain can be well managed with the appropriate use of analgesics. While there are many factors that contribute to poor pain management—lack of assessment and inadequate or inapposite use of analgesics are primary, and modifiable, factors.[35] Thus, it is the responsibility of clinicians to be knowledgeable about the analgesics used to treat pain, including onset, peak action, and duration of the drug(s) administered; common side effects, and methods of managing those side effects.[36] Easy access to an equianalgesic table assists in providing good pain control when switching from one opioid to another and from one route to another. This approach is particularly important when preparing the postsurgical patient for discharge with an oral analgesic.

The objective for postsurgical and procedural pain is to prevent and control pain.[22, 24] This does not mean that patients will be pain free, a misconception that some patients and families have when entering the hospital. This misconception is best addressed during the preoperative pain assessment by collaboratively setting goals for pain control and function. A multimodal approach (balanced analgesia), which includes opioids, nonopioids such as nonsteroidal anti-

inflammatory drugs (NSAIDs), and adjuvant medications such as anticonvulsants, is recommended. (For more detail go to the "Balanced Analgesia" section in this chapter.) Following the WHO's analgesic ladder for control of cancer pain, the Clinical Practice Guideline Committee recommended the use of NSAIDs for mild to moderate pain with the addition of opioids for moderate to severe pain.[22]

Principle of Analgesic Management of Pain

Based upon evidence and clinical practice, there are several principles of analgesic management to meet the objective of preventing moderate to severe pain:

- When continuous pain is anticipated, a fixed-dose schedule (around the clock) should be used.
- A PRN order of a rapid onset analgesic may be necessary to control activity-related (breakthrough) pain.
- To ensure opioids are safely administered, begin with a low dose and titrate to comfort.
- Modification in analgesic administration is based upon assessment of the effect of the previous dose, including change in pain intensity, relief, and side effects experienced.
- Patients respond differently to various opioid and nonopioid analgesics; therefore if one drug is not providing adequate pain relief, another in the same class may result in better pain control.
- Assessment of effect should be based upon the onset of action of the drug administered; for example, IV opioids are reassessed in 15–30 minutes, whereas oral opioids and nonopioids are reassessed 45–60 minutes after administration.

Opioid Analgesics

A series of three systematic reviews have been published in the past 5 years examining the efficacy, safety, and side effect profile of opioids used to manage postsurgical pain.[2, 37, 38] The first review[3] concluded that patient-controlled analgesia (PCA) and epidural routes of administration were superior to intramuscular (IM) injections when pain intensity and relief were considered. The safety of opioids used to control postsurgical pain was examined for hypotension and respiratory depression; observed rates were less than 5 percent for hypotension and less than 1 percent for respiratory depression.[37] The most common opioid side effects included 25 percent nausea, 20 percent vomiting, 23.9 percent mild sedation, 2.6 percent excessive sedation, 14.7 percent pruritis, and 23 percent urinary retention. The use of intravenous PCA was associated with the highest levels of nausea and sedation, whereas epidural analgesia was associated with the highest rate of urinary retention.[38] This series of systematic reviews suggests the IM route of administration produces the poorest outcomes. Approximately one in every four patients will experience common opioid side effects; however, the rate of excessive sedation, respiratory depression, and hypotension related to opioids are low in the postsurgical population.

Patient and Family Education

Beginning with the *Acute Pain Clinical Practice Guideline*,[22] patient and family education has been a central recommendation for acute pain management. This education is best

implemented during the presurgical clinic visit or during admission pain assessment. The essential elements of pain education include telling the patient the following:

- Preventing and controlling pain is important to your care.
- There are many interventions available to manage pain; analgesics (opioid and nonopioid) are the most effective in managing acute pain.
- Some people are afraid of using opioids because of the side effects and risk of addiction. Side effects can be managed effectively with medication. The risk of addiction when using opioids to control acute pain is extremely low.
- Your responsibility in achieving good pain control is to tell us when you are experiencing pain or when the nature or level of pain changes.
- Complete pain relief usually is not achievable; however, we will work with you to keep pain at a level that allows you to engage in activities necessary to recover and return home.

This last comment flows directly into a discussion about goals for pain management during the hospitalization. This goal is set in light of the functional requirements (e.g., when ambulation will begin, need for deep breathing) to promote recovery. Thus, the patient, family member(s), and nurse collaboratively set a tolerable or satisfactory level of pain and function during the hospitalization, which is documented either in the patient's room or record so that all clinicians are working toward the same goals for pain control. Shared goal setting is one dimension of relational coordination associated with adequate postsurgical pain management.[39] Information obtained from the pain history (e.g., previous experience with pain and what helped or did not help, typical coping strategies used) will assist in developing a plan of care that incorporates the patient's preferences into the plan.

Patient-Nurse Interactions

One of the earliest evidence-based protocols was developed as part of the Conduct and Utilization of Research in Nursing (CURN) project. *Pain: Deliberative Nursing Interventions*[40] describes an approach to a patient's complaint of pain that includes skilled communication to determine the patient's needs. While administering analgesics may be the most appropriate way to meet the patient's needs, the nurse may uncover other factors contributing to discomfort, such as uncomfortable position, thirst, or the need to urinate.[40] Addressing these needs will improve patient comfort and communicate the nurse's desire to promote comfort. McCaffery[35] suggested that the time spent with the patient to communicate concern and caring may go a long way in providing patient comfort. The content of this 5-minute conversation may include the following:

- Listening to patient concerns
- Communicating the desire to help the patient become more comfortable
- Determining strategies that might achieve more comfort[35] (p. 78)

Communication with patients is one of the core dimensions of relational coordination, an approach examined in the orthopedic surgical population.[39] In a cross-sectional study of nine hospitals, Gittell and colleagues[39] found that the better the relational coordination, the better the postsurgical pain relief. Of note, four dimensions (frequent communication, shared goals, shared knowledge, and mutual respect among clinicians) were associated with this improvement in pain control. Thus, this study suggested that communication, goal setting, and patient education contributed to better pain outcome.

Nondrug Techniques To Manage Pain

People naturally use many nondrug strategies, such as distraction, imagery, and massage, to alleviate pain. During episodes of acute pain, patients may rely on these previously used and "proven" methods. For example, Kwekkeboom[41] found women recovering from breast and gynecological surgery used a variety of nondrug techniques in addition to analgesics to relieve pain at home. Although the techniques varied, methods to increase relaxation were common (e.g., breathing, meditation, imagery, and music). Hospitalized patients also may use techniques that have worked for them in the past; in a study of nondrug techniques to manage postsurgical pain, Pellino and colleagues[42] reported that between 19 and 28 percent of patients in the usual care control group used nondrug techniques during the first 3 days after surgery. Thus, patients in pain may spontaneously (i.e., without instruction or help) use a wide variety of nondrug methods to control their pain. Before suggesting or instructing patients in the use of nondrug techniques, nurses need to be aware of the methods used effectively and preferred by the patient. For example, in a trial of five cognitive-behavioral techniques to manage cancer pain in ambulatory patients, Anderson and colleagues[43] noted that a number of patients had difficulty using their assigned technique because it did not match their usual coping style. In addition to applying the wrong technique, instructing patients in the use of a specific technique, such as imagery, may undermine their confidence in the techniques they typically use to control pain.

Nurses have used nondrug techniques for years to help patients manage pain. These techniques have been labeled differently over the years. Noninvasive, nonpharmacological, nondrug, and complementary therapies have been used interchangeably to reflect nonmedical therapies. McCaffery[35] noted that there is no classification system for these nondrug techniques. For the purposes of this chapter, techniques will be grouped as cognitive and physical. Cognitive techniques focus primarily on mental functions that require some degree of attention. Distraction or focusing attention away from the pain may be one of the primary mechanisms resulting in pain relief. Relaxation and music are included in this cognitive category. Physical techniques focus on altering physiological processes that may reduce pain. Massage and the application of heat and cold are included in this category. One possible mechanism of action for massage and heat/cold therapy is the stimulation of the large diameter fibers, which are hypothesized to reduce central pain transmission. Reducing muscle tension, which may contribute to pain transmission, is another possible mechanism of action.

Relaxation. There are many methods available to achieve a relaxation response. Some require initial training and practice to be used effectively; progressive muscle relaxation, systematic relaxation, and autogenic training are skills that require some practice. Each session using progressive, systematic, or autogenic training may take 15–30 minutes. Typically in research, the instructions are delivered via audiotape, a method that may be used for hospitalized patients as well. Simpler forms of relaxation, which may be more suitable to institute during an acute pain episode, include jaw dropping and rhythmic breathing.

Reviews on the effectiveness of relaxation for pain relief have arrived at different and often opposite conclusions.[44–46] This is not surprising because of the wide variety of techniques that were used as well as the small number of studies published (11 to 12 in the most recent reviews). The recent randomized clinical trials also contribute to this inconsistency.[43, 47, 48] Therefore, the current evidence does not support a consistent, predictable effect of relaxation on pain.

Music. Sedating or soothing music is instrumental, rhythmic, and 60–80 beats per minute. In much of the research, musical pieces are selected from five types of music identified by Good

and colleagues:[49] synthesizer, harp, piano, orchestral, or slow jazz. The intervention is delivered via audiotape and headphones. The duration is typically 20–30 minutes and may involve a single or multiple exposures.

A recent meta-analysis of 51 studies examining the effect of music on pain concluded that although music produced a significant reduction in pain intensity (0.5 units), this result may not reflect a clinically important change.[50] Gordon and colleagues[24] suggest a 1.5 to 2.0 unit change in pain intensity on a 0–10 scale constitutes a clinically important difference. Despite the large number of studies included, approximately 50 percent were of low quality, leading to low confidence in the results of the analysis. Contrary to previous meta-analyses,[51] Cepeda and colleagues[50] did not find differences in pain reduction related to whether the music was patient- or clinician-selected. Recently published studies, all conducted on patients undergoing cardiovascular procedures, found significant short-term reductions in pain, distress, or anxiety after exposure to music.[52–54] In each of these studies, music was used during an episode of increased pain (e.g., getting up from a chair). While these studies hold promise, currently the evidence for the effectiveness of music in reducing acute pain is weak to moderate.

Massage. Massage is defined as the systematic manipulation of soft tissues by manual or mechanical means.[55] Nurses have used massage—a back rub—to improve circulation, promote comfort, and enhance sleep. More recently investigators have examined hand and foot massage as an alternative to back or body massage. The duration of massage varies from 5 to 20 minutes. Wong and Keck[56] suggested that 20 minutes of massage was required to achieve the desired effect, but little evidence exists to substantiate this claim.

Reviews of the massage literature conclude it has a beneficial effect on anxiety and tension, depression, and stress hormones (cortisol and catecholamines).[57, 58] The evidence on the beneficial effects of massage on reducing pain is positive, but involves few studies, so that firm conclusions cannot be drawn. More recent studies produced inconsistent findings, particularly in terms of the effect of massage on pain control.[56, 59–62] As with the relaxation and music literature, studies of the effect of massage suffer from methodological problems[57] that produce unstable or biased results.

Heat/cold therapy. The application of heat and ice to reduce pain or promote comfort has been a common nursing intervention, which may require a physician's order to implement.

Despite the use of heat and cold by nurses, there are few studies investigating the impact on pain or function. A meta-analysis of heat and cold for low-back pain concluded that continued use of heat (over a 5 day period) improved pain intensity and function.[63] Only two studies on the use of heat for postsurgical pain were found, and the findings from these were inconclusive.[64] The application of ice/cold for low-back pain has limited evidence to support it's use.[63] Cold therapy has been investigated in patients undergoing orthopedic surgeries (primarily total knee arthroplasty) and has been found to improve pain, range of motion, and function.[65] However, a study by Smith and others[66] found that pain was similar with the cryo pad (a new technology to deliver cold therapy) and the compression bandage applied by the surgeon at the end of surgery; in addition, the cold therapy increased the cost of care and took more nursing time. Thus, using cold therapy via the cyro pad provides no benefit over compression bandages after knee replacement and is less cost efficient.

Use of multiple nondrug therapies for pain management. Introduction to a variety of nondrug techniques may be used to better meet patients' needs. Two recent studies examined the effect of providing multiple nondrug techniques (e.g., a cafeteria style) on postsurgical pain. In both studies, the interventions were developed to allow the patient maximum control and require

minimum nursing time. Common techniques used in both studies included relaxation, music, and massage.[42, 67] While it is too early to determine if providing a pain "tool kit" will have benefit to postsurgical patients, Kshettry and colleagues[67] demonstrated the feasibility of implementing such a program in a busy intensive care unit (ICU).

Evidence-Based Practice Implications

Lack of adequate assessment and inappropriate treatment remain the major factors of undertreatment of pain. There is ample evidence that the appropriate use of analgesics—the right drug(s) at the right intervals—can provide good pain relief for the majority of patients. Thus, institutions should place their money and effort on improving these provider behaviors (assessment, prescription and administration of analgesics).[35] The use of nondrug therapies is recommended in most pain guidelines; however, the evidence for their consistent benefit in terms of pain intensity, relief, or improved function is weak at best. This result does not mean a nondrug technique, or several techniques provided cafeteria style, may not improve a patient outcome. The nurse who uses these techniques should be aware that the effect is not predictable.[35]

Ensuring Patient Safety

Following are some patient safety issues that relate to pain management:

- When administering sedatives, consider the patient's physical safety (e.g., using bed rails, fall precautions, assistance with ambulation).
- Eliminate errors related to PCA infusions (improper dose/quantity, wrong drug, drug omission) by using systems to double-check drug and dose (e.g., bar coding, nurse-nurse checking).[68]
- Eliminate errors and complications related to catheter administration (initial dose testing, monitoring catheter and response to medication).[69]
- Nondrug techniques have minimal adverse events reported and do not pose safety issues.
- Protect skin when applying heat or cold.

Tools To Assess Pain Intensity in Cognitively Intact Adults

The first step in relieving pain to prevent its harmful effects, and doing so safely, is to assure that patients are properly assessed for pain so that appropriate pain relief measures can be implemented. Otherwise, pain may be unnoticed by clinicians or may be undertreated.

Self-report is the most reliable way to assess pain intensity. When the patient is able to report pain, the patient's behavior or vital signs should never be used in lieu of self-report. For the cognitively intact adult, assessment of pain intensity in the clinical setting is most often done by using the zero to 10 numerical rating scale or the zero to 5 Wong-Baker FACES scale.[70] The NRS consists of a straight horizontal line numbered at equal intervals from zero to 10 with anchor words of "no pain" for zero, "moderate pain" for 5, and "worst pain" for 10. The FACES scale consists of six faces showing progressive pain intensities, beginning with a smiling face and ending with a crying face.

Once the patient knows how to use a pain intensity scale, the patient should be taught how to establish a comfort-function goal. This is the pain intensity at which the patient is easily able to

perform necessary activities, such as ambulating after surgery or being able to concentrate on job-related activities. Interventions are implemented to achieve and maintain this pain rating as much of the time as possible.[70]

Tools To Assess Pain Intensity in Cognitively Impaired Adults

When the patient is unable to self-report pain, other less reliable measures must be used to identify the existence of pain and estimate the probable intensity. These assessment measures form a hierarchy, arranged in order of probable importance:[70, 71]

- Conditions, such as surgery, or procedures, such as wound care, that are likely to cause pain.
- Patient behaviors that are likely to indicate pain. A behavioral assessment tool, discussed below, may be used. Whenever possible, a pain behavior scale should be chosen that has been researched for reliability and validity in the clinical setting.
- Knowledge of others who know the patient, such as the family or caregivers. They should be asked if they see behaviors that may indicate pain or if they know of preexisting conditions, such as arthritis, that cause pain.

If any of the above suggest pain is present, the clinician may assume pain is present and use the acronym APP to record assessment when a pain intensity rating cannot be obtained. Next, a conclusion is made about an appropriate intervention based on the probable intensity of pain. If appropriate, a trial dose of analgesic is given and the patient's behavior is observed before and after this intervention. If the behavior subsides, this may indicate that indeed the patient has pain and that the analgesic should be continued. If there is no change in behavior, a stronger dose of analgesic may be indicated.[71]

Behavioral assessment tools are helpful in identifying the existence of pain and evaluating interventions. These scales are of two types: (1) pain behavior scales, and (2) pain behavior checklists. Some of these scales are scored by identifying the number or intensity of behaviors. However, this score is not a pain intensity score. No research as yet confirms that a pain behavior score is a pain intensity score.[71] Therefore, it is unsafe to use pain behavior scores as pain intensity scores. A patient with only a few behaviors may have as much pain as a patient with many more behaviors.

An example of a pain behavior scale is the Behavioral Pain Scale (BPS), developed for use in the critically ill patient in the ICU.[72] It evaluates and scores three categories of behavior:

1. Facial expression, scores range from 1 for relaxed to 4 for grimacing
2. Upper-limb movement, scores range from 1 for no movement to 4 for permanently retracted
3. Ventilator compliance, scores range from 1 for tolerating ventilator to 4 for unable to control ventilation

Once again, a score above 3 may indicate pain is present and the score can be used to evaluate intervention, but cannot be interpreted to mean pain intensity. For a pain behavior scale to be useful, the patient must be able to respond in all categories of behavior. For example, the BPS would be useless in a patient who is receiving a neuromuscular blocking agent.

Behavior checklists differ from pain behavior scales in that they do not evaluate the degree of an observed behavior and do not require a patient to demonstrate all of the behaviors specified, although the patient must be responsive enough to demonstrate some of the behaviors. These

checklists are useful in identifying the patient's "pain signature," that is, the pain behaviors unique to the individual.[73]

An example of a pain behavior checklist is the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC).[74] The PACSLAC evaluates 60 behaviors such as facial expressions, activities, and mood. A check mark is made next to any behavior the patient exhibits. The total number of behaviors may be scored, but again, this cannot be equated with a pain intensity score. It is unknown if a high score represents more pain than a low score. In other words, a patient who scores 10 out of 60 behaviors does not necessarily have less pain than a patient who scores 20.[71] However, in an individual patient, a change in the total pain score may suggest more or less pain. A more comprehensive description of pain assessment tools for the cognitively impaired are located at the following Web site in the education section of Pain in the Elderly: http://www.cityofhope.org/PRC/.

Balanced Analgesia

Analgesics are usually divided into three categories: (1) nonopioids, which include acetaminophen and NSAIDs; (2) opioids, which include morphine-like drugs; and (3) adjuvant analgesics, which include local anesthetics and anticonvulsants. Using an analgesic from each one of the three groups, referred to as balanced or multimodal analgesia, may improve the safety of analgesic therapy. When more than one analgesic is used, the same level of pain relief may be achieved with a lower dose of each analgesic. For example, use of a local anesthetic along with an opioid usually allows reduction of the opioid dose needed for adequate pain control.

Safe Use of Opioids

Of all the analgesics used in pain control, the most safety issues arise with the use of those referred to as mu opioids, or morphine-like drugs such as morphine, hydromorphone (Dilaudid™), and fentanyl. Clinicians fear causing harm with these analgesics by administering too much and causing life-threatening respiratory depression. Sometimes this fear results in undertreatment of pain. Clinicians need to be educated about the effective methods of preventing respiratory depression and appropriate use of naloxone if respiratory depression does occur.

Opioid-induced respiratory depression is preceded by an increasing level of sedation. An alert patient will not suddenly succumb to respiratory depression. Consequently, respiratory depression can be prevented by observing sedation levels and decreasing the opioid before respiratory depression occurs. Box 1 presents a sedation scale that nurses can use at regular intervals to monitor patients receiving opioids. This scale should be used for all opioid naïve patients with moderate to severe pain when opioid dosing is initiated. These patients should be monitored at least every 2 hours during the first 24 hours of opioid therapy. Using this scale, the nurse knows when it is or is not safe to administer additional opioid and when the opioid dose should be decreased or stopped.

When selecting a sedation scale for prevention of opioid-induced respiratory depression, care must be taken to be sure that the selected scale matches the intended purpose. For example, the Ramsey is appropriate for monitoring the patient's tolerance for ventilation in the ICU, but is not intended for use in prevention of opioid-induced respiratory depression. It contains irrelevant items, such as agitation, which have nothing to do with opioid-induced respiratory depression.

Nurse monitoring of sedation levels and respiratory status is more appropriate for preventing opioid-induced respiratory depression than relying on pulse oximetry or apnea monitory. These

can give a false sense of security.[75–77] Further, decreased oxygen saturation is a later sign of impending respiratory depression. Capnography may more accurately detect respiratory depression and apnea;[78] however, further research is required to recommend widespread use of the method outside of the operating room or post-anesthesia care unit. The use of mechanical monitoring is recommended if a patient has a preexisting condition that requires it, such as sleep apnea or chronic obstructive pulmonary disease.[76]

Instructions for the safe use of naloxone to reverse clinically significant opioid-induced respiratory depression are included in Box 1. Naloxone must be titrated carefully. Giving too much naloxone or giving it too fast can precipitate severe pain and increase sympathetic activity leading to hypertension, tachycardia, ventricular dysrhythmias, pulmonary edema, and cardiac arrest.[79]

The IM route of administration is not recommended for pain management.[76] It is painful, and it has unreliable absorption with a 30–60 minute lag time to peak effect and a rapid drop in action. In addition to being ineffective, the IM route is dangerous because patients are often alone at the time of peak effect of the opioid administered, can become excessively sedated, vomit, and aspirate. A better alternative is the intravenous (IV) route of administration. Points to consider in the overall safe management of opioid naïve patients receiving IV or intraspinal analgesia are in Box 2.

Box 1: Pasero - McCaffery Opioid-induced Sedation Scale

S = Sleep, easy to arouse

Acceptable: No action necessary; supplemental opioid may be given if needed.

1 = Awake and alert

Acceptable: No action necessary; supplemental opioid may be given if needed.

2 = Slightly drowsy, easily aroused

Acceptable: No action necessary; supplemental opioid may be given if needed.

3 = Frequently drowsy, arousable, drifts off to sleep during conversation

Unacceptable: Decrease opioid dose by 25–50 percent . Administer acetaminophen or an NSAID, if not contraindicated, to control pain; monitor sedation and respiratory status closely until sedation level is less than 3.

4 = Somnolent, minimal or no response to physical stimulation

Unacceptable: Stop opioid. Notify anesthesia provider; very slowly administer dilute IV naloxone (0.4 mg naloxone in 10 mL saline; 0.5 mL over 2-minute period); administer acetaminophen or an NSAID, if not contraindicated, to control pain; monitor sedation and respiratory status closely until sedation level is less than 3.

Source: Pasero C. *Acute pain service: policy and procedure guideline manual*. Los Angeles, CA: Academy Medical Systems, 1994; Pasero C, Portenoy RK, McCaffery M. Opioid analgesics, In: McCaffery M, Pasero C. *Pain: clinical manual*. 2nd ed. St. Louis, MO: Mosby; 1999. p. 161-299. Copyright Chris Pasero, 1994. Used with permission.

Box 2: Safe Care of the Opioid Naïve Patient Receiving Opioids by IV or Intraspinal Routes

- Develop standardized, preprinted order sets that include
    - Opioid prescription
    - Administration of nonopioid analgesia, e.g., acetaminophen and an NSAID
    - Monitoring parameters
    - Activity, ambulation
    - IV access if indicated
    - Management of breakthrough pain
    - Treatment of adverse effects
    - When to notify anesthesia or primary care provider (e.g., unrelieved pain, excessive adverse effects)
- Monitor sedation and respiratory status every 1 to 2 hours for the first 24 hours after opioid therapy is initiated, then every 4 hours until IV or intraspinal opioid therapy is discontinued, then routine in stable patients (see Sedation Scale, Box 1).
- Monitor other vitals signs every 4 hours until IV or intraspinal opioid therapy is discontinued, then per routine in stable patients (evaluate need to monitor blood pressure more often in some patients).
- When possible, avoid sedating drugs for treatment of opioid-induced adverse effects, such as antihistamines for pruritus and antiemetics for nausea.
- Develop criteria for selecting appropriate patients to receive
    - Patient-controlled analgesia (PCA)
    - Family-controlled analgesia (parent or significant other)
    - Nurse-activated dosing (primary nurse)
- Teach patients, family members, and visitors about the proper use of PCA and the dangers of anyone other than the patient or an authorized person pressing the button.

Source: Pasero C, McCaffery M. Authorized and unauthorized use of PCA. Am. J. Nurs. 2005;105(7):30,31, 33; Pasero C, Portenoy RK, McCaffery M. Opioid analgesics, In: McCaffery M, Pasero C. *Pain: clinical manual*. 2nd ed. St. Louis, MO: Mosby; 1999 p. 161-299. Copyright Chris Pasero, 2005. Used with permission.

Research Implications

The evidence base supporting the use of analgesics to manage acute pain is strong and clear—to date, analgesics, particularly opioids, are effective in controlling acute pain. Undertreatment of acute pain, however, remains prevalent despite the availability of analgesics and guidelines. Undertreatment is attributed to clinician behaviors—lack of adequate pain assessment and inadequate prescription and administration of analgesics—that are modifiable.

Thus, the research in this area needs to be directed toward effective strategies for changing clinician attitudes and behaviors that will result in better pain management for patients.

The evidence base for the use of nondrug therapies to manage acute pain requires further development; the current knowledge does not support achieving consistent outcomes from these therapies. Lack of standardization of nondrug therapies is one of the drawbacks of the current literature. Using standard relaxation or massage techniques with a determined duration (i.e., dose) and frequency (i.e., interval) would improve our ability to summarize the literature and determine the effectiveness of these therapies for pain control.

Conclusion

Education about safe pain management will help prevent undertreatment of pain and the resulting harmful effects. Safety includes the use of appropriate tools for assessing pain in cognitively intact adults and cognitively impaired adults. Otherwise pain may be unrecognized or underestimated. Use of analgesics, particularly opioids, is the foundation of treatment for most types of pain. Safe use of analgesics is promoted by utilizing a multimodal approach, that is, using more than one type of analgesic to treat the individual's pain. Opioid use is often avoided or inadequate for fear of causing life-threatening respiratory depression. Nurse monitoring of sedation levels when opioids are initiated is one way to assure safety. While nondrug techniques pose minimal safety issues, the current evidence does not support that these techniques produce consistent, predictable pain management outcomes.

Search Strategy

The terms "pain assessment" and "pain management" were used in the literature search. The research was limited to the English language, published in the last 10 years, meta-analyses, practice guidelines, literature reviews, clinical trials, and randomized clinical trials (RCTs). The literature for nondrug techniques was searched using the key terms "relaxation," "music," "massage," "heat and cold," and "pain." The nondrug literature was limited to the English language, meta-analysis, and literature reviews.

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Evidence Table for Pain Assessment and Pain Management

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Anderson 2006[43]	Relaxation	Randomized controlled trial	Pain intensity Quality of life, cancer specific Mood Symptom severity Symptom interference Self-efficacy	Cancer clinic N = 57 chronic cancer pain requiring opioids	Relaxation Distraction Positive mood delivered via audiotape at home 20 minute tape used 5x/week for 2 weeks Wait listed control	Significant pre-post reduction in pain intensity using relaxation and distraction. No difference in outcome when adherence to intervention examined. No difference for positive mood on any outcomes. In poststudy interview, patients reported immediate relief with use of relaxation or distraction tape, but pain returned immediately after use. Some mismatch between patient preference and type of technique randomly assigned. Pain reduction was short.
Cashman 2004[37]	Respiratory and hemodynamic adverse events related to opioid analgesia	Systematic literature review	Respiratory depression Hypotension	Published literature 165 papers > 20,000 patients	Analgesic techniques IM PCA Epidural	Respiratory depression defined differently across studies; incidence differed based upon definition. Incidence of respiratory depression as measured by low ventilatory frequency < 1 percent. Incidence of hypotension related to analgesia < 5 percent .

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cepeda 2007[50]	Music	Meta-analysis	Pain intensity Pain relief Opioid use	51 RCTs reviewed > 2,600 patients All types of pain	Music	Studies of postsurgical pain showed a 0.5 reduction in intensity with music (14 studies). Patient- versus provider-selected music showed no benefit in pain intensity. Patients exposed to music had 70 percent greater likelihood of reporting > 50 percent pain relief than those not exposed (4 studies). Patients exposed to music required 57 mg less of morphine in 1st 24 hours postsurgery than those not exposed (5 studies). No difference in medication side effects by use of music (4 studies). Clinical importance of benefit of music not clear.
Chandler 2002[64]	Heat/cold	Literature review		2 studies Acute pain		Limited evidence to support the use of heat for pain control in clinical settings.
Chang 2006[54]	Music	Randomized controlled trial	Pain intensity Heart rate (HR) Resp rate (RR) Blood pressure (B/P) Oxygen saturation (SpO2) Collected 15, 30, and 45 minutes after clamp applied	ICU in 2 acute care hospitals in Hong Kong N = 43 compression with C-clamp after percutaneous cardiac intervention	Patient selected music from 15 selections of soft, slow, nonlyric music Control: usual care	Significant difference in pain intensity after 45 minutes of compression. Patients exposed to music had significant reduction in pain. Patients in control group had significant increase in pain. HR, RR, and SpO2 significantly lower with music at 30 and 45 minutes compared to control. Systolic B/P, HR, and RR declined with music over time. Analysis controlled for multiple comparisons. Music has benefit during a painful procedure in ICU.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
De Jong 2006[45]	Relaxation	Systematic literature review	Pain intensity Pain distress	11 studies reviewed Postsurgical and procedural (burn care) pain	Rhythmic breathing Simple relaxation	Review sought to identify evidence for simple relaxation techniques (e.g., breathing) on pain during burn wound care. No research published with adults during acute phase. Most promising technique is rhythmic breathing with jaw relaxation.
Dolin 2002[3]	Efficacy of analgesic administration techniques	Systematic literature review	Pain intensity Pain relief	Published literature 165 papers > 20,000 patients	Analgesic techniques IM PCA Epidural	Incidence of: Moderate to severe pain: 29.7 percent Severe pain: 10.9 percent Poor pain relief: 3.9 percent Fair-to-poor pain relief: 19.4 percent Highest incidence with IM technique. Significant decline in severe pain over time (years of publication).
Dolin 2005[38]	Adverse (side) effects to opioid analgesics via 3 modes of administration	Systematic literature review	Nausea Vomiting Sedation Pruritis Urinary retention	Published literature 283 papers > 100,000 patients	Analgesic techniques IM PCA Epidural	Incidence of adverse effects to opioids across all 3 techniques: Nausea: 25 percent Vomiting: 21 percent Mild sedation: 23.9 percent Excessive sedation: 2.6 percent Pruritis: 14.7 percent Urinary retention: 23 percent
Field 1998[57]	Massage	Literature review	Multiple outcomes of a wide variety of diseases		Massage therapy	Consistent findings are that massage decreases anxiety, depression, cortisol, and catecholamines. Massage and vibration studies for many types of pain included; weak evidence that moderate vibration for 25–45 minutes over extended time may reduce pain. Methodological problems in design (nonexperimental and/or nonrandom assignment) and sample size noted.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
French 2007[63]	Heat/cold	Systematic literature review	Pain intensity Physical function Overall improvement Patient satisfaction Adverse effects	9 papers 1,117 patients Acute, subacute, and chronic low-back pain	Superficial heat/cold	Heat wrap produced a 17 percent reduction in pain after 5 days (2 studies). Disability reduced with heat wrap after 4 days (2 studies). Heat produced adverse effect (pinkness of skin) in 6/128 patients. Limited evidence that cold therapy has an effect on pain.
Good 2005[48]	Relaxation	Randomized controlled trial	Pain intensity Pain distress Opioid use Days 1 & 2 Secondary analysis of larger study included in lit review on music and relaxation	4 hospitals in United States N = 167 Intestinal surgery	Jaw relaxation Patient selected music (5 types) Combined relaxation + music Control: 15 minutes quiet rest	3 intervention groups reported significantly less pain than control group at rest and before and after recovery from ambulation (16–40 percent less). No difference among interneuron groups for pain intensity immediately after ambulation. Relaxation or music are effective in reducing acute pain; the combination did not improve effect.
Hattan 2002[60]	Massage	Randomized controlled trial	Psychological well-being (e.g., pain, anxiety, calm) Heart rate (HR) Resp rate (RR) Blood pressure (B/P)	Teaching hospital in United Kingdom N = 25 post-CABG patients	20 minute foot massage 20 minute guided relaxation Delivered on day 2 postsurgery Control: usual care	No difference in physiologic measures pre-post treatment. Significant difference in pre-post change in perception of calm; massage significantly higher than control; no significant difference between relaxation and control. No difference in change scores for pain, anxiety, relaxation, or rest.
Hulme 1999[59]	Massage	Randomized controlled trial	Pain intensity Analgesic use Quality of care (satisfaction)	Day surgery unit in United Kingdom N = 59 women day surgery for sterilization	5 minute foot massage postsurgery Control: usual care	Significant decrease in pain during the early postsurgical period (both groups). No difference in pain intensity reported by group. Pattern over time showed patients who received massage reported less pain than controls. No difference in analgesic use over the early and postdischarge periods.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hutchison 2007[4]	IV PCA analgesia	Literature review		Published literature	None	MEDMARX data on IV PCA errors identified most common errors and reasons for those errors. Recommendations from report outlined for prescription, administration, and modification of PCA analgesia.
Kwekkeboom 2006[46]	Relaxation	Systematic literature review	Pain intensity Pain distress Pain relief	15 RCTs published 1996–2005 Acute and chronic noncancer pain	Relaxation, 5 types PMR Autogenic Systematic Jaw relaxation Rhythmic breathing	8/15 studies had positive results for pain intensity. 8/13 had positive results for pain relief. Pain relief improved significantly only when relaxation used multiple times; single-use studies showed no difference. Relaxation reduced distress (4/5 studies). Insufficient evidence to support broad application of relaxation for pain control.
McRee 2003[61]	Massage	Randomized controlled trial	Anxiety Heart rate (HR) Blood pressure (B/P) Cortisol Prolactin Analgesic use	Hospital in United States N = 52 surgical patients	Swedish massage Music (1 selection) Massage + music 30 minutes for each group delivered presurgery Control: usual care	No difference among groups for pre- or post anxiety, prolactin, cortisol, physiologic variables, or analgesic use. Significant decline in anxiety, prolactin pre-post surgery for all groups. None of the interventions demonstrated a beneficial effect on outcomes in early period after surgery.
Pellino 2005[42]	Nondrug tool kits	Randomized controlled trial	Pain intensity Interference Anxiety Control over pain Opioid use	Hospital in United States N = 65 Elective orthopedic patients (total hip or knee)	Tool kit included Tape player Soothing music Relaxation tape 9 PMR) Massager (hand held, nonelectric) Stress ball Control: usual care	Patients receiving tool kits used more nondrug therapies postsurgically; control patients also reported using some nondrug techniques spontaneously. No difference between groups on pain intensity, interference, control, or anxiety. Patients with tool kits used significantly less opioid on day 2 but not day 1.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Richards 2000[58]	Massage	Systematic literature review	Relaxation Comfort Sleep	22 studies Published 1980–1999	Massage	Consistent finding that massage decreased anxiety and/or tension (8/10 studies). Massage produced physiologic relaxation (7/10 studies). Massage has immediate benefit on pain (3/3 studies; cancer pain). Inconclusive findings of effect of massage on sleep related to methodological problems.
Roykulcharoen 2004[47]	Relaxation	Randomized controlled trial	Pain intensity Pain distress Anxiety Opioid use	Hospital in Thailand N = 102 adults; abdominal surgery	Systematic relaxation for 15 minutes after 1st ambulation via audiotape Control: 15 minutes quiet rest	Relaxation significantly reduced pain intensity and distress pre-post intervention. No difference in anxiety or opioid use.
Kshettry 2006[67]	Nondrug tool kits	Randomized controlled trial	Pain intensity Tension Heart rate (HR) Blood pressure (B/P) Complications	Hospital in United States N = 104 CV surgery in ICU	Combination of preop Guided imagery relaxation + gentle touch or light massage and postop music + gentle touch or light massage Control: usual care	Pain intensity and tension significantly lower for tool kit patients on days 1 & 2 postsurgery. No differences noted in physiologic variables between groups. No difference in complication rates. These nondrug techniques are safe and easy to use in an critical care area.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Seers 1998[44]	Relaxation	Systematic literature review	Pain intensity Pain distress Anxiety Analgesic consumption	7 RCTs 352 patients, 150 received relaxation training 33 studies did not meet inclusion criteria Surgical and procedural pain	Relaxation	3/7 studies showed significant reduction in intensity and/or distress. 4/7 showed no significant difference. No adverse effects reported. Weak support for relaxation for acute pain control.
Sendelbach 2006[53]	Music	Randomized controlled trial	Pain intensity Anxiety Heart rate (HR) Blood pressure (B/P) Opioid use	3 hospitals in United States N = 86 undergoing CV surgery	20 minutes of music twice/day for 3 days postsurgery Patient selected 1/3 choices Control: 20 minutes of rest twice/day	Significant reduction in pain intensity and anxiety pre-post treatment for patients exposed to music. No difference in physiologic variables between groups. No difference in opioid use between groups. Because of missing data, results reported for PO day 1 AM and PM and PO day 2 AM only.
Smith 2002[66]	Heat/cold	Randomized controlled trial	Pain Swelling Flexion Opioid use Blood loss Transfusion Length of stay	N = 84 Total knee replacement	Cold therapy via cryo-pad technology vs Compression bandage applied by surgeon	No difference in outcomes related to type of treatment. Cost analysis indicated compression bandage less costly and more efficient in terms of nursing time.
Taylor 2003[62]	Massage	Randomized controlled trial	Pain intensity Pain affect Anxiety Distress Analgesic use Systolic B/P Cortisol (24 hr urine) Complications Length of stay (LOS)	Teaching hospital in the United States N = 105 abdominal surgery for suspected gynecological cancer	45 minutes Swedish massage for 3 days postsurgery 20 minutes vibration for 3 days+ PRN postsurgery Control: usual care	Multivariate analysis revealed no differences among groups on intensity, pain affect, anxiety, or distress. No differences found for secondary outcomes (analgesic use, cortisol, B/P, complications, LOS). Some benefit for massage and vibration over usual care were found with univariate analyses, but differences were small and may not be clinically important.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Voss 2004[52]	Music	Randomized controlled trial	Pain intensity Pain distress Anxiety	Hospital in United States N = 61 CV surgery patients	Patient selected music (6 types) Scheduled rest Control: usual care 30 minutes during chair rest	Significant reductions in pain intensity, distress, and anxiety pre-post chair rest for music and rest groups. Post hoc test indicated patients exposed to music reported significantly less pain intensity, distress, and anxiety than the rest or control patients. Music reduced outcomes from 57–72 percent after 30 minutes of chair rest compared to controls.
Wong 2004[56]	Massage	Pretest, post-test	Pain intensity Distress Heart rate (HR) Resp rate (RR) Blood pressure (B/P)	Teaching hospital in United States Postsurgical patients	20 minute foot and hand massage No control	Significant decrease in pain intensity and distress pre-post massage. Significant decrease in HR and RR; differences small and not clinically important. No difference in B/P pre- to postmassage.

Chapter 18. Medication Management of the Community-Dwelling Older Adult

Karen Dorman Marek, Lisa Antle

Background

For many older adults, the ability to remain independent in one's home depends on the ability to manage a complicated medication regimen. Nonadherence to medication regimens is a major cause of nursing home placement of frail older adults.[1] In the United States, an estimated 3 million older adults are admitted to nursing homes due to drug-related problems at an estimated annual cost of more than $14 billion.[2] Older adults are the largest users of prescription medication, yet with advancing age they are more vulnerable to adverse reactions to the medications they are taking. Approximately 30 percent of hospital admissions of older adults are drug related, with more than 11 percent attributed to medication nonadherence and 10–17 percent related to adverse drug reactions (ADRs).[3–5] Older adults discharged from the hospital on more than five drugs are more likely to visit the emergency department (ED) and be rehospitalized during the first 6 months after discharge.[6] Nursing interventions that assist older adults in managing their medications can help prevent unnecessary, costly nursing home admissions, hospitalizations, and ED visits, as well as improve their quality of life.

The purpose of this review was to identify evidence-based interventions related to medication management and the community-dwelling older adult. The focus of this review was interventions that fall within the scope of practice of the registered nurse. The guidelines do not address the specific intervention of medication prescribing. However, the interventions are applicable to professional nurse providers whether they are prescribing or not. This chapter discusses risk factors for problems in medication management followed by evidence-based interventions in areas of medication reconciliation, medication procurement, medication knowledge, physical ability, cognitive capacity, intentional nonadherence, and ongoing monitoring.

Risk Factors

There is a wide variety of factors that place the community-dwelling older adult at risk for problems in medication management. The young-old (ages 66–74) have been found to be more adherent to medication regimens than middle-aged older adults, but after age 75, older adults present decreased comprehension of medication instructions and adherence.[7–15] Living arrangements influence the older person's ability to manage medications, and older adults who live alone were found to be more prone to medication errors.[16–21] It is postulated that this is related to the fact that there is no one to monitor, assist, or remind the older person about taking their medications. Persons with chronic disease, especially depression, have a higher incidence of nonadherence to their medication regimen.[7, 10, 22–30] Many of the risk factors related to inadequate medication management are items that are more prevalent in older adults living in the community. Other factors that will be discussed in more detail later in the chapter are physical impairments such as poor vision, grip strength, and cognitive decline.

Older adults are more prone to adverse events due to the clinical complexity of their care rather than age-based discrimination.[31] A study of older adult outpatients who took five or more medications found that 35 percent experienced adverse drug events.[32] In addition, individuals with complex regimens had difficulty naming and explaining the purposes of medications and appeared to be at high risk for nonadherence.[33] The greater the medication complexity, the less likely the older adult is to adhere to the medication regimen.[34] The larger the number of medications, the more likely the older adult will be nonadherent.[3, 9, 13, 19, 28, 35–46] It is not only the number of medications but also the number of doses per day and actions related to taking medications that contribute to complexity of a medication regimen.[34] In a study of medication compliance, the compliance rate was 87 percent for daily dosing, 81 percent for twice a day, 77 percent for three times a day, and 39 percent for four times a day.[47] In addition, a change in prescribed drug regimen has been found to be a predictor of medication nonadherence in older adults.[9] Finally, the number of prescribing providers adds to the complexity of managing one's medications, and persons with more than one prescribing provider were found to be prone to medication errors.[16, 19]

Research Evidence

Medication Reconciliation

Medication reconciliation is the first step in assisting older adults in the medication management process. Multiple studies have demonstrated discrepancies from 30 percent to 66 percent in what medications were ordered by the prescribing provider and the actual medications the older adult was taking.[16, 48–52] Prescribing providers were often unaware of prescribed medications their patients were taking,[16, 53–55] and the larger the number of prescribing providers, the greater the chance of medication discrepancies.[3, 42, 56, 57] A study of elderly patients 2 days after hospital discharge found 64 percent were taking at least one medication that was not ordered, 73 percent failed to use at least one medication according to instructions, and 32 percent were not taking all drugs ordered at discharge.[58] Another challenge in reconciliation of medications is determining exactly what medications older adults are taking in their home. One study found 49 percent of community-based older adults kept stores of old medications from the year before, and 6 percent admitted they self-prescribed medications on at least one occasion.[59] Over the counter (OTC) medication use also needs to be assessed, because estimates of older adults' use of OTC drugs range from 32 percent to 86 percent.[60–62] A recent study of older adults with hypertension attending a blood pressure clinic found 86 percent reported two or more self-medication practices using OTC drugs that could result in an adverse drug interaction.[63]

Multiple studies have demonstrated that 10–74 percent of medications prescribed for older adults were inappropriate.[48, 57, 64–74] A study of "brown bag" medication reviews, in which patients bring all of their medications with them (often in a brown paper bag) to a medical or pharmacy consultation, revealed that 12 percent of the patients had medication problems that could potentially result in hospital admission.[75] A review of ED visits of patients 65 years and older found 10.6 percent of the visits were related to an adverse drug event, and 31 percent had at least one potential adverse drug interaction in their medication regimen.

Pharmacy reviews have demonstrated a reduction in polypharmacy in older adults and decreased adverse drug events in older patients.[76–82] Beer's set of criteria for potentially inappropriate medication use in older adults is one example of criteria developed for pharmacy

screening.[83, 84] There are a variety of drug interaction programs that quickly identify adverse drug interactions.

Also, patients who were given a medication card with a list of current medications were more compliant with their medication regimen.[85] Use of a medication list that is shared with the patient's primary care physician decreased patient rehospitalizations in one study.[86]

Medication Procurement

Not filling or refilling prescriptions is a common cause for medication nonadherence in older adults.[87–91] In a study of elderly patients at 15 days posthospitalization, 27 percent had not filled their new prescriptions.[92] Patients who participated in programs that provided pharmacy delivery and refill reminders had fewer adverse drug events and higher compliance than those who did not.[78]

If the cost of medication is viewed as high, older adults are more likely to not adhere to their medication regimen and be hospitalized.[3, 11, 56] Lack of funds, especially at the end of the month, is one reason older adults delay filling prescriptions.[93] In addition, chronically ill older adults are more likely to experience financial burdens associated with covering out-of-pocket costs for their prescription medications, cut back on medications due to cost, and use less medicines monthly.[89, 93–98] A study of use of medications after an increase in the copayment found a reduction in use of up to 45 percent in nonsteroidal anti-inflammatory drugs and 23 percent in antidiabetic drugs.[99]

Older adults who have insurance to cover medications have greater adherence.[12, 14, 19, 100] In one study, both adherence to medications and clinical outcomes improved while the number of hospitalizations declined when cardiovascular drugs were provided to indigent patients who could not afford to buy them.[101]

Medication Knowledge

Studies of older adults' knowledge of medications have found more than 50 percent knew the names and purpose of their medications; however, less than 25 percent knew the consequences of drug omission or toxic side effects.[9, 16, 54, 102] For example, one study of elderly patients with congestive heart failure found that 30 days after a new medication was prescribed, only 64 percent of the patients could identify when they were supposed to take their medicine.[103] Also, older adults were found to have insufficient knowledge of inhaler technique and understanding how medications can improve their asthma.[104] Noncompliant patients on anticoagulant therapy were more likely to report they did not know why their medication was prescribed.[105] In a study of OTC medication use, few older adults knew precautions related to the OTC drugs they were taking.[61] One study of older adult medication knowledge found that older adults understood prescribed medications better than OTC drugs, especially nutritional supplements.[106]

Patient education is a key intervention to assist older adults with medication management. Patient knowledge of drugs is positively associated with adherence.[16, 21, 91, 105, 107–112] However, older adults require specific educational methods. Learning is more effective in older adults if information is explicit, organized in lists, and in logical order. Instructions that are compatible with the older adults' schema for taking medications are better remembered,[113] and well-organized prescription labels are more useful for older adults.[114] Pictures are not helpful unless the picture is clearly related to the content.[115–118] A combination of both oral and written formats was identified by older adults as most helpful.[119] Medication schedules or charts in combination with teaching or counseling enhances patient medication adherence.[85, 86, 120–124] Four weeks after

starting a new medication for a chronic illness, patients identified a substantial need for further information.[125] Studies have demonstrated that patient education and counseling over several home visits or with followup phone calls produces increased medication adherence in recipients.[126–141]

Physical Ability

Poor vision and low manual dexterity are associated with poor medication self-management.[9,21,39,142–144] The inability to read medication labels has been associated with nonadherence to long-term medications in the elderly.[43,145] One study found 28 percent of community-based older adults did not keep their medication bottles properly closed so that they could open them, and 47 percent admitted that labels on their medications were unclear and they could not read them due to poor eyesight, inability to read English, or small writing on the label.[59] Studies have demonstrated that from 31 percent to 64 percent of older adults living at home have difficulty opening medication containers, with childproof containers presenting the most difficulty.[9,144,146] In studies of persons with chronic obstructive pulmonary disease (COPD), 38 percent used their inhaled medications with poor technique,[89] and poor hand strength was associated with nonadherence in inhaler use.[147] In another study of COPD patients, more than 50 percent had difficulties with their inhalers.[112]

Medication-container modification is one area of intervention for older adults who have difficulty opening or reading containers. Use of nonchildproof containers is one option for older adults. However, blister packs or other variations of unit dose packaging have resulted in increased compliance.[148–150] In a recent study of older adults, 64 percent were unable to open childproof containers, and 10 percent were unable to use blister packs.[9] Also, different tablet formations that increase the ease of breaking tablets have been found to increase patients' abilities to comply with their medication regimen.[151] Finally, talking medication containers and large-print labels are modifications that can be useful for persons with visual impairment.

Cognitive Capacity

Poor cognition is associated with both over adherence and under adherence of a prescribed medication regimen.[9,14,18,28,37,38,142–144,152–155] A study of community-dwelling women found that 22 percent were unable to accurately perform a routine medication regimen; however, only 2 percent self-identified that they had difficulty with their medications.[156] Forgetting is a major reason medication doses are missed.[9,78,88,89,157–162] The most prominent type of medication noncompliance is dose omission, but overconsumption is a common mistake, especially in persons on a once-daily dose schedule.[163]

There are a number of interventions to assist older adults with remembering to take their medications. One simple method is the use of memory cues that prompt patients to take their medications.[148] Development of memory cues must be tailored to the patient's lifestyle.[90,164] Placing medication in a special place and use of a daily event such as meal time improve medication adherence.[91,106,165,166] A study that examined the most common ways older adults remembered to take their medications found the following methods to be beneficial: (1) placing containers in a particular location, (2) taking medications in association with meals/bedtime, (3) using a timed pill box, (4) reminders from another person, and (5) using written directions or a check-off list.[159]

Compliance aids such as pill box organizers have been found to increase medication adherence.[16,78] Medication schedules and calendars are helpful, especially in combination with education and use of a pill box.[38,40,78,120,150,167,168] In addition, electronic monitoring that provides feedback to the user increases adherence.[141,169–171] Older patients using a voice-reminder-message medication dispenser were significantly more compliant than those using a pill box or self-administering medications.[172,173] Patients using topical pilocarpine were significantly more compliant using an electronic medication alarm device.[174] Programs that use daily telephone reminder calls also have demonstrated increased medication compliance.[155,175] Several studies have demonstrated that dose simplification from two times a day to one time a day produces higher compliance and improved patient outcomes.[122,176–182]

Intentional Nonadherence

One study of chronically ill persons who were starting a new medication found that almost a third did not take their medication as prescribed, and half of the time it was deliberate.[125] Older adults' perceptions of the seriousness of their illness and vulnerability to complications were significantly related to medication adherence.[13,46,90,91,97,166,183] In fact, low self-efficacy and beliefs that others are responsible for one's health care are predictors of medication nonadherence.[21,89,105,159,184–194]

A major reason that older adults skip doses or stop taking their medications is related to medication side effects.[9,11,16,26,38,46,89,91,93,110,125,159,161,162,191,195–198] In a comparison of compliant and noncompliant patients in fluvastatin treatment, the noncompliant patients were more likely to experience side effects of the medication.[199] Six months after discharge for acute coronary syndrome, 8 percent of those taking aspirin,12 percent of those taking beta-blockers, 20 percent of those taking ACE inhibitors, and 13 percent of those taking statins had discontinued taking their medications.[200]

Use of commitment-based interventions has been found to increase self-efficacy and medication compliance.[201] Education that addresses patient involvement with decisionmaking, such as focusing on appropriate versus inappropriate use of medication, can improve self-efficacy.[202] Patients with depression who participated in a program to enhance self-management and prevent relapse had significantly greater long-term adherence to their medication regimen.[203] Patients whose provider had an open, collaborative communication style also were more adherent to their medication regimen.[204]

Ongoing Monitoring

Older adults have narrow therapeutic windows and require close monitoring, especially when on multiple medications.[205] Ongoing monitoring of the older adult's medication management is critical. A study of home care patients found 16 percent had skipped a medication in the last 24 hours, 6 percent were taking the wrong dose, and 5 percent were experiencing adverse effects from their medication.[87] In one study, symptomatic hypotension was identified in 13 percent of community-based elderly.[67] In another study, older adults treated for urinary tract infections and sleeping disorders experienced a significantly higher risk of ADRs.[206] A review of ED visits of patients 65 years and older found 10.6 percent of the visits were related to an adverse drug event, and 31 percent had at least one potential adverse drug interaction in their medication regimen.[207] Pharmacist management of repeat prescriptions found 12.4 percent of patients had compliance

problems, side effects, ADRs, or drug interactions.[208] A total of 35 percent of elderly ambulatory patients reported at least one adverse event within the previous year.[209]

Monitoring medication adherence is an ongoing process. The longer people are on a medication, the more likely they are to have difficulty following the medication regimen.[179, 210] For example, in one study, only 31 percent of people with type 2 diabetes who were on oral hypoglycemics adhered to their medication regimen.[211] In another study, persons on oral hypoglycemic medications were nonadherent an average of 64.7 days in one year.[212] Since adherence to medication regimen for type 2 diabetes is strongly associated with metabolic control, interventions related to monitoring and improving adherence are critical.[213]

Patients taking Digoxin who are not adherent have an increased number and duration of hospitalizations and twice the mortality rate than those who are adherent.[214] Also, in a study of long-term compliance of antihypertensive drugs, patients on ACE-inhibitors, beta-blockers, calcium channel blockers, and diuretics were more likely to be noncompliant,[215] as were persons using bronchodilators and benzodiazepines.[60]

Practice-Implications: Medication Management Practice Guidelines

Medication Reconciliation

1. Review with patient all prescribed and nonprescribed medications the patient is taking. Include over-the-counter (OTC) medications, herbs, and vitamins.[216]
2. Screen for adverse drug interactions. If adverse drug interactions are identified, report to the prescribing provider any medications of concern.[76–82,84,216]
3. Identify the primary or secondary medical diagnosis related to each prescribed medication. If the medical diagnosis is unknown, request the diagnosis from the prescribing provider.[84,216]
4. For patients age 65 and older, apply Beer's criteria for inappropriate medication for the elderly. If any medications appear in Beer's criteria, report to the prescribing provider any medications of concern.[84]
5. Provide to the prescribing provider(s) a list of all medications (prescribed and OTC) the patient is taking and a list of corresponding medical diagnoses.[216]
6. Verify prescribed medications and related medical diagnoses with the prescribing provider(s).[84]
7. Provide the patient or caregiver a current list of all medications the patient is taking with dose and frequency; have the patient share this list with the prescribing provider or other health care providers as needed.[85,86,216]

Medication Procurement

1. Assess the patient's or caregiver's ability to procure medications.[87–92]
    a. Identify how and where the patient obtains and refills prescriptions.[87–92]
    b. Assess how the patient pays for medications.[3,11,56]
    c. Assess if medications doses are ever missed due to lack of funds.[93]
2. If the patient or caregiver has difficulty obtaining or refilling prescriptions, assist the patient with creating a system to procure medications via

   a. Pharmacy delivery.[78]
   b. Refill reminders or automatic refill service.[78]
   c. Scheduling family or friends to pick up medications.
3. If funds to purchase medication are a problem,[89,93–98]
   a. Refer the patient to a social worker to obtain Medicare Part D coverage, other insurance coverage, or participation in drug company programs.[12,14,19,99,100]
   b. Consult with the pharmacist regarding use of generic drugs.
   c. Consult the prescribing physician about availability of drug samples.[101]

Medication Knowledge

1. Assess the patient's or caregiver's knowledge of
   a. Dose and frequency of medications taken.[9,16,33,54,102,103]
   b. Special instructions related to medications, such as "take with food."[33]
      i. If the patient uses an inhaler, understanding of the correct inhaler technique.[104]
   c. Medication mode of action.[9,16,54,102]
   d. Side effects to monitor and report.[9,16,54,102]
2. With each change in medication regimen (including OTC drugs), review medication purpose, dosage, frequency, side effects to monitor and report, and other medication-specific instructions.[61]
3. Interventions related to medication knowledge include[16,21,91,105,107–112]
   a. Provide written instructions related to medications in large letters and bullet or list format.[115–119]
   b. Tailor instructions to how the patient takes his or her medicine.[113]
   c. Group information starting with generalized information, followed by how to take the medicine, and then the outcomes such as side effects to watch for and when to call the doctor.[114–118]
   d. Use medication schedules or charts to reinforce instructions.[85,86,120–124]
   e. If the patient did not know important medication information at a previous encounter, review dose, time, side effects to monitor and report, and special instructions at the next visit.[125–141]

Physical Ability

1. Assess for decreased manual dexterity or vision impairment and its affect on the patient's ability to identify the correct medication, open medication containers, and prepare medications (e.g., breaking tablets) for administration.[9,21,39,43,142–145]
   a. Observe the patient opening medication containers.[9,59,144,146]
   b. If the patient uses an inhaler, observe the use of the inhaler.[89,112,147]
   c. If the patient is required to break tablets, assess his or her ability to do so.[151]
   d. If the patient is unable to open or see the label and contents of each medication container, provide one of the following:
      i. Pill box or other easy-open container.[150,172,217] If the patient is unable to fill the pill box, identify someone who can assist him or her.
      ii. Medication calendar with pill box.[155,167,168,218]
      iii. Blister packs.[138,149] Consult the pharmacy about the availability of the drug in blister packs or nonchildproof containers.

iv. If tablet breaking is required and the patient has difficulty doing it, consult with the pharmacist about tablets that are easier to break or tablets that are the correct dosage without requiring breaking.[151]

Cognitive Capacity

1. Assess the patient's or caregiver's cognitive capacity to organize and remember to administer medication.[106, 156]
    a. Assess when doses are taken.
    b. Assess what cues the patient uses to remember to take medication.
    c. Assess what dose is most difficult to remember.[9,78,88,89,157–162]
    d. Assess how often a dose is missed or an extra dose is taken.[9,14,18,28,37,38,142–144,152–155]
2. Teach the patient or caregiver the use of memory cues based on one of the following methods:[148,159]
    a. Clock time. Ask if the patient or caregiver is usually aware of the time of day or keeps track of time through a watch or clock.
    b. Meal time.[90,91,106,164–166] Ask if the patient eats meals at a regular time.
    c. Daily ritual, such as using the bathroom in the morning, shaving, or hair combing.[90,91,106,164–166]
3. If the patient requires additional support,
    a. Provide memory-enhancing methods or devices such as
        i. Medication calendar or chart.[38,40,78,120,150,167,168]
        ii. Electronic reminder or alarm.[141,169–171,174]
        iii. Voice-message reminder.[172,173]
        iv. Telephone reminder.[155,175]
        v. Pill box.[16,78] (If the patient is unable to fill a pill box, identify someone who is willing to assist him or her.[158])
        vi. Electronic medication dispensing device.[173]
        vii. Combine methods and devices when possible.[38,40,78,120,150,167,168]
    b. Discuss dose simplification with the prescribing provider.[122,176–182]

Intentional Nonadherence

1. Assess if medication doses are missed intentionally.[125]
    a. Drugs at high risk for intentional noncompliance include the following:
        i. ACE-inhibitors[200,215]
        ii. Beta-blockers[200,215]
        iii. Calcium channel blockers[200,215]
        iv. Diuretics[215]
        v. Bronchodilators[60]
        vi. Benzodiazepines[60]
    b. If the patient intentionally misses doses, assess the reason(s).
        i. Belief medication is not helping.[13,46,90,91,97,166,183]
        ii. Fear of adverse side effects.[13,46,90,91,97,166,183]
        iii. Side effects.[9,11,16,26,38,46,89,91,93,110,125,159,161,162,191,195–198]

   c. The following medications are most risky for patients to miss:
      i. Coumadin[105]
      ii. Digoxin[214]
      iii. Beta-blockers[200]
      iv. Insulin
      v. Prandinm® (repaglinide)
      vi. Antibiotics
      vii. ACE-inhibitors[200]
2. If the patient misses medication doses for reasons related to health beliefs,
   a. Explore with the patient his or her health concerns for not taking medication.[202]
   b. Discuss the benefits of taking medication as prescribed.[202]
   c. Provide positive reinforcement for taking medication as prescribed.[201]
3. For patients on high-risk medications, reinforce the danger of missing medication doses.[105]
4. If the patient misses medication doses for reasons related to medication side effects,
   a. Explore with the patient a plan to manage the side effects.[203]
   b. Modify the regimen to reduce the side effects.

Ongoing Monitoring

1. For all patients on a prescribed medication regimen, monitor the patient with each encounter for the following:
   a. Medication adherence
      i. Monitor both under- and overadherence.[87,179] Overconsumption occurs frequently in a once-daily dose schedule.
      ii. For persons using inhalers, assess
         1. Inhaler emptying rate.[89,104,147]
         2. Reported forgetfulness.[104]
         3. Use of short-acting inhaler.[89,104]
   b. Medication side effects[67,205]
      i. If medication side effects present, notify the prescribing provider, as appropriate.
   c. Lab work, as appropriate, for prescribed medications[216]
      i. Cockcroft-Gault Formula or other creatinine clearance measure at least annually. If creatinine clearance <50 ml/min, notify the prescribing provider.
   d. Medication effectiveness[205]
      i. If signs and symptoms of the problem the medication is treating are present, notify the prescribing provider, as appropriate.

Research Implications

There is a large volume of research related to medication management and the elderly. Medication management is a complex process that must be interdisciplinary in its approach. Many of the evidence-based interventions discussed are not discipline specific. A team of providers is needed to provide safe and therapeutic medication management.

There is a large amount of research related to risk factors for medication nonadherence. However, there is less evidence related to appropriate interventions to enhance adherence and medication self-management. In addition, the most effective programs have multiple interventions, so identifying the specific evidence for each intervention component is difficult. For example, one study included a combination of interventions of medication review, modification of containers, medication education, and a drug reminder chart.[138] All are important components of a medication program for older adults, yet it is difficult to identify the evidence supporting each component. What is promising is the use of technology to assist in medication management.[173,219] This includes clinical screening software for adverse drug interaction and potentially inappropriate prescribed medications, electronic adherence monitoring, and electronic medication reminders. Much of this new technology is currently being tested.

Conclusion

Medication management is a complex process that consists of multiple activities. Factors associated with problems in the performance of these activities include living alone, impaired vision, impaired cognitive function, ages 75 and older, having three or more medications and/or scheduled doses in one day, and more than one prescribing provider. Medication reconciliation is a key first step in medication management. Multiple studies have demonstrated large discrepancies in what medications are ordered by the prescribing provider and the actual medications the older adult is taking. Evidence supports medication reconciliation interventions that include a screen for inappropriate medications and adverse drug interactions, in addition to verification of medications that are prescribed. Other areas of medication management include assessment and interventions related to medication procurement, medication knowledge, physical ability, cognitive capacity, and intentional nonadherence. Ongoing monitoring of these areas is crucial.

Nurses play a pivotal role in the medication management process of older adults. Considering the expense of prescription drugs in the current health care system, a small investment in providing comprehensive assessment and interventions to assist older adults in accurate and safe management of their medications will provide cost-effective care and increase the quality of life of older adults struggling to manage their often-complex medication regimens.

Search Strategy

To conduct this review, a search was done in August 2005 of PubMed®, the Cumulative Index to Nursing & Allied Health Literature, Cochrane Database of Systematic Reviews, HealthStar, ISI Web of Science, Social Service Abstracts, Database of Abstracts of Reviews of Effectiveness, and Internet searches for citations occurring from January 1990 to August 2005. Key search terms used alone and in combination included medication adherence, compliance, elderly; aged; outcomes; polypharmacy; medication management; chronic illness; chronic disease; and individual types of chronic illnesses. All searches were limited to patients ages 65 and older and Web sites in the English language. The ISI Web of Science was used to track citations to major works, and article references were reviewed for inclusion. Bibliographies of retrieved articles also were searched for relevant articles not identified in the reference database searches.

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Evidence Table. Medication Management of the Community-Dwelling Older Adult (Includes studies design level 4 and above)

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Allard 2001[220]	Inappropriate prescribed medication	Randomized Controlled Trial (RCT)	1. RCT (Level 2) 2. Error over time (Level 2)	1. Community-dwelling older adults, age > 70 years and taking > 3 drugs 2. Treatment (*n* = 136) • Subgroup received case conference w/ intervention (*n* = 80) 3. Control (*n* = 130)	Medication review by nurse, pharmacist, and physician with monthly nurse followup. Potentially inappropriate prescriptions (PIPs) reported to prescribing physician.	Mean PIPs decreased in treatment group, but not significant.
Andrejak 2000[176]	Medication adherence	RCT	1. RCT (Level 2) 2. Clinical outcome (Level 1)	1. Multicenter: 6 month study, persons 18 and older with essential HTN (diastolic BP,95-115) 2. Mean age 57 3. Two treatment groups: • Twice-daily dosing (*n* = 62) • Once-daily dosing (*n* = 84)	Dose simplification: once a day, group one; twice a day, group two.	Evidence suggests that daily dosing enhances daily compliance, missing fewer doses, and taking medications on time as scheduled by the patient's provider ($P < 0.01$).
Bond 2000[208]	Medication adherence	RCT	1. RCT (Level 2) 2. Adverse events (Level 1)	1. Outpatient general medical clinics (19) 2. Community pharmacies (*n* =62) 3. Two groups: • Treatment (*n* = 904) • Control (*n* = 1,397)	Pharmacists monitored for • compliance • adverse reactions • symptoms • medication problems	The intervention group had more compliance problems identified ($P = 0.001$), while the control group had more items prescribed ($P = 0.003$) and resultant higher prescription costs.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Bonner 2002[53]	Medication compliance	Non-compar-ative study	1. Observational study without controls (Level 5) 2. Surrogate outcome: observed errors (Level 2)	1. Rural general practice older adults (50) 2. Selection: • Random presentation at surgery • > 4 meds • Significant medical history	1. Clinical pharmacist medication screening 2. Physician verification and correction of errors transcribed to a portable medication summary card	40% of subjects noncompliant, 8% of clinical pharmacist's medication issues required a change in therapy, and 18% reported medical information to the clinical pharmacist that the physician was unaware. The use of a medication card summary implemented via clinical pharmacist and physician intervention was ineffective in improving older adult medication compliance.
Bouvy 2003[131]	Medication compliance	RCT	1. RCT (Level 2) 2. Error over time (Level 2)	Heart failure patients treated with loop diuretics in an outpatient heart failure clinic or admitted to participating hospitals • Treatment (*n* = 74) • Usual Care (*n* = 78)	Pharmacist led monthly medication education for 6 months	Medication education decreased the number of missed doses (relative risk 0.33 [CI 95% 0.24–0.38]) and consecutive missed doses (relative risk 0.32 [CI 95% 0.19–0.55]). No significant difference in rehospitalization rate, mortality, and quality of life (QOL).
Cargill 1992[126]	Medication compliance	RCT	1. RCT (Level 2) 2. Error over time (Level 2)	1. Age 60and older 2. Three groups (total *n* = 70) • Control • Education • Education & followup phone call	1. Home visits: medication education, followup phone call 2 weeks s/p medication education 2. Compliance measured via pill count	Followup phone calls & education improved compliance (*P* = 0.0097). Compliance decreased as prescribed medications increased (*P* = 0.0097). Compliance was higher with home visit nurse led medication education with supportive followup.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Coleman 2004[49]	Care transition	Prospective cohort study	1. Non-RCT (Level 3) 2. Adverse events (Level 1)	1. Age 65 and older posthospitalization 2. Two groups: • Treatment (*n* = 158) • Control (*n* = 1,235) from administrative data	1. Medication self-management 2. Patient-centered record 3. Primary care and specialist followup 4. Education of warning signs and symptoms of worsening condition.	Odds ratios comparing rehospitalization 30 days: 0.52 (95% CI = 0.25–0.96), 90 days: 0.43 (95% CI = 0.25–0.72), and 180 days: 0.57 (95% CI = 0.36–0.92). Median time to first rehospitalization decreased (*P* = 0.003). Care transition was effective in decreasing hospital admissions. Intervention patients reported high levels of confidence in care management.
Day 1998[221]	Medication knowledge and compliance	RCT	1. RCT (Level 2) 2. Pretest/post-test (Level 3)	1. Rehabilitation Hospital patients 2. Mean age = 64.8 3. Two groups: • Self-administered medication during hospitalization (*n* = 24) • Nurse-administered medication (*n*=15)	1. Self-administration of medications while hospitalized. 2. Education	No significant differences found between groups. Small sample size.
Detry 1995[181]	Medication compliance	Non-RCT	1. Non-RCT (Level 2) 2. Observed errors (Level 3)	1. Persons treated with slow release nifedipine or amlodipine 2. for at least 4 weeks prior to study inclusion. 3. Mean age = 60 4. Two groups: • crossover at 6 weeks • once a day (*n* = 160) • twice daily (*n* = 160)	Dose simplification: once daily amlodipine versus twice daily slow release nifedipine for 4 weeks	Compliance with once-a-day dosing was higher than twice-daily dosing (*P* < 0.001). No significant difference in BP was identified.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Dezii 2001[177]	Dosing medication compliance	Retrospective cohort study	1. Retrospective cohort comparison (Level 4) 2. Medication errors related over time (Level 2)	1. HTN patients new to therapy 2. Two groups: • Single pill group (n = 969) • Two pill combination group (n = 624)	Dose simplification	Dose simplification to single-pill dosing vs. two-pills dosing significantly increased the persistence with prescribed therapy ($P < 0.05$).
Eisen 1990[182]	Medication compliance	RCT	1. RCT (Level 2) 2. Observed errors over time (Level2)	1. VA medical center clinic HTN patients 2. Three groups: • Once-daily dose (n = 45) • Twice-daily (n = 40) • Three times daily (n = 20)	1. Dose simplification 2. Measurement by electronic blister pack that recorded medication removal.	Once-a-day dosing adherence rate was higher than 3-times-a-day dosing ($P < 0.05$). Compliance increased as number of daily doses decreased.
Esposito 1995[167]	Medication adherence	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Age 65 and older at hospital discharge 2. Four groups: • Group I – standard education (n = 11) • Group II – standard education and 30 minute verbal instructions (n = 8) • Group III – standard education and medication schedule (n = 10) • Group IV – standard education, medication schedule, and 30 minute verbal instructions (n = 14)	Medication schedule with verbal reinforcement.	Higher compliance rates were found in subjects who used medication schedule. Pilot, small study.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Fillet 1999[76]	Polypharmacy	Noncom-parative study	1. Observational study without controls (Level 5) 2. Measurable outcomes with unestablished connection to outcome (Level 3)	1. Medicare managed care organization patients 65 and older on 5 or more medications, over 3 month period. 2. 5,737 identified as high risk and surveyed, with 2,615 responding (response rate = 46%). 3. 275 primary care physicians surveyed, with 56 (20%) responding.	1. Identification of patients at risk for polypharmacy. 2. Empowerment letters sent to patients with brown bag to encourage a primary care provider (PCP) appointment for medication review. 3. All PCPs provided with practice guidelines regarding polypharmacy and patient-specific medication management reports.	17% of patients informed their PCP about a new prescription or nonprescription medication they were taking. The review resulted in medication changes in 51% of the reviews. 29% reported a decrease in frequency of dosing, and 20% had a medication discontinued. 45% of the physicians reported at least one medication change.
Friedman 1996[132]	Medication Adherence	RCT	1. RCT (Level 2) 2. Clinical outcome (Level 1)	1. Persons age 60 and older under treatment for hypertension from community sites such as senior centers with BP>160/90 2. Two groups: • Treatment (n = 133) • Control (n = 134)	1. Automated telephone patient monitoring and counseling. 2. Weekly-treatment subjects reported self-measured BP, knowledge, and adherence to medications and side effects.	Medication adherence was higher (P = 0.03) and diastolic blood pressure lower (P = 0.02) in the treatment group.
Fulmer 1999[175]	Medication compliance	RCT	1. RCT 2. Observed errors (Level 2)	1. Community dwelling, age 65 and older with diagnosis of CHF 2. Three groups: • Control (n = 14) • Telephone (n = 13) • Videophone (n = 15)	1. Telephone group received daily telephone call reminders. 2. Videophone group received daily videophone call reminders.	Control group had lower compliance than the groups who received either videophone or telephone calls (P < 0.04).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Goodyer 1995[123]	Medication compliance	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Outpatient clinic patients 70 years and older with chronic stable heart failure 2. Two groups: • Treatment (*n* = 50) • Control (*n* = 50)	Three month pharmacist-led medication counseling with three home visits	Compliance and medication knowledge were higher in treatment group ($P < 0.001$). Both exercise and distance to breathlessness improved in the treatment group and worsened for controls ($P < 0.01$). No significant changes were noted in Nottingham Health profile.
Hawe & Higgins 1990[222]	Medication compliance	Non-RCT	1. Nonrandomized control trial (Level 3) 2. Errors over time (Level 2)	1. Inpatient persons age 55 and older 2. Two groups assigned by month of admission: • Treatment (*n* = 149) • Control: received dummy intervention (*n* = 119)	1. Group-based inpatient educational session followed by individual pharmacist predischarge instruction and individual medication record card. 2. Measurement: • Compliance by subject report • Interviews 1 month and 3 months postdischarge	No significant difference in compliance at 1 and 3 months; however, the program was effective in a subgroup of persons taking four or more drugs, with the treatment group compliance rate at 55% versus the control at 32% at 3 months.
Hanlon 1996[77]	Inappropriate medications	RCT	1. RCT 2. Adverse events (Level 1)	1. Patients 65 and older of a general medical VA clinic 2. Two groups: • Treatment (*n* = 105) • Control (*n* = 103)	1. Pharmacist met with patients during scheduled clinic visits evaluating drug regimens. 2. Recommendations made to prescribing physician.	Inappropriate prescribing lower in treatment group ($P = 0.0006$), fewer ADRs in intervention group ($P = 0.19$).
Hayes 1998[117]	Medication knowledge	RCT	1. RCT (Level 2) 2. Knowledge post-test (Level 3)	1. Patients discharged from three rural emergency departments, age 60 and older. 2. Two groups: • Treatment (*n* = 30) • Control (*n* = 30)	Geragogy-based medication instruction sheets	Utilization of Geragogy-based medication instruction sheets increased patient knowledge of medications ($P = 0.16$).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Huang 2004[135]	Medication education	Non-RCT	1. Nonrandomized control trial (Level 3) 2. Clinical outcomes (Level 1)	1. Patients of district health center, 65 and older, diagnosed with diabetes mellitus, living alone, with resting BP less than 160/100 mmHg. 2. Matched on age, sex, education, and history of diabetes. 3. Three groups: • Group 1 – home-based nursing (*n* = 15) • Education program (*n* = 15) • Control (*n* = 14)	1. Group 1 – daily nurse visits to supervise diet, exercise, medication, and self-monitoring blood sugar. 2. Group 2 – weekly nurse visits to supervise diet, exercise, medication, and self-monitoring blood sugar. Nursing weekly home visits vs. daily home visits.	Both intervention groups had reductions in blood sugar and HGA1c ($P < 0.001$), cholesterol, & LDL ($P < 0.05$). Subjects with daily nurse visits had greater weight loss ($P < 0.05$).
Kimberlin 1993[82]	Medication compliance and knowledge	Non-RCT	1. Nonrandomized trial (Level 3) 2. Adverse events (Level 1)	1. Subject criteria • Age 60 or older • Capable of self-care • Taking four or more medications or medications from a list of targeted drugs with narrow therapeutic ranges or likely to cause problems in the elderly. 2. Two subject groups: • Treatment (*n* = 410) • Control (*n* = 352) 3. Pharmacist assignment to treatment (n = 55) or control (n = 33).	Intervention pharmacists participated in home study and 1-day workshop on drug therapy for elderly patients.	Subjects of intervention pharmacists more likely to report pharmacists provided information and assessed for problems than were control subjects. No significant differences were found in compliance or hospitalizations. However, the addition of each medication in the drug regimen elevated the odds of a subject reporting a problem with med therapy by 1.115.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Krska 2001[81]	Medication review	RCT	1. Group RCT (Level 2) 2. Errors over time (Level 2)	1. Community-dwelling older adults • Age 65 or older • Four or more medications • At least two chronic conditions 2. Two groups: • Treatment (*n* = 168) • Control (*n* = 164)	Pharmacist medication review with pharmaceutical care plan with medication regime changes in collaboration with general practitioner.	All subjects reviewed had at least two PCIs, and a greater number were resolved at followup in the intervention group. No significant difference was found in quality of life or cost between groups.
Leirer 1991[155]	Medication adherence	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Community-dwelling older adult volunteers • Mean age 70.9 2. Excluded cognitively impaired, depressed, debilitating conditions, or taking two or more medications. 3. Two groups: • Treatment (*n* = 8) • Control (*n* = 8)	1. Both groups given medication schedule and portable bar code reader to record simulated medication taking for 1 week. 2. Treatment group received voice mail reminders.	Voice mail reminders enhanced medication adherence ($P = 0.03$), memory failure contributes to medication nonadherence ($P = 0.05$).
Lipton 1994[80]	Medication compliance and resource utilization	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Geriatric hospitalized patients on three or more medications at discharge. 2. Two groups: • Treatment (*n* = 350) • Control (*n* = 356)	Pharmacist-led drug consultation service at hospital discharge, 1 week, 2–4 weeks, 2 months, and 3 months postdischarge via phone (85%) or home visit. Followup phone calls.	Pharmacist consultation decreased medication complexity ($P < 0.001$), number of medications ($P < 0.001$), and average daily doses ($P = 0.02$) at 3 months. Medication compliance, missed doses, and knowledge were impacted the greatest at 3 months ($P < 0.001$). No significant difference in health care use or charges were identified.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Lourens 1994[85]	Medication compliance	RCT	1. RCT (2) 2. Errors over time (Level 2)	1. Outpatient clinic (mean age 72) 2. Two groups: • Counseling only (*n* = 49) • Counseling and medication card (*n* = 48)	1. Pharmacist counseling both groups. 2. Written medication card in treatment group.	Subjects with written medication card had both higher knowledge increased compliance (*P* < 0.001).
Lowe 1995[223]	Medication compliance	Prospective cohort study	1. Nonrandomized control trial (Level 2) 2. Errors over time (Level 2)	1. Hospitalized older adults (mean age 79) 2. Two groups: • Treatment (*n* = 42) • Control (*n* = 37)	1. Inpatient self-medication management program 2. Education	Both compliance (*P* = 0.02) and medication knowledge (*P* < 0.001) were higher in the self-medication management group.
Lowe 2000[138]	Medication compliance	RCT	1. RCT (Level 2) 2. Errors over time (Level2)	1. Community-dwelling older adults, > 65, taking three or more medications 2. Two groups: • Intervention (*n* = 73) • Control (*n* = 79)	Pharmacist-led Intervention that included • Medication review and verification with PCP • Modification of medication containers • Medication education • Drug reminder chart	Medication review, verification, education, and modification of containers increased medication compliance (*P* < 0.0001) and medication knowledge (*P* < 0.0005).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Malone 2001[224]	Optimizing medication therapy	RCT	1. RCT (Level 2) 2. Clinical outcome (Level 1)	1. Older adult ambulatory veterans (mean age = 66.8) who were high risk for drug-related problems. 2. High risk defined as having three or more of the following criteria: • 5 or more medications • 12 or more daily doses • 3 or more chronic conditions • 4 or more changes to drug regimen over past year • Taking less than 80% of prescribed medications • On medications that require monitoring 3. Two groups: • Treatment (n = 523) • Control (n = 531)	1. Intervention subjects received a minimum of three ambulatory clinical pharmacist in-person visits or phone calls. 2. Intervention protocol included • Physical assessment: • Compliance monitoring • Lab monitoring • Drug screening • Identifying untreated diseases • Referrals to primary care and specialist physicians	Clinical pharmacist-led intervention had no effect on HRQOL. Change in health status declined less in treatment (P < 0.004), but was not clinically meaningful. Intervention dose-response relationship for general health perceptions (P < 0.004), vitality (P < 0.006), and change of health over the past year (P < 0.007) was found.
McKenney 1992[171]	Medication compliance	RCT	1. RCT (Level 2) 2. Clinical outcome (Level 1)	1. Ambulatory patients from retirement community or primary care center 2. Age 50 or older 3. Treated for HTN for 12 months 4.Four groups	1. Group A (n = 17): control 2. Group B (n = 18): timepiece cap as stimulant strategy 3. Group C (n = 18): timepiece cap + pocket-size BP recorder 4. Group D (n = 17): timepiece cap + pocket-size BP recorder + BP cuff for self-monitoring	Timepiece cap used alone improved compliance significantly (P < 0.01) and lowered mean SBP/DBP lower (P < 0.01). The addition of blood pressure reporting card and home blood pressure monitoring increased compliance and reduced BP (P < 0.01).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Meredith 2002[79]	Inappropriate prescribing	RCT	1. RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Newly admitted Medicare home health care patients 2. Selection criteria • At least 4 weeks of skilled service • At least one medication problem • Age 65 and older 3. Two groups: • Treatment (*n* = 130) • Control (*n* = 129)	Medication improvement program • Screen for duplication, cardiovascular issues, use of psychotropics, and NSAIDs. • Medication use plan discussed directly with prescribing physician by home care nurse.	Intervention improved medication use in 12 patients per 100 (95% CI = 0.0–24.0, *P* = 0.051), by decreasing medication duplication in 47 patients per 100 (95% CI = 20–74, *P* = 0.003), and improvement of the use of cardiovascular drugs in 37 patients per 100 (95% CI = 9–66, *P* = 0.17). No significant changes in clinical outcomes of general health (SF-36, cognitive impairment (MMSE) and ADLs.
Murray 1993[150]	Medication compliance	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Persons 60 and older living in urban public housing for older adults on at least three medications 2. Three groups: • Group 1 (*n* = 12): conventional packaging, varied dosing • Group 2 (*n* = 10): conventional packaging and BID dosing • Group 3 (*n* = 9): unit-of-use packaging and BID dosing	Unit-of-dose packaging: single cup holding all meds to be taken at dosing time and BID dosing	Compliance in older adults was higher with dose simplification and unit-of-dose packaging (*P* = 0.017).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Naunton 2003[78]	Medication compliance	RCT	1. RCT (Level 2) 2. Adverse events (Level 1)	1. Community-dwelling older adults age 60 and older on four or more medications 2. Two groups: • Intervention (*n* = 57) • Control (*n* = 64)	1. Pharmacist home visit 5 days after hospital discharge included medication review, compliance encouragement, education, intervention when appropriate, with communication to community providers. 2. Followup at 90 days.	Intervention group had a median of three drug-related problems at 5-day visit and had declined to one problem at 90 days, compared to two problems for the control group ($P < 0.0001$). Intervention group unplanned rehospitaliztions were lower ($P < 0.0001$) and compliance higher ($P < 0.0001$).
Park 1992[168]	Medication adherence	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Community-dwelling older adults • Taking two or more medications • Age 60 or older 2. Four groups: • Control (*n* = 16) • Medication schedule chart (*n* = 15) • Medication organizer (*n* = 15) • Schedule and organizer (*n* = 15)	Use of medication schedule and organizer compliance devices	Omission errors were the lowest in the group that used both schedule and medication organizer. Adults ages 71 and older had a lower rate of adherence (85%) than adults ages 60–70 (94%).
Patton 1997[128]	Medication adherence	Pre- and post-test	1. Nonrandomized control study (Level 3) 2. Clinical outcomes (Level 1)	1. HMO clinic patients with SBP 145 or greater and DBP 85 or higher consistently for at least 6 months. 2. Total subjects = 107 3. Median age 69	1. Nurse interactive education with written information. 2. Followup phone calls at 1, 3, 6, and 12 months after initial education.	Medication education with telephone followup decreased SBP/DBP ($P < 0.01$). Older adults had a greater reduction in BP ($P = 0.01$).
Pereles 1996[225]	Medication compliance and knowledge	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Geriatric rehabilitation inpatients 2. Two groups: • Treatment (*n* = 51) • Control (*n* = 56)	Inpatient program that included three stages of increasing responsibility to independently self-medicate.	Treatment group at 1 month had fewer self-medication errors than control ($P < 0.001$). No difference between groups in knowledge, morale.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Perri 1995[170]	Medication compliance	Non-RCT	1. Non-RCT (Level 3) 2. Errors over time (Level 2)	1. Community-dwelling pharmacy customers taking a chronic medication with a new refill or prescription 2. Two groups: • Intervention (*n* = 88) • Control (*n* = 98)	Stimulant "counter cap" prescription vile that indicates when cap was last opened.	Subjects using the counter cap had improved medication compliance (*P* = 0.0366).
Piette 2000[129]	Medication adherence	RCT	1. RCT (Level 2) 2. Clinical outcomes (level 1)	1. Adults receiving diabetes treatment at a county health clinic 2. Mean age 56 3. Two groups: • Intervention (*n* = 124) • Control (*n* = 124)	1. Biweekly automated assessment and self-care education telephone calls 2. Nurse educator followup	Intervention group monitored glucose, feet, and weight more frequently and had fewer problems with medication adherence (*P* < 0.03). HbA_{1c} lower in intervention group (*P* = 0.01).
Raynor 1993[120]	Medication compliance	RCT	1. RCT 2. Errors over time (level 2)	1. Inpatient adults taking 2–6 medications 2. Four groups: • Nurse standard counseling • Nurse counseling and reminder chart • Pharmacist counseling • Pharmacist counseling and reminder chart	1. Counseling 2. Reminder chart or medication schedule	Groups that received reminder chart had higher medication compliance and medication knowledge than those that received counseling only (*P* < 0.01).
Rich 1996[127]	Medication adherence	RCT	1. RCT 2. Errors over time (level 2)	1. CHF patients at hospital discharge, age 70 or older 2. Two groups: • Intervention (*n* = 80) • Control (*n* = 80)	Comprehensive patient education, dietary and social service consultations, med review, and intensive postdischarge followup.	Intervention group medication adherence at 30 days posthospitalization higher than control group (*P* = 0.003).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Robbins 2004[141]	Medication adherence	Non- RCT	1. Non-RCT (Level 3) 2. Errors over time (Level 2)	Females age 65 and older with osteoporosis taking low-dose estrogen (*n* = 109)	Educational program • Monthly phone calls for 12 months. • Quarterly clinic visits. • Pill box for 6 months. • Minority women (*n* = 44) used an electronic monitoring bottle for an additional 6 months.	Adherence improved with the electronic monitoring bottle at 12 months ($P < 0.05$) in the minority women.
Rudd 2004[140]	Medication compliance	RCT	1. RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Adults treated for hypertension in an outpatient clinic 2. Mean age = 60 3. Two groups: • Treatment (*n* = 74) • Control (*n* = 74)	1. Nursing case management with patient instruction on use of blood pressure equipment and self-monitoring. 2. Followup nurse calls at 1 week, 2 and 4 months. 3. Hypertension management program with standardized algorithms to modulate drug therapy based on subject's reported home blood pressure.	Intervention group had lower BP and higher adherence ($P < 0.05$).
Smith 1997[136]	Medication compliance	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Adults age 65 and older at discharge from the hospital 2. Two groups: • Treatment (*n* = 28) • Control (*n* = 25)	1. Pharmacist inpatient discharge education related to pharmaceutical plan of care 2. Telephone help line	Intervention group compliance higher 10 days postdischarge ($P < 0.01$).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Solomon 1998[226]	Medication compliance	RCT	1. RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Outpatient clinic patients with hypertension or COPD 2. Mean age 66 3. Treatment HTN (*n* = 63), COPD (n = 43) 4. Control HTN (*n* = 70), COPD (*n* = 55)	Standardized pharmaceutical care, including assessment and regularly scheduled therapeutic and educational interventions.	HTN intervention group had greater SBP decrease, higher compliance, and fewer hospitalizations than HTN control ($P < 0.05$). COPD treatment group had lower use of other providers at 4 weeks (when compared to the COPD control group).
Stewart 2003[137]	Medication adherence	RCT	1. RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Patients attending hypertension clinic, mean age = 57 2. Two groups: • Treatment (*n* =41) • Control (*n* =42)	1. Both groups participated in an educational program related to management of hypertension and cardiovascular risk modification. 2. Treatment group received six telephone calls to patient and six to family member over 34 weeks.	Group receiving telephone calls had greater weight loss ($P = 0.007$), knowledge related to hypertension ($P = 0.008$), adherence to medication regimen ($P = 0.05$).
Sturgess 2003[217]	Medication compliance	Group RCT	1. Group RCT (Level 2) 2. Errors over time (Level 2)	1. Community-dwelling older adults age 65 and older taking four or more medications and were regular visitors to participating pharmacies 2. Ten pharmacies randomized so that five were interventional and five were control. 3. Total of 191 subjects recruited: • Intervention (*n* =110) • Control (*n* = 81)	Intervention pharmacies received intensive training related to • Disease management education • Rationalized medications • Compliance strategies • Monitoring for 18 months	Compliance greater ($P < 0.05$) and fewer problems with medications ($P < 0.05$) in intervention group when compared to control. No difference between groups in health care costs, utilization, and quality of life was identified.

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Taylor 2003[122]	Medication review	RCT	1. RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Outpatient clinic patients with three or more of the following high-risk factors: • 5 or more medications • 12 or more doses per day • 4 or more medication changes in past year • 3 or more concurrent diseases • history of medication noncompliance 2. Two groups: • Treatment (*n* = 33) • Control (*n* = 36)	1. Pharmacist intervention that included • Medical record review • Medication history review • Pharmaceo-therapeutic evaluation • Patient education • Monitoring 2. Length of treatment 1 year	Ratings for inappropriate prescribing improved in the intervention group while decreasing in the control group. In the intervention group, knowledge scores were higher (*P* = 0.000), number of prescribed medications decreased (*P* = 0.002), patient satisfaction was higher (*P* = 0.000), number of hospitalizations (*P* = 0.003) and ED visits (*P* = 0.044) were both lower when compared to the control group.
Varma 1999[124]	Medication compliance	RCT	1. RCT (Level 2) 2. Clinical outcome (Level1)	1. Persons age 65 and older with CHF who were hospitalized or attended outpatient clinic 2. Two groups: • Intervention (*n* = 42) • Control (*n* = 41)	1. Pharmacist-led medication education 2. Medication review with dose simplification	Treatment group had higher knowledge of medications (*P* = 0.0026) and fewer hospital admissions (*P* = 0.006). No difference identified in quality of life between groups.
Ware 1991[148]	Medication compliance and medication packaging	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Setting both inpatient at a geriatric assessment and rehabilitation unit and postdischarge 2. Two groups: • Treatment (*n* = 4) • Control (*n* = 39)	1. Webster-Pak medication packaging unit-dose system 2. Hospital practice prior to discharge in both groups	Compliance was higher in subjects who used unit-dose packaging system (*P* < 0.05).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Weinberger 2002[130]	Medication Compliance	Group RCT	1. Group RCT (Level 2) 2. Clinical outcomes (Level 1)	1. Pharmacy customers who had COPD or asthma as an active problem and received 70% or more of medications from a single drug store 2. Three groups: • Intervention (*n* = 447) • Control group with peak expiratory flow rates (PEFR) monitoring (*n* = 363) • Usual care control (*n* = 303)	Tailored education by pharmacist based on patient-specific data provided to the participating pharmacists.	Treatment group had higher PEFRs compared to control groups (*P* = 0.02), more satisfaction with their pharmacist (*P* = 0.001), and more satisfied with their health care at 6 months (*P* = 0.01) when compared to the control groups. The asthma patients in the pharmaceutical care group had more breathing-related ED and hospital visits than the usual care group (odds ratio, 2.16 [CI 95% 1.76–2.63; *P* < 0.001]); however, the mean age for this group was 45, younger than the COPD group whose mean age was 62.
Wilson 2001[151]	Medication compliance	RCT	1. RCT (Level 2) 2. Indirect connection to outcome (Level 3)	1. Community-dwelling outpatients over age 70 with type 2 diabetes 2. Two groups of 15 each	1. Use of Glynase Prestabs for easier tablet breaking. 2. Use of push-and-snap method to break tablets.	Higher percentage of successful tablet breaking and less pain for Glynase Prestabs than generic tablets.
Winland-Brown 2000[172]	Medication adherence	RCT	1. RCT (Level 2) 2. Errors over time (Level 2)	1. Residents of older adult independent living facility, continued monitoring 2. Three groups: • Pre-filled pill box (*n* = 16) • Voice activated (*n* = 24) • Control (*n* = 21)	Medication management methods • Pill box • Medication dispenser with voice-activated reminders	Numbers of missed doses were fewer in voice-activated group (*P* < 0.01) compared to control and compared to prefilled pill box (*P* < 0.01).

Source	Safety Issue Related to Clinical Practice	Design Type (level)	Study Design, Study Outcome Measure(s) (level)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Wong 1987[149]	Medication adherence	Prospective cohort study	1. Cohort study with controls (Level 4) 2. Errors over time (Level 3)	1. Geriatric outpatient setting 2. Two groups of 11 each with crossover after 3 months	Blister-packed medications for 3 months and standard pill bottles for 3 months	Compliance was higher when subjects took medication via blister packaging (P = 0.01).

Chapter 19. Care Models

Bonnie M. Jennings

Background

The organization of care delivery is determined by a variety of factors such as economic issues, leadership beliefs, and the ability to recruit and retain staff. Ideally, evidence of the effect of care models on quality and patient safety would also be a major factor in decisionmaking.

Historically, four traditional care models have dominated the organization of inpatient nursing care. Functional and team nursing are task-oriented and use a mix of nursing personnel; total patient care and primary nursing are patient-oriented and rely on registered nurses (RNs) to deliver care.[1, 2] In the late 1980s, a number of nontraditional nursing care delivery models emerged that use various mixes of licensed and unlicensed nursing personnel.[3–5]

Care models do not exclusively pertain to the organization of nursing care, however, or the inpatient setting. Models have been examined for medical housestaff,[6] pharmacy services,[7] and social workers.[8] They have been considered for ambulatory care,[9–12] home care,[13–15] and nursing homes.[16] Care models also exist for specific patient populations such as elderly patients,[17–20] people with mental health needs,[21] and individuals with chronic conditions[22] to include disease management models[23, 24] and the use of technology.[25]

Research Evidence

Despite the interest in a variety of care models, it is difficult to discern which models work best. Neither the traditional nor the nontraditional inpatient nursing care models have been evaluated rigorously for their effects on patient safety.[2, 4, 26] Emerging models from other care disciplines, other settings, and particular patient populations are also lacking rigorous empirical assessments of their relationship to patient safety.

A number of investigations examining care models addressed nurses' perceptions of the care model.[1, 27–38] Only two investigations combined the nurses' perceptions with patient safety measures.[39, 40]

Several studies did not meet the criteria for inclusion in this review, largely due to weak designs. Of these, some reported pilot data,[6, 7, 13, 24, 41, 42] some were quality-improvement projects,[14, 17, 43] and others used qualitative methods.[32, 36,44–48] Like the quantitative studies, the rigor of the qualitative investigations varied. However, these qualitative studies illuminate important aspects of care models not evident in quantitative investigations. For example, Ingersoll[32] and Redman and Jones[36] were among the first investigators to assess the effects of patient-centered care models on nurse managers. The data from both of these studies expose the pressure and role confusion experienced by nurse managers. Subsequently, a quantitative investigation found nurse managers experienced a high level of emotional exhaustion, a key component of burnout.[49]

Among the quantitative studies of care models included in the evidence table, only one used a design that combined systematic review and meta-analytic techniques.[23] No randomized controlled trials were identified. The remaining seven studies used Level 3 designs. In two of

these studies, large databases were used to examine different care models for home-based long-term care[15] and mental health services.[21]

All five studies of nursing care models meeting inclusion criteria focused on acute care work redesigns in which the mix of nursing personnel was altered in some way. For each of these five investigations, data were reported from only one hospital.[39, 40, 50–52] Of these studies, one evaluated changes in care delivery models at one university teaching hospital with two campuses in the same city.[39] The remaining studies were smaller in scale focusing data collection on one,[50, 51] two,[52] or three units[40] in the same facility. Most often, measurements were done at three points in time—pre-implementation, and at 6 and 12 months after the model was introduced.[39, 40, 52]

Evidence-Based Practice Implications

The eight studies in Table 1 illustrate two main clusters of research. The first pertains to studies of inpatient nursing care models. Statistically discernible differences were rarely evident, and when they were, there was no clear pattern to guide practice.[39, 40, 50–52] For example, there were statistically fewer falls reported in two studies after units implemented care models using fewer RNs, presumably because there were more staff to assist patients.[50, 51] Fewer medication errors were detected in only two reports.[39, 52] However, quite unexpectedly and counter intuitively, postoperative pain scores were statistically higher on a unit after the number of RNs increased.[50]

There were no consistent patterns visible in findings among the studies that followed changes in the care model over time—before implementation and at 6 and 12 months.[39, 40, 52] However, the studies with multiple measurements showed that initial indicators of success were rarely sustained over time. This is similar to results from the study by Greenberg and colleagues[21] in which most positive effects of change lasted only one year. Despite the growing number of work redesign studies, the findings are too disparate even among those with stronger designs to offer a clear direction about practice changes to improve patient safety.

The second cluster of care model studies consists of three investigations that were conducted by other disciplines.[15, 21, 23] These studies demonstrate that the interest in determining which care models operate best is not isolated to nursing. The improved ability to detect statistical differences in these models may derive from their large sample sizes, their statistical techniques, or their use of different outcomes. The systematic review and meta-analysis of disease management programs for individuals with depression offers the strongest evidence for guiding care delivery.[23] With only one study of consumer-directed home-based long-term care,[15] and one of service-line delivery of mental health services,[21] practice changes for these areas should be considered carefully.

Research Implications

We actually know very little about the relationship between care models and patient safety. Randomized controlled trials (RCTs) might contribute evidence that would help investigators, administrators, and policy makers sort through the confusion. RCTs would be particularly difficult to conduct, however, given the need to have longitudinal data. The rapidly changing health care environment is not conducive to such endeavors.

The most glaring need relates to clarifying the work that needs to be done for patients and then determining which clinicians are best suited to provide it. Looking only at the work of nurses, which has dominated studies of care models in acute care settings, fails to consider nonnursing staff who are critical to the patient care mission.

We also know very little about care models that promote patient safety in outpatient settings, home care, or long-term care. These are areas that remain to be explored.

Conclusion

Care delivery models range from traditional forms, such as team and primary nursing, to emerging models. Even models with the same name may be operationalized in very different ways. The rationale for selecting different care models ranges from economic considerations to the availability of staff. What is glaring in its absence, however, is the limited research related to care models. Even more sparse is research that examines the relationship between models of care and patient safety. Ideally, future studies will not only fill this void, but the models tested will be developed based on a comprehensive view of patient needs, taking the full complement of individuals required to render quality care into account.

Search Strategy

Both MEDLINE® and CINAHL® databases were searched from 1995 to 2005 to identify research-based articles published in the English language that were pertinent to this review. Search terms were identified with the guidance of a reference librarian. The term "care models" was not a search option in CINAHL®. Therefore the CINAHL® search terms included "care delivery modules," "nursing care delivery systems," and "care modules." The MEDLINE® search was based on two terms, "care models" and "organizational models." Together, these searches yielded 549 citations, 55 in CINAHL® and 494 in MEDLINE®.

The abstracts for each of the 549 citations were reviewed. From this assessment it was determined that 82 of the articles were sufficiently focused on nursing or patient care models and should be considered further. Most of the 467 papers that were omitted used the word "model" in their title, but the work was not related to care models per se. For example, articles about medical management models were not used in this review. Additionally, a number of papers addressed topics with no discernible connection to care models (e.g., life support decisions for extremely premature infants).

The 82 articles were located and carefully read. As a result, 31 additional papers were omitted from the actual analysis. Reasons for these omissions included the lack of sufficient detail about the study, duplicate publications, and studies of advanced practice nurses. This left 51 articles for consideration in this review.

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Table 1. Evidence Table for Care Models

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Barkell 2002[50]	Inpatient nursing work redesign	Pretest (January–June 1999) and post-test (January–June 2000) (6)	Design: Level 3 Patient outcomes: pneumonia, urinary tract infection (UTI), postoperative pain perception (Level 2), patient satisfaction	A surgical unit in a 508-bed teaching hospital in the Midwest, all patients under DRGs 148 (major small and large bowel procedures with comorbidities or complications) & 149 (bowel resection without complications); 59 patients pre-, 37 patients post; 59% female pre- and post	Total patient care. In this intervention, the ratio of RNs to unlicensed assistive personnel increased as compared to the ratio in the previous model of team nursing. The total budgeted full-time employees decreased with the total patient care model.	Pain scores for postoperative days 1 and 2 were higher with total patient care (P = 0.017). Pneumonia and UTIs occurred too infrequently to analyze. There was no detectable statistical difference in patient satisfaction.
Benjamin 2000[15]	Home-based long-term care	Cross-sectional (4)	Design: Level 3 Patient outcomes: safety (physical and psychological risk, sense of security), unmet needs (activities of daily living) (Level 2), patient satisfaction	In-Home Supportive Services (IHSS) program in California; 1,095 IHSS Medicaid beneficiaries with disabilities in professional agency models (PAMs) and consumer-directed models (CDMs): about half the recipients were over age 65 (50% PAM, 54% CDM), most were female (77% PAM, 70% CDM); CDM recipients had more functional impairments	Professional agency model vs. consumer-directed model	Both models had positive outcomes. Absolute differences were small but statistically significant for safety, unmet needs, and service satisfaction, with the CDM scores more positive.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Greenberg 2003[21]	Changed organizational structure	Nonrandomized trial (3)	Design: Level 3 Patient outcomes: continuity of care, readmission (Level 2)	139 Veterans Administration Medical Centers; facility-level data for patients receiving mental health services over a 6-year period	Service-line organization (interdisciplinary) v. profession-based leadership	Statistically significant effects were demonstrated in care continuity and readmission rates within 180 days during the first year after implementing a mental health service line. A few continuity effects lasted 3 or more years, but most positive effects lasted only 1 year.
Grillo-Peck and Risner 1995[51]	Inpatient nursing work redesign	Pretest (January–June 1992) and post-test (January–June 1993) (6)	Design: Level 3 Patient outcomes: falls, medication errors, procedure errors, nosocomial infections (Level 2), length of stay	A neuroscience unit in an 800-bed not-for-profit hospital in Ohio, all patients under DRG 14 (cerebrovascular disease excluding transient ischemic attack): 71 patients pre-, 85 patients post; 56% female pre-, 55% post	Nursing partnership model (fewer RNs, more unlicensed assistive personnel)	The only statistically detectable differences related to fewer falls (X^2 = 4.77, $P \leq 0.05$).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Heinemann 1996[52]	Inpatient nursing work redesign	Nonrandomized trial with the same variables measured at 3 points in time using different patients (6 months before the change, 6 and 12 months after the change) (3)	Design: Level 3 Patient outcomes: falls, medication errors, intravenous (IV) infections (Level 2), patient satisfaction	A 518-bed private, not-for-profit hospital in Florida, all patients on two randomly selected medical-surgical units; pilot unit had 36 beds for general surgery/ trauma patients (*M* patient days for a 6-month period = 5,477), control unit had 34-beds for orthopedic/trauma patients (*M* patient days for a 6-month period = 4,654).	Partners in patient care (PIPC)—experimental (pilot) unit; Total patient care—control unit.	Significant differences between the units were evident only when the ratio of events to patient days was examined: medication errors (*P* = 0.008) and falls (*P* = 0.037), but not for IV infections (*P* = 0.309). Patient satisfaction scores were higher on the pilot unit.
Neumeyer-Gromen 2004[23]	Models of care for patients with depression	Systematic review (11) and meta-analysis (1)	Design: Level 1 Patient outcomes: depression severity (Level 1), adherence to treatment regimen, (Level 2), patient satisfaction	Only randomized controlled trials published from 1992 to 2002; 10 studies met the inclusion criteria; patients had a mean age of 43 years, 71% were women, and about 70% were white, 75% were diagnosed with major depression	Disease management programs (DMP) to implement guideline-driven care	Relative risk (RR) for the effect of DMP on depression severity was 0.75 (95% confidence interval [CI] = 0.70–0.81, *P* < 0.00001). The study with an ongoing intervention over 2 years showed a significant advantage of DMP (RR = 0.44, 95% CI = 0.28–0.67). Adherence to medication for at least 90 days favored DMP (RR = 0.59, 95% CI = 0.46–0.75, *P* = 0.00001). The overall effect for patient satisfaction favored DMP (RR = 0.57, 95% CI=0.37–0.87, *P* = 0.009).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Seago 1999[39]	Inpatient nursing work redesign	Cross-sectional, same variables measured at 3 points in time using different patients (6 months before the change, 6 and 12 months after the change) (4)	Design: Level 3 Patient outcomes: medication errors, falls, pressure ulcers, (Level 2), patient satisfaction	A large university teaching hospital with two campuses: patient days—30,462 at time 1, 29,584 at time 2, 29,210 at time 3	Change in care model from primary care to patient-focused care	A statistically significant decrease was found only for medication errors (0.97% before the change; 0.78% at 6 months, *P* = 0.016; 0.80% at 12 months, *P* = 0.027).
Tourangeau 1999[40]	Inpatient nursing work redesign	Nonrandomized trial with the same variables measured at 3 points in time using different patients (6–7 months before the change, 6 and 12 months after the change) (3)	Design: Level 3 Patient outcomes: IV therapy outcomes, falls, medication incidents, call bell usage	A 258-bed acute care community hospital in Toronto; all patients on three medical-surgical units; the experimental units had 57 beds (general medicine/surgery) and 70 beds (medicine/geriatric rehabilitation); the control unit had 38 beds (postcoronary)	Unlicensed assistive personnel (UAP)-RN partnership model on two experimental units; Total patient care with an all-RN staff on the control unit	Adverse IV outcomes decreased in all units; falls decreased initially on the experimental units and then increased; falls declined on the control unit at all measurement points; on all units, medication incidents increased from baseline to 6-months and then decreased below baseline; call bell usage declined dramatically at 6-months then increased to a rate similar to baseline.

Chapter 20. Leadership

Bonnie M. Jennings, Joanne Disch, Laura Senn

Background

Reports from the Institute of Medicine (IOM) have emphasized that leadership is essential to achieving goals related to quality care[1] and patient safety.[2] Leadership is expected from individuals at all levels of an organization, from the executive suite to those working directly with patients. Leadership is also expected regardless of where care is delivered—inpatient units, clinics, settings for ambulatory procedures, long-term care facilities, or in the home.

Because of the breadth and complexity of the literature on leadership, the authors narrowed the focus to leadership at two distinct levels of health care organizations. First, the literature on executive leadership was reviewed, with a particular focus on the relationship between the chief executive officer (CEO) and chief nurse officer (CNO), to examine leadership by individuals responsible for setting the organization's vision and direction related to quality of care and patient safety. Second, an exploration of the literature related to the leadership exerted by nurses and physicians as co-leaders of the patient care areas—that is, the type of leadership provided by co-leaders who are responsible for actualizing the vision and creating the local environment in which care is provided—was conducted.

A search of the relevant literature yielded little useful information on either of these leadership topics. Studies relating to the CNO or the individual in an equivalent position focused on hospital directors,[3] nursing home administrators,[4] CEOs and boards of directors,[5] and CNOs,[6–29] with no empirical evidence regarding the CEO-CNO relationship. Thus, the focus on the CNO shifted to reporting findings regarding the CNO's leadership style and its impact on the organization.

On the second level, that of nurse-physician co-leadership, there was a similar void in the literature. Thus, this chapter describes the very few studies that have examined nurse-physician co-leadership and reports findings from interventional studies on the broader context of nurse-physician collaboration and its impact on quality and safety of patient care. Collaboration is certainly a precursor to nurse-physician co-leadership.

Research Evidence

Executive Level

Only two investigations were found that linked CNO leadership to quality care and patient safety. A case study was done to examine the influence of the CNO in revitalizing the flagship hospital of a large, integrated health system.[7] Features of patient safety were among the outcomes evaluated at baseline, 18 months, and 36 months. Patient falls and nosocomial bloodstream infections declined over time from baseline; patient satisfaction with nursing care improved. The other investigation examined the relationship of both leadership and communication to quality care in 15 nursing homes from four States.[4] The nursing home administrators were invited to participate, but the findings did not reflect how many actually responded. Nonetheless, clinical staff (n = 656) provided important insights regarding what

promoted the best care possible. The top three responses regarding what facilitated good care and what interfered with providing good care were communication, staffing, and leadership. The study findings were not specific, however, as to whether the participants were addressing executive leadership.

Studies involving CNOs frequently examined leadership styles and behaviors. Transformational leadership captured the interest of several investigators.[11–13, 21, 23, 24] Although these studies were often framed to indicate a preference for a transformational style, the findings reflected that leadership is complex and multidimensional. CNOs typically used combinations of transformational, transactional, and laissez-faire leadership.[13, 21, 23] Moreover, four homogeneous leadership groupings were found among 84 CNOs based on combinations of high and low transformational and transactional behaviors.[11]

The need for a comprehensive assessment of leadership was put into perspective in a study involving a random sample of 477 CNOs who were members of the American Organization of Nurse Executives (AONE).[21] Both transformational and transactional leadership had a negative relationship with alienative (unfavorable) organizational commitment among registered nurses (RNs). However, transactional leadership demonstrated a stronger ($r = –0.31$; $P < 0.01$) association with alienative organizational commitment than transformational leadership ($r = –0.24$; $P < 0.05$).

Other styles of leadership were also assessed; however these findings could not be explicitly linked to CNOs. Rather, the investigators considered leadership from nurse administrators, allowing the possibility that participants may have reflected on leadership from nurse managers. Nevertheless, authoritarian leadership interfered with work empowerment.[20] Conversely, connective leadership—which was largely composed of the elements of transformational leadership—was predictive of empowerment.[18] A study involving 6,526 RNs from Canada illustrated the need to examine the full repertoire of leadership styles.[30] A heretofore unrecognized leadership style—resonant leadership—lessened the impact of restructuring.

Another approach to assessing CNO leadership was to compare how CNOs perceived their leadership with how various other individuals perceived the CNO leadership style. These studies, involving CNO direct reports,[11] the individuals to whom CNOs reported (usually the chief operating officer, COO),[13] nurse managers (NMs),[15, 19, 21] staff nurses,[21] and influential colleagues,[14, 17] further verified the complexities of leadership. For example, although there were discrepancies between CNOs and their direct reports regarding how often CNOs used transformational leadership, the direct reports were more satisfied with the CNO leadership style than the CNOs expected.[13] Based on data from the same study, however, no differences in ratings of work group effectiveness were found, among the three groups (CNOs, direct reports, CNO supervisors).

NMs (n = 87) who agreed with their CNOs' (n= 22) leadership style were more likely to be satisfied with their jobs.[15] In another study conducted in a 700-bed acute care setting during an organizational transition, a rating scale and interviews were used to identify the executive behaviors that were most important to NMs.[19] Although it was not clear whether CNOs per se were considered, communication and high visibility on work units were the top 2 of the 10 most desired behaviors.

A study of nurse leadership in four hospitals—two with Magnet status and two without Magnet status—found that leadership affected staff nurse job satisfaction.[25] Based on survey responses from 305 staff nurses and interviews with 16 nurse leaders, some of whom were CNOs, the investigator concluded that staff nurses were more satisfied when nurse leaders were

visible and responsive, when they supported autonomous decisionmaking, and when there was adequate staffing.

Another group of studies examined skills essential to being a successful CNO, especially given how the role is changing.[8, 10, 17, 27, 28] For example, in a study conducted in one U.S. city involving CNOs and female leaders in other fields, six categories of essential leadership skills were identified: (a) personal integrity, (b) strategic vision/action orientation, (c) team building/communication, (d) management and technical competence, (e) people skills, and (f) personal survival skills.[10] A Delphi study conducted in 22 European countries identified 16 relevant CNO qualities.[17] Communication ranked first, followed by teamwork, leadership, strategic thinking, political astuteness, professional credibility, integrity, personal qualities, innovation, decisionmaking, promotion of nursing, research skills, physical characteristics, information handling, good management, and conflict resolution. The rankings from a European study differed from rankings derived from a U.S. study in which clinical knowledge ranked first of 14 items, communication ranked eighth, and teamwork was not in the rankings.[8] Attributes of successful nurse leadership in acute care settings were compared between 16 leaders at Magnet (n = 7) and non-Magnet hospitals (n = 9).[27, 28]

Additionally, researchers have found that organizational characteristics such as culture and size may alter the expression of leadership.[13, 27] Gender is another factor that has been assessed regarding CNO leadership. In one study, gender was deemed irrelevant because of the effective way in which the hospital leadership teams interacted.[27]

A final set of studies concerning CNOs provided evidence using qualitative methods.[6, 9, 16, 24, 26, 29] Some of these studies were conducted to delineate key executive leadership characteristics.[24, 26] For example, based on interviews with 10 CNOs, key characteristics included knowing how to use power; being visible; having a vision for the organization; motivating staff; empowering staff; and being open, honest, and personable.[24] Similarly, 16 nurse leaders—some of whom were CNOs—from four acute care hospitals were interviewed to identify effective leadership traits.[26] The categories that emerged were (a) core principles and value system guiding leadership (e.g., leading to serve, striving for excellence, a passion for nursing); (b) use of quantitative data to influence decisionmaking; and (c) collaborative teamwork among patient care staff to provide excellent care, and among management to support one another and staff. Findings from other qualitative investigations included a serendipitous finding about obstacles CNOs face in all aspects of their work;[9] determining CNO leadership behaviors across three hierarchical domains of leadership: strategic, organizational (administrative management), and production (creating goods and services);[16] how the merger of business (managed care) and medicine widened the gender gap in health care leadership;[6] and thought processes used by expert CNOs in making decisions.[29]

Nurse-Physician Co-Leaders

While there is a growing body of research described later in this chapter on the impact of collaboration between nurses and physicians who are caregivers,[31–45] there is a notable absence of research on the impact of a collaborative relationship between the nurse and physician co-leaders of patient care units. Presented in this section is a brief history of the concept of partnered leadership and a description of the one study found on this specific type of nurse-physician relationship.

The importance of a focus on collaboration and partnered leadership between nurse and physician is not a new concept, but rather one that has been in the literature for more than 25

years. In 1981, the National Commission on Nursing urged trustees and administrators to "promote and support complementary practice between nurses and physicians" and to "examine organizational structure to ensure that nurse administrators are part of the policymaking bodies of the institution and have authority to collaborate on an equal footing with the medical leaders in the institution"[46] (p. 62). Similarly, the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCAHO) required that activities of critical care units be guided by a multidisciplinary approach, including nursing and medical input.[47] Shortly thereafter, the American Association of Critical Care Nurses and the Society of Critical Care Medicine jointly developed a position statement outlining 10 principles for optimizing resources in critical care units. While all of the principles reflect a commitment to medical and nursing co-leaders, the following two are particularly relevant[48] (p. 43).

- #1—Responsibility and accountability for effective functioning of a critical care unit must be vested in physician and nurse directors who are on an equal decisionmaking level.
- #10—Close collaboration between the directors is essential for successful management.

More recently, Gilmore[49] has advanced the concept of *productive pairs*. He noted that as organizations become increasingly complex with rapid change, leaders are less able to possess all of the knowledge and expertise needed. Thus, a model of leadership that is based on a partnership between two individuals who share common goals and come from different, yet complementary, disciplines could be very effective.

Productive pairs possess several characteristics: separate, yet complementary, bodies of knowledge; understanding and valuing each other's areas of expertise; enough time or history together to explore the interdependencies; trust of one another that enables direct, frank exploration of issues; a commitment to the partnership and avoidance of efforts at triangulation; and a shared passion for a common goal or vision.

One study that specifically examined how physician leaders and nurse administrators worked together was by Tjosvold and MacPherson.[50] Physician and nursing administrator pairs were interviewed on how they worked together in managing areas within the hospital. Incidents they used to describe their relationship were coded as cooperative, competitive, or independent, and then related to outcomes.

Incidents in which goals were cooperative were ones in which physicians and nurse administrators discussed their issues constructively, had positive effect, strengthened their relationship, made progress on the task, promoted the organization's effectiveness, developed confidence in future work, and fostered quality care. Incidents in which goals were competitive were negatively related to productive interaction and outcomes. When the partners felt competitive, they were unable to exchange ideas openly, initiatives did not progress, and the relationship and quality of care were compromised. Constructive controversy (open-minded discussion, occurring within a strong cooperative context, or various perspectives that allow disagreement and exploration in a respectful manner) enabled the pairs to discuss their views productively and resulted in constructive outcomes. On the other hand, when constructive controversy occurred in a competitive context, problems ensued, such as resistance, a close-minded discussion of ideas, and an impaired working relationship.

Nurse-Physician Collaboration

As a backdrop for considering collaboration between nurse and physician leaders of the team, we examined the research on collaborative relationships between nurses and physicians.

Collaboration is the "process of joint decision making among independent parties involving joint ownership of decisions and collective responsibility for outcomes. The essence of collaboration involves working across professional boundaries"[31] (p. 186). Assumptions have been advanced that greater collaboration between nurses and physicians results in improved quality of patient care.

One of the first, and most often cited, studies on collaboration was conducted by Knaus, Draper, Wagner, and Zimmerman in 1986.[32] These researchers analyzed patient outcomes in 13 intensive care units (ICUs) and found a significant relationship between the presence of excellent interaction and coordination of care among nurses and physicians and improved patient outcomes. In subsequent work, Shortell, Zimmerman, and Rousseau [38] looked at communication and coordination in 42 ICUs, but they were unable to differentiate ICUs according to risk-adjusted survival. However, these researchers noted that communication and coordination helped decrease length of stay.

Baggs and others[34, 35] investigated the perceptions of physician-nurse collaboration and either negative outcomes (e.g., death or readmission to the ICU) or the transfer of patients from the ICU to an area of less intensive care. In the first study of one ICU,[34] these researchers found that the more collaboration nurses reported, the lower the risk of a negative patient outcome. In the second study in three different types of ICUs,[35] reports of collaboration by nurses in the medical ICU correlated significantly with patient outcomes: When the nurse reported full collaboration, the patient's risk of negative outcome was 3 percent; when the nurse reported no collaboration, the patient's risk increased to almost 14 percent. These findings were not observed in the surgical ICU or the community hospital ICU. Interestingly, in both of the studies, the reports of collaboration by attending physicians and residents were not associated with patient outcomes in any site. Differences in perceptions about collaboration have been found by other researchers as well, with physicians consistently perceiving higher levels of collaboration than nurses.[33, 40, 43] A study by Hojat and colleagues[39] in Mexico, however, found the opposite.

Evidence-Based Practice Implications

Executive Level

It is very difficult to link leadership to patient safety because the evidence pool is quite limited. Across studies of CNO leadership, weak designs prevail and the specific topics studied are very diffuse. As a result, it is difficult to make statements to guide practice.

A modest body of evidence is accruing about leadership styles. These studies illustrate that multiple styles of leadership may be operationalized concurrently. Evidence related to transformational leadership suggests that researchers need to consider multiple types of leadership and how the types work together, helping to limit bias created by studying only transformational leadership—or advocating for transformational leadership as a superior style. The evidence simply does not support that view.

Nurse-Physician Collaboration

On behalf of the Cochrane Collaboration, Zwarenstein and Bryant[51] completed an international review on collaboration and found several hundred studies on the topic. After examining the abstracts, these colleagues reviewed the full text of 31 studies and found three studies that were "methodologically adequate and evaluated relevant interventions"[51] (p. 4), although one study eventually had to be excluded because it was difficult to sort out the impact of combined interventions.[52] The first retained study by Curley and colleagues[53] used a randomized, controlled method to examine the impact of interdisciplinary rounds on aspects of inpatient care. These researchers found a shorter length of stay (5.46 vs. 6.06 days) and lower total charges ($6,681 vs. $8,090) for patients receiving care from the interdisciplinary team.

The second retained study at a Thai academic hospital[54] compared average lengths of stay for females in a control ward with those for females in a second ward in which frequent rounding and weekly team case conferences occurred. There were no significant differences found, although patients in the interventional ward had shorter lengths of stay, when patients who died while in the hospital were excluded. These studies are reported in Evidence Table 2.

The inclusion criteria for the Cochrane Collaboration report were very restrictive and the results do not provide health care leadership with enough relevant information to guide quality improvement projects. However, a recent critical review[55] was completed that incorporated a wider range of methodological designs to help illuminate findings from experimental research on the impact of nurse and physician collaboration on quality and safety of patient care.

The review was limited to outcome-based experimental studies completed in the United States that focused on the acute care setting and nurse-physician collaboration. Seventeen studies met the inclusion criteria,[31, 37, 53, 56–69] and the findings from this review demonstrated that outcomes could be grouped into three categories: professional outcomes, organizational outcomes, and patient outcomes.

Professional outcomes were measured in several different ways, but the most frequent evaluation was in communication skills. Other areas measured were teamwork, leadership, job satisfaction, and collaboration. Organizational outcomes were very straightforward and consisted of only three major types: length of stay (LOS), readmission rates, and hospital costs. Eight of the studies that were reviewed focused on patient outcomes. Patient care outcomes ranged from anxiety, depression, and pain to functional status, length of time on a ventilator, and diabetes management. Usually the data collected were from medical records and interviews with patients or their proxies and could be considered reasonably reliable.

The types of interventions used to improve collaboration had four basic threads: interdisciplinary rounding, development of protocols, staff education of patient care guidelines, and easier access to information at the patient's bedside. These threads are closely related to the attributes of collaboration: people working together, cooperation, sharing responsibility in decisionmaking, communication, and coordination of care.

The studies that surveyed health care providers' perceptions used a little broader spectrum of interventions. Similarities were in the use of patient rounds, patient care guidelines, and increased access to patient information. But these studies employed other interventions that included such things as establishing contacts with key stakeholders to discuss roles and responsibilities, appointing more physician helpers (NPs), appointing medical directors, providing classes on the processes of communication and teamwork, and restructuring of the organization to decentralize professionals. One study,[61] which identified nine significant

findings, employed a high-quality, randomized controlled design that used five interventions to achieve its results: (1) daily review by medical director of medications and procedures; (2) daily rounds by multidisciplinary teams; (3) daily assessments by nurses; (4) protocols to improve patients' self-care; and (5) early, ongoing emphasis on returning home. The design and interventions of this complex study were well thought out, and the study subsequently demonstrated significantly improved patient outcomes in very elderly (older than 70 years), frail patients, as well as improvement in organizational outcomes. Details of the 17 studies are in Evidence Tables 2 and 3.

It is apparent that there is a dearth of methodologically sound studies on nurse-physician collaboration. While nurses and physicians universally acknowledge the importance of collaboration, we actually know very little about what it is, how it works, and whether it makes a difference. Furthermore, we have some evidence to suggest that nurses and physicians define collaboration differently and use different criteria to assess whether it's present.[33, 40] To a large extent, this is because collaboration is part of a complex set of related concepts, often defined and operationalized very differently, e.g., as teamwork,[36, 70, 71] collegiality,[45, 72] communication,[73–75] trust,[31, 76] and coordination.[32, 38]

Additional challenges to establishing a strong evidence base include the following:

- Current studies focused on only one of several possible interconnecting factors. Without adequate theoretical frameworks or sophisticated methodology, it is difficult to sort out the contributions of individual factors in a complex situation.
- Studies typically focused on interventions within one or a few patient care areas, and usually within one institution.
- Outcomes measured tended to be objective and easily quantifiable, such as length of stay,[53] cost,[53] mortality,[32, 34, 35, 38, 57] or readmission rates,[34, 35] which are certainly important. However, we also need more studies on some of the more qualitative outcomes, such as patient satisfaction and morbidity, staff morale and retention, and patient safety.

Findings indicated only one study that specifically targets the physician and nurse as co-leaders,[50] and this was a correlational study in British Columbia. A second study, by Boyle and Kochinda,[74] implemented a collaborative communication intervention to ICU nursing and physician leaders, along with several other identified leaders such as the clinical nurse specialist, in two diverse ICUs, using a pretest–post-test, repeated measures design. The intervention included a series of educational and experiential modules, yielding improved communication skills, leader satisfaction, and perceived problem-solving ability. Though this study included nursing and physician leaders, several other individuals were included in the intervention and did not target or emphasize the special role of the clinical co-leaders.

Why are there so few studies examining the relationships between and impact of co-leaders in health care, given the extensive emphasis on leadership in health care today? Dougherty and Larson[77] noted that most research done on collaboration was conducted by nurses, and thus, the idea of examining aspects of a partnership wasn't equally valued. Fagin[78] noted that physicians are not interested in interprofessional relationships in general, and that health professions' curricula do not include sufficient content in this area, although thoughts are changing as the result of a number of national initiatives to promote interprofessional education and common competencies.[79–82] Two other factors that contribute to this gap are that (1) the role of medical director as co-leader of a clinical area is not a widespread phenomenon and, if in place, is usually seen in ICUs, emergency rooms, and other specialty areas; and (2) funding by the National

Institutes of Health and other major funding agencies follows the biomedical model of health care research.

What We Do Not Know—Research Implications

Executive Level

Although there is a strong belief that executive leadership is essential to underpin patient safety, it is difficult to support that idea from an empirical base. The strongest statement that can be made based on empirical studies is that it is unwise to view transformational leadership as a preferred style, particularly when this style is assessed independent of other leadership styles and organizational variables. We actually know very little about leadership—what works, what does not, and leadership style impact on patients, staff, and the organization. Ironically, although leadership is a topic of tremendous interest, little empirical evidence exists.

Nurse-Physician Collaboration

While the impact of collaboration between nurses and physicians has been studied, we have scant strong, empirical evidence that collaboration makes a difference. What is needed are consistent definitions of the concept, use of tools with appropriate psychometric properties to measure the concepts, interventional studies, and sampling from more than one or a few organizations.

There is much work to be done, and there are a number of helpful resources for getting started. The recent work of Gene Nelson, Paul Batalden, and their colleagues[83–85] at Dartmouth and elsewhere on clinical microsystems provides a framework for examining the role of leadership in the patient care area. Ingersoll and Schmitt[86] wrote a comprehensive review of the literature on work groups and patient safety that highlights teamwork, collaboration, communication, and other relevant concepts. Dougherty and Larson[77] recently reviewed the scope, psychometrics, and use of five instruments that have been used to measure nurse-physician collaboration; while the instruments differ significantly from each other, the authors concluded that they offer a good starting place for aiding future research.

A final comment and return to an original point: In addition to research needed on nurse-physician collaboration, significant attention must be paid to examining the experience and impact of nurses and physicians functioning as co-leaders of clinical areas. What are the factors that enhance their ability to model collaboration and co-create healthy work environments that benefit patients, families, and all members of the health care team? What are the barriers? What are individual, institutional, and societal strategies that can be implemented to a healing environment for patients, families, and all caregivers?

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Evidence Table 1. Findings on Impact of CNO Leadership Style

Source	Safety Issue Related to Clinical Practice	DesignType	Study Design, Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dunham-Taylor 2000[13]	Leadership	Cross-sectional (4)	Design: Level 3. Outcomes: CNO leadership style, work group effectiveness.	National study from all States; 396 CNOs, at least 3 direct reports for each CNO (N = 1,115), CNO's boss (N = 360); most CNOs were married (77%) females ((93%) in their 40s (54%) with a master's degree (61%). On average, they had 24 years experience in nursing and 9 years in executive positions. Direct reports and boss characteristics were not described except to note that most bosses were COOs.	Comparing scores on leadership styles, workgroup effectiveness.	There was a significant difference in how CNOs rated themselves and the ratings from their direct reports for transformational, transactional, and laissez-faire leadership. No statistically significant differences were found among CNOs, their direct reports, and CNO bosses in regard to work group effectiveness. Staff were more satisfied with the CNO leadership style than the CNO expected. Organizational characteristics played a role with more transformational CNOs in organizations that were participative.

Source	Safety Issue Related to Clinical Practice	DesignType	Study Design, Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Leach 2005[21]	Leadership	Cross-sectional (4)	Design: Level 3. Outcomes: Organizational commitment which was assessed according to 3 types-moral (normative, internalized identification), calculative (remunerative or compliance), and alienative (negative resistance).	A national random sample of CNO AONE members working in hospitals and a convenience sample of NM (n = 148) who reported to the CNO and 651 staff nurses who reported to a participating NM. CNOs from 35 States returned 102 usable surveys. All but one CNO were women. They had more than 15 years experience in nursing, and 70% had more than 15 years experience in management. Almost 80% had master's degrees. NMs were mostly women (95%). Most had been in nursing for more than 15 years (75%), most had more than 15 years experience in management, and 40% held a master's degree or higher. The staff nurses were mostly women (64%), and most had 11 or more years experience in nursing (62%). Almost 40% had a BSN.	Leadership and nurses' organizational commitment.	CNOs and NMs had a leadership profile that illustrated elements of both transformational and transactional leadership. Both styles of leadership showed a negative and statistically significant relationship with alienative organizational commitment. Both leadership styles were positively and statistically significantly for CNOs and NMs. No relationship was found between NM and staff nurse organizational commitment.

Evidence Table 2. Cochrane Collaborative Results: Randomized Controlled Trial Focused on Increasing Collaboration between Nurses and Physicians

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Curley 1998[53]	Collaboration	Randomized controlled trial–6 month prospective trial, with patients randomly admitted to different doctor groups (Firms).	Variables measured were length of stay (LOS), hospital charges, provider satisfaction, ancillary service efficiency, readmission rates, and quality of patient care. Using hospital billing system, medical records, and surveys.	Medical unit inpatients at large county hospital affiliated with university; used a 30-bed nursing unit; each firm had 25 attending physicians and 25–30 residents. 1,102- total number of patients: 535 in control group 567 in intervention group	Interdisciplinary rounds—MDs, RN (patient care coordinator), pharmacist, nutritionist, and social worker daily rounding; orders written during rounds; chart taken with MD on rounds.	Significant increase in provider satisfaction and perceived collaboration in the areas of understanding patient's plan of care, communication, and teamwork. Some decreases in LOS, readmission rates, and hospital costs.

Evidence Table 3. Outcome-Based, Experimental Studies Focused on Increasing Collaboration between Nurses and Physicians

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Inouye 1993[56]	Nurse-physician collaboration	Prospective cohort study with stratified and matched cohort analysis; not randomized.	Variables measured were functional decline—overall; functional decline—matched cohort analysis; using interviews; self reported activities of daily living (ADLs); mini-mental exam; confusion assessment; physical exam; and medical records for risk assessment.	Medicine units. Huge differences in baseline data. Required matched cohorts to further analyze data. 216 total 85 intervention 43 RN/MD group 42 RNonly group 131 control 66 matched cohorts	Identification and surveillance of frail older people. Twice weekly rounds of the geriatric care team. Nursing-centered educational program.	Improvement in functional decline significant only after using matched-cohort analysis.
Gallager 1998[57]	Nurse-physician collaboration	Retrospective and prospective study, convenience sample, repeated measures done quarterly; for 11-month period.	Variables measured were frequency of blood glucose monitoring; nutrition assessment; insulin management; change to glucose intolerance enteral formula as recommended by protocol; using medical records review.	All tube-fed patients admitted to a 16-bed ICU, community hospital; 65 eligible 35 participants who met criteria.	Interdisciplinary collaboration in study design, organization, and implementation of a performance improvement initiative using the Plan/Do/Check/Act process: a group formed; critical blood glucose levels defined; interventions defined.	Improvement in BG monitoring, nutrition assessment, insulin management, and hyperglycemia control.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lassen 1997[58]	Nurse-physician collaboration	Design – retrospective and prospective comparisons of patient charts 1 year prior to intervention, right after intervention, and then 1 year after intervention, for a 3-month period of time during each interval.	Variables measured were quality of patient care; costs; length of stay (LOS), number of antibiotics received, and readmissions rates. Using medical records review.	350-bed tertiary hospital. All children admitted with sepsis during study period.	Protocol development for management of rule-out sepsis – Education of RNs and MDs in the nursery for 3 months.	Decrease in patient anxiety and confusion; significant decrease in cost and LOS, and mixed results in readmission rates.
Jordan-Marsh 2004[59]	Nurse-physician collaboration	Pre- and post-intervention data collection, total 14 quarters; 2–8 were implementation, 9–13 were maintenance.	Variables measured were documentation of pain; evaluation of effectiveness; improved pain management measured as doses of analgesia; improved pain management measured by analgesia type. Using chart audit (10% of charts each month), pharmacy records of drugs dispensed to ward, and census.	Patients on a pediatric ward in large urban hospital. Between 715 and 840 patient days per quarter.	Multifocal approach for QI-Referral book; resident experts; flow sheet; classes, policy, and protocol; rounds weekly; interdisciplinary plans; change nurses' scope of practice to include giving morphine IV; agenda item for P&T Comm; etc.	Decreased reports of pain by patients; increased evaluation of effectiveness; and improvement of pain management.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kollef 1997[60]	Nurse-physician collaboration	Randomized controlled trial during a 4-month period; stratification according to ICU site.	Variables measured were duration on mechanical ventilation; need for reintubation; LOS; hospital mortality rate; and cost. Using medical records review.	In medical ICU and surgical ICU in 2 teaching hospitals; 4 units total. 377 total 179 intervention group (protocol directed) 178 control group (physician directed)	Protocol-directed weaning from mechanical ventilation developed by medical director; education of nursing and respiratory staff before implementation.	Significant decrease in duration on mechanical ventilation; decreased costs and LOS; and mixed results with readmission rates.
Landefeld, 1995[61]	Nurse-physician collaboration	Randomized control trial – randomly assigned to acute care program for elderly or usual care.	17 different measures looking at ability to perform ADLs – using different time frames, controlling for risk factors; plus LOS and costs. Using interviews, medical records and Universal Bill (1982).	>70 yr, admitted to general medical unit 651 total 327 intervention group 324 control group	Daily review by medical director of meds and procedures; daily rounds by multidisciplinary team, daily assessments by nurses; protocols to improve self-care; early, ongoing emphasis on returning to home.	Numerous quality of patient care outcomes were significant; also found a decrease in cost and LOS, and a mixture of results for readmission rates.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Henneman. 2001[37]	Nurse-physician collaboration	Pre- and post-quasi-experimental; compare patient outcomes 1 year before and 1 year after intervention.	Variables measured were length of time of mechanical ventilation; length of time in the ICU; cost and complications. Using Medical records; mortality rates, readmission rates to any ICU; staffing patterns, years of experience of nursing and respiratory therapy staff, and management choices.	8-bed medical ICU; no differences between control and experimental groups 207 total 77 control group 124 intervention group	Multidisciplinary rounds every morning; assessment data and progress available in medical record (both groups); assessment data and weaning progress flow sheet on board and flow sheet at patient's bedside (for intervention group only).	Significant decrease in length of time on ventilator; significant decrease in LOS; some decrease in hospital costs; and mixed results for readmission rates.
Vazirani 2005[62]	Nurse-physician collaboration	Quasi-experimental; 1 control and 1 intervention unit; over a 2-year period.	Variables measured were collaboration with MDs; NPs, RNs; communication; LOS; cost and readmission rates. Using surveys of nurses (biannually); attending MD (every 2 weeks), and residents (every month).	2 acute care inpatient medical units; no crossover between units with MDs or RNs; staffing and demographics of patients and nurses same between units. House staff – 111 (58%) Attending physicians – 45 (69%) Nurses – 123 (91%)	Appointment of an NP; appointment of hospitalist medical director; institution of daily multidisciplinary rounds–lasted 15 minutes per team.	Significant increase in perceived collaboration. (RNs had better communication only with NPs; MDs had better communication with fellow MDs and NPs, and increased collaboration amongst themselves.) Some decrease in LOS and hospital costs; and mixed results for readmission rates.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Trey 1996[63]	Nurse-physician collaboration	Descriptive, retrospective	Variable measured was clarity of roles. Using nurse manager's report.	Ambulatory care center of a large teaching hospital. Nurses, surgeons and anesthesia staff; no size given	Clarification, discussion, and resolution of ambiguous roles. Job descriptions of nurse manager and medical director were written and implemented.	Nurse manager reported that intervention helped nurses identify MD and RN responsibilities.
Dechairo-Marino 2001[64]	Nurse-physician collaboration	Pre- and post-test, intervention study – convenience sample. Surveyed at baseline and 1 month prior and 3 months after completion of interventions.	Variables measured were perceived collaboration scores and satisfaction with decisionmaking. Using Bagg's Collaboration and Satisfaction about Care Decisions questionnaire (adapted version).	RNs working on 3 medical-surgical units and 2 ICUs; 87 pretest 65 post-test; approx 50% response rate: 60% attendance rate for intervention.	Activities – developed the Operating obtained endorsement; incorporated principles into unit activities; offered 4 hour, one session class re: concepts.	Significant increase in perceived level of collaboration and the nurses' satisfaction with decisionmaking process.
Boyle 2004[65]	Nurse-physician collaboration	Quasi-experimental, prospective, intervention study. Intervention group – Pretest–post-test, followup immediately after intervention. Control group (unit staff) – F/U pretest and 6 months after intervention to explore penetration.	Variables measured were communication skills and leadership skills; situational stress and personal stress. Using collaboration skill simulation vignettes, ICU nurse-physician questionnaire, and ICU outcomes.	2 ICU units used; both had same leadership, staffing levels, and technology. Unit A = 4 beds with only 11 diagnoses; 9 nurses; 3 MDs. Unit B = 22 beds with 162 diagnoses; 38 nurses; 14 MDs. 10 leaders for both units.	6 modules on Interaction Process – 23.5 hours using adult learning methods; 2 4-hr sessions over 8 months. Participants also received coaching and reinforcement between sessions.	Significant improvements in communication skills and leadership skills and leadership characteristics exhibited; significant improvement in professional satisfaction in relationship to personal stress and situational stress; mixed results with all other parameters measured.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wyly 1996[66]	Nurse-physician collaboration	Descriptive study of quality improvement project.	Variables measured were satisfaction with workshop and staff's plan to use elements in their work. Using surveys.	600 staff nurses	2-day training workshop, creating a learning climate that facilitates participation. Focused on Interdisciplinary teams; high-risk infant and family interventions in the neonatal ICU and through transition to community.	High satisfaction with workshop and high level of intent to use elements in their work.
Foley 1997[67]	Nurse-physician collaboration	Pre- and post-test; control and intervention groups; tested 2 months after intervention; convenience sample;	Variables measured were communication skills with physicians and interactions with patients. Using Nurse-Physician-Patient Interaction/Communication Survey and demographics.	Control group from 2 units, intervention group from another unit 66 total 28 intervention group 38 control group	Nurses engage in 2 different 15-minute videotaped case scenarios using standardized patients and standardized physicians, 1 week apart; rate themselves on a "Performance Assessment Checklist."	No significant results in nurses' communication skills with patients and physicians.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Narasimhan 2006[68]	Nurse-physician collaboration	Prospective, quasi-experimental, with testing at baseline, 1 week, 6 weeks, 9 months after implementation of intervention.	Variables measured were staff's level of understanding goals for the day; communication; desire to continue to use worksheet; and belief the worksheet had a positive effect on patient outcomes. Using surveys.	16-bed medical ICU, closed unit RNs – baseline – 21 6 wk – 14 9 mo – 18 MDs – baseline – 12 6 wk – 14 9 mo – 17 Response rate not given.	Daily goals worksheet that included consents, tests, medications, sedation, analgesia catheters, consults, nutrition, mobilization, family discussions, and dispositions (not part of the Medical Record).	Increased perception of collaboration (i.e., understanding patient goals and communication process) for both RNs and MDs.
Lorenzi 1993[69]	Nurse-physician collaboration	Single group pre- and post-test design, repeated measures at baseline, 3 months, and 6 months.	Variables measured were job satisfaction; level of nurse-physician collaboration; broad knowledge base of sickle-cell; and demographics variable (years of experience and present employment status). Using knowledge-based test, job satisfaction tool, and surveys.	42 eligible 18 participants 40% response rate	Education program for nurses; 10 hours of sickle-cell disease process, treatment, interventions, and relaxation techniques; Implementation of a comprehensive guideline for the care of sickle-sell patients.	Significant improvement in collaboration with MDs, and an increase in job satisfaction for RNs. Demographic variables were significant for years of experience and present employment status.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Liedtka 1998[31]	Nurse-physician collaboration	Postintervention survey.	Variables measured were differences and similarities of nurses', physicians', and administrators' perceptions of factors correlated with successful collaboration. Using questionnaires and interviews.	Large, academic health center, 3 service lines, and 3 professions surveyed 346 eligible 124 participants 36% response rate	Organization restructure to service lines; Implementation of a new organizational structure that has nonnursing professionals report to unit managers instead of central department.	Increased perception of factors that are correlated with successful collaboration in RNs, MDs, and administrators.

Chapter 20a. [Vignette] Transforming Health Care for Patient Safety: Nurses' Moral Imperative To Lead

Diana J. Mason

Background

On July 16 and 17, 2004, the *American Journal of Nursing*, University of Pennsylvania School of Nursing, Hospital at the University of Pennsylvania, and Infusion Nurses Society held an invitational State of the Science Symposium on Safer Medication Administration in Philadelphia. Funded by a small conference grant from the Agency for Healthcare Research and Quality (AHRQ grant no. 1 R13 HS14836-01) and educational grants from industry, the meeting brought together diverse health care professionals and groups —nurse clinicians, educators, administrators, and researchers; pharmacists; physicians; industry representatives; consumers; and professional organizations—to examine the current research on safe medication administration, barriers to improving the integration of this research into practice, and recommendations for overcoming these barriers.

Research Priorities and Barriers

The participants identified the following research priorities[1] (p. 8–9):

1. How do safety climate, error reporting, and root-cause analysis affect patient safety, quality of care, and both patient and clinician satisfaction?
2. How can individuals and organizations integrate and sustain best practices to detect, reduce or eliminate, and mitigate the errors that occur?
3. What patient-centered approaches result in medication error reduction in ambulatory and long-term care settings?
4. How do current practices and near misses make medication administration safer?
5. What is the impact of safer medication administration practices on health care costs and patient outcomes?

The participants identified the following barriers to safer medication administration[1] (p. 6–7):

1. There is a lack of a "just culture of safety" in many health care facilities.
2. There is a lack of interdisciplinary collaboration and communication.
3. Nurses' work environments do not support safety.
4. Voices of frontline nurses are missing in decisionmaking and systems design related to medication safety.
5. There are difficulties in translating research into practice.
6. Policies to effect medication safety are not driven by evidence.
7. There is insufficient funding for research on medication safety.

Note that the use of technology to reduce medication errors—or the lack of such technology—is not specified as a research priority or as a barrier to improving care. This may seem curious since health care systems are lagging behind other industries in the development and use of technology for reducing error, but its absence highlights other concerns. For example, while it is often assumed that technology will help only to reduce errors, there is evidence that it

sometimes introduces errors, often because of factors such as inadequate training of the users of the technology and poor communication.[2–4] At a national nursing conference in 2003, some of the companies that make bar-coding technology and advanced intravenous pumps (referred to as "smart pumps" because of their ability to track and report data about their use) noted that nurses often develop work-arounds when they believe that the technology is not efficient. For example, one company representative said that some nurses using his company's bar-coding technology would print out a list of all of the unit's patients with their bar-codes, then swipe these bar-codes—instead of the one on the patient's wristband—against the medication bar-codes, clearly defeating the purpose of the bar-coding technology. In the nurses' eyes, they were making more efficient a process that they viewed as cumbersome and time consuming.

Technology's absence from the research priorities and barriers also reflects the pressing reality of working nurses: too many work in environments that give lip service to patient safety, but seldom recognize that nurses are the key to quality and safety. Technology alone will not make patients safer. We must focus on decisionmaking and communication if patients are to be safer.

Defining "Error"

While companies work on developing cutting-edge technologies and health care facilities focus on root-cause analyses and systems of care, Cook and colleagues[5] found that health care workers don't even agree upon what constitutes an error.[*] In the landmark report, *To Err Is Human: Building a Safer Health System,* error is defined as a "failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim"[6] (p. 3). But Cook and colleagues found that nurses, physicians, pharmacists, and administrators don't all embrace this definition. Their findings suggested that the staff may "fail to appreciate complex, less easily categorized" errors. Indeed, many reported that they were reluctant to identify diagnosis and treatment errors as such. In fact, one glaring theme of this research was that nurses' actions can lead to errors, but physicians make "practice variances." These "practice variances" were also referred to as "suboptimal outcomes" or "differences in clinical judgment," not errors. Some of the practice variances or suboptimal outcomes included

- Delays in treatment
- Use of outmoded treatments
- Failure to employ necessary diagnostic tests
- Failure to act on the results of tests
- Errors in administration of treatment
- Failure to communicate with staff and patients

Note that this variance in the definition of error occurred despite respondents reporting that their facilities were genuinely concerned about safety (90 percent of all respondents) and didn't punish people who reported safety discrepancies (94 percent).

Assigning Responsibility for Patient Safety

One conclusion that can be drawn from the study is that nurses are viewed as having the responsibility, but not the authority, for ensuring patient safety. In a prior study, Cook and Hoas[7]

[*] While this was a multimethod study conducted in rural hospitals, reviewers of the paper noted that the findings were consistent with what existed in their regions of the country that were urban and suburban.

found that only 8 percent of physicians viewed nurses as key members of the decisionmaking team in their institutions. And in their 2004 study, Cook and colleagues[5] reported that 96 percent of nurses and more than 90 percent of all others viewed nursing as having primary responsibility for patient safety. How can nurses be responsible for patient safety if they don't feel safe in challenging a physician's order?

Cook and colleagues[5] found that nurses were reluctant to discuss physician "practice variances" or errors with them because of nurses' perceived lack of authority to question the physician, a desire to maintain collegial relationships with physicians, prior experience with being rebuffed by a physician when the nurse questioned a medical practice, and a lack of support from administration when nurses do question or challenge physician practice.

The administrators' views of the situation supported the nurses' perceptions. Administrators believed that administrators had a limited role in questioning medical practice because of their own lack of clinical expertise. "According to many administrators, the responsibility for determining that an error has occurred rests with the physician"[5] (p. 36, 39). And pharmacists concurred that, while they were confident in their ability to recognize errors, they acknowledged that "differences among the four professions concerning definitions of error and scope of practice limit their ability to record problems as errors or initiate procedural changes"[5] (p. 39).

The participants in the study by Cook and colleagues[5] acknowledged that a lack of consensus about what constitutes an error leads to an underreporting of errors. As one nurse participant noted, "The physician told me it's not an error, so we don't need to file an incident report"[5] (p. 40), illustrating the relationship between agreed-upon definitions of error and the willingness to document, correct, or prevent errors. How can safe systems of care be developed to avoid more complex errors involving diagnosis and treatment if physicians define such mistakes as "practice variances" rather than errors, and others are not willing to correct this misconception?

Communication

Interdisciplinary communication is crucial to patient safety. In 1986, Knaus and colleagues[8] reported in the *Annals of Internal Medicine* that nurse-physician communication was the single most important predictor of mortality rates in 13 intensive care units in academic medical centers. But the study did little to prompt a concerted effort to improve such communications. Rosenstein and O'Daniel[9] reported on a convenience survey of 1,500 VHA[†] nurses and physicians. The survey found that 75 percent of respondents had witnessed "disruptive behavior" by physicians, and 68 percent had witnessed such behavior by nurses. Furthermore, 17 percent reported that adverse events occurred as a result of the disruptive behaviors. Some of the participating physicians said that nurses' reports of the patients' conditions are sometimes frustratingly inadequate.[9] On the other side, nurses reported that they will not call abusive physicians about their patients. Consider the following quotes from nurses in this study"[9] (p. 61-62):

- Delay in patient receiving meds because RN was afraid to call the MD.
- Most nurses are afraid to call Dr. X when they need to, and frequently won't call. Their patients' medical safety is always in jeopardy because of this.
- Adverse event related to med error because MD would not listen to the RN.

[†] VHA, formerly Voluntary Hospital Association, is a national consortium of nonprofit hospitals and medical practices.

- RN did not call MD about change in patient condition because he had a history of being abusive when called. Patient suffered because of this.
- RN called MD multiple times re: deteriorating patient condition. MD upset with RN calling. Patient eventually had to be intubated.
- Poor communication post-op because of disruptive reputation resulted in delayed treatment, aspiration, and eventual demise.

The Moral Imperative

Why and how is the moral imperative to act in the best interests of the patient lost in the turf battles and rigid organizational hierarchies that exist in most health care facilities? Health care leaders must come to grips with this question if patients' lives are to be spared and we are to live by the adage of "First, do no harm." These are long-standing issues, but the current focus on patient safety provides nurses with the opportunity to call for, demand, and lead organizational and interdisciplinary changes that will put patients first.

Current initiatives that are focusing on improving team communication, improving patient safety and quality, and ensuring that nurses are at the tables where quality of care and patient safety are discussed—whether within health care facilities, in national patient safety initiatives, or in public policy arenas—are encouraging. For example, the Robert Wood Johnson's Nursing Initiative embraces the idea that nurses are the key to quality. One project under its initiative is Transforming Care at the Bedside (TCAB), a joint project of the foundation and the Institute for Healthcare Improvement that focuses on empowering the bedside nurse in medical-surgical units. Using a rapid-cycle feedback method of quality improvement, interdisciplinary teams at select hospitals have examined interventions to improve the quality of care, such as rapid-response teams to assist nurses on these units to evaluate and intervene appropriately on patients with deteriorating conditions, and color-coded systems to alert administrators when staff are overloaded on a unit to the point of jeopardizing patient safety. For more information on TCAB, go to http://www.ihi.org/IHI/Programs/StrategicInitiatives/TransformingCareAtTheBedside.htm.

While such initiatives are extremely important to the health of nursing and patients, leading changes to promote patient safety requires more than empowering nurses on the unit level. Nurses must be knowledgeable about the factors that lead to errors, be willing to act to fix the problems contributing to the errors, call for public policies that will support safer work environments, conduct research on the compelling questions that touch on nurses' contributions to patient safety, and make personal commitments to modify their own behaviors that may contribute to unsafe care. In this latter case, consider some of the research on nurses' work hours. Rogers and colleagues[10] reported in *Health Affairs* on a study of 363 nurses who volunteered to keep diaries on their workhours and errors. Eighty percent of the nurses reported working longer than their designated shift, with 40 percent of the shifts being more than 12 hours. About two-thirds worked overtime 10 or more times during the 28-day period of data collection, and one-third worked overtime every day. The nurses reported that they committed 199 errors and 213 near errors. In fact, 30 percent reported making at least one error, and 32 percent at least one near error. The researchers found a significant increase in risk of error after 12.5 hours worked, when working more than 40 hours in a week, and when working overtime. While those who volunteered for the study may have been more motivated to report on extended work schedules that were unsatisfactory to them, the study provided beginning data for understanding the relationship between workhours and errors.

In April 2006, Trinkoff and colleagues[11] reported on a work patterns survey of randomly selected nurses in two States funded by the National Institute for Occupational Safety and Health, adding to our understanding of the extent to which nurses are working unsafe hours and schedules. A significant portion of the respondents worked more hours than has been recommended by the Institute of Medicine: 28 percent worked 12 or more hours per day, including 52 percent of hospital staff nurses; 33 percent worked more than 40 hours a week; and 17 percent worked mandatory overtime. Furthermore, 19 percent of respondents worked more than one job. In this group, 37 percent worked 12 or more hours a day, 45 percent worked more than 40 hours a week, and 18 percent worked 6 or 7 days a week.

The Institute for Women's Policy Research[12] notes that hospitals have resorted to unsafe staffing practices (understaffing, overtime, use of contingency workers, and one-time bonuses for new hires) instead of wage increases in response to their inability to recruit sufficient numbers of nurses. Yet nurses who volunteer to work two jobs or extended work hours are associated with fatigue and subsequent errors, compromising patient safety. Nurses must continue to push for institutional and public policies that will support safer work environments, including adequate staffing ratios (for example, through legislating minimum ratios or transparency in public reporting of ratios, and through union contracts that set ratios or require that bedside nurses be involved in staffing decisions), elimination of mandatory overtime, and whistle-blower protections.

Conclusion

The current spotlight on patient safety provides nurses with an opportunity and the moral responsibility to call for changes in health care facilities' policies and operations that we know are detrimental to the safety of patients. The challenge is for all nurses to seize this opportunity. TCAB and other quality improvement initiatives provide nurses with the support and tools for leading changes in their workplaces. Nurse administrators must model leadership behavior if their staffs are to lead on the unit level. Nurses have a moral imperative to act on behalf of their patients. Anything less violates the patient advocacy mantle that we claim as a core nursing role.

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Chapter 20b. [*Vignette*] Who Should Lead the Patient Quality/Safety Journey?

Joanne Disch

Batalden and colleagues[1] remind us that improving quality and safety for patients and families requires leaders to lead—and that the words *leader, leading,* and *leadership* stem from *laitho* or *laithan,* meaning "way," "journey," or "to travel."[2, 3] Much has been written about the need for and characteristics of leadership for this journey.[4–8] This section challenges Chief Nurse Executives (CNEs) to lead the journey and highlights how patients, their families, and health care organizations would benefit immeasurably if CNEs stepped forward and accepted this leadership role. There are many examples across the country where this has been exquisitely demonstrated.

The CNE should lead the journey because the nursing profession has been at the forefront of assuring quality and safety. Before the first Institute of Medicine study,[9] or the *Chicago Tribune* article with the headline "Nursing Mistakes Kill Thousands,"[10] or the National Patient Safety Foundation, or the Institute for Healthcare Improvement, there were nurses at all levels in hospitals and health care organizations concerned about patient safety and quality of care. For decades, nursing leaders like Marie Zimmer and Norma Lang have developed and tested quality indicators. For generations, nurses have taken seriously their Code of Ethics and their role as one who "promotes, advocates for, and strives to protect the health, safety and rights of the patient."[11] Florence Nightingale reminded us that "the very first requirement in a hospital [is] that it should do the sick no harm"[12]—and proceeded to set up systems and practices that are still being used today to enhance the quality and safety of patient care.

The CNE should lead the journey because nurses understand what the issues are. While many physicians, administrators, policymakers, and others have come to realize only recently that health care is frighteningly unsafe, nurses have been raising concerns for many years. Nurses do not need to be alerted to the dangers of malfunctioning equipment, or the likelihood of medication error when getting medications ready and being interrupted 16 times, or the safety threat when orientation to the new computer system is inadequate, or the potential for serious injury to the patient and self when struggling to lift a 287 pound patient. Nurses are there 24/7 and, through the nursing lens, recognize the system issues, dangerous shortcuts, work-arounds, and waste.

The CNE should lead the journey because nurses have workable solutions. We recognize the problems, and we also have solutions. We blend practical wisdom with scientific knowledge and finely-honed interpersonal skills or, as a Boston cab driver once noted, we're "caring, shrewd, and a little bit crazy." We see the big picture and the details—the interconnectedness among departments and professions. We understand everything that needs to be done to complete the job, whatever it is. We are holistic—whether it be caring for a patient in the context of family, or coming up with a solution to a problem that incorporates the concerns of everyone involved. And nurses are resourceful. Who else can coordinate the administration of three antibiotics, two units of packed cells, and four units of platelets; cajole the pharmacist to bring up a missing drug; hunt down the needed blood filter, extra IVAC, flexicare mattress, cardiac chair for a wife; and find a nurse to work an extra 12-hour shift for nights—all within an 8-hour period?

As leaders within their organizations, CNEs have the background, perspective, and platform to help their organizations seriously tackle safety issues that jeopardize patient care and that face nurses and their colleagues daily. They can

- Create a healthy culture that promotes safety, inquiry, continuous learning, and collaboration.
- Design systems and processes that help people do their best work and deliver quality care (safe, timely, effective, efficient, equitable, patient-centered).
- Acquire and align resources to get the work done and achieve organizational goals.
- Assure the existence of a professional practice environment that values evidence as a basis for decisionmaking and the ongoing development of everyone.
- Implement quality and safety programs that are effective, supported, embedded in the culture, and get the job done.

What Are the Barriers to CNEs Taking on This Particular Leadership Journey?

Barriers can exist at the organizational or individual level. These include

- *Organizations* that rely on hierarchical structures with a traditional complement of leaders, and that sustain a culture that resists change and blames individuals for system failures.
- *Organizational leaders* who impose arbitrary solutions and/or weigh financial imperatives more heavily than quality/safety concerns.
- *CNEs themselves* who retreat behind balance sheets and abdicate their role as senior patient care officers and architects for a truly professional practice environment for nurses.

In addition, a number of other factors make this journey difficult, such as a lack of resources, insufficient time, pressures from competing priorities, and the complexity of the health care system.

Evidence and Collaboration Will Enable This Journey To Be Taken Successfully

- **Evidence** that clearly outlines strategies that improve safety and quality while using reasonable levels of resources. The idea that quality is more expensive is wrong, and more is not always better, e.g., when patients get extra doses of medications, or two x-rays when one is ordered, or extra days in the intensive care unit when transfer orders are held up. CNEs can extract excellent, evidence-based strategies from this book and build the business, legal, and ethical case for safety and quality.
- **Collaboration** among nurses, physicians, other care providers, staff, boards of trustees, and organizational leaders who share a passion and commitment for a safer health care experience. The vast majority of individuals in health care want to collaborate, but don't always know how to do it. Most often, the CNE has the knowledge, perspective, and aptitude to skillfully bring people together to achieve common goals— in this case, quality and safety for patients, their families, and caregivers.

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Chapter 20c. [Vignette] Creation of a Patient Safety Culture: A Nurse Executive Leadership Imperative

Victoria L. Rich

Background

In 2004, the Healthcare Leadership Alliance, which includes the American Association of Nurse Executives and other health care executives, identified a core set of competencies for executive leaders in health care.[1] The identified core competencies for nurse executives in health care were: (a) leadership, (b) business skills and principles, (c) communication and relationship management, (d) professionalism, and (e) knowledge of the health care environment. Patient safety is identified as a key element of concern in the health care environment. Within the context of the core five competencies listed above, seven imperatives were identified to develop a patient safety culture: [1]

- To support the development and implementation of an organization-wide patient safety program
- To design safe clinical systems, processes, policies, and procedures
- To monitor clinical activities to identify both expected and unexpected risks
- To support a nonpunitive reporting environment and reward systems for reporting unsafe practices
- To support safety surveys, responding and acting on safety recommendations
- To ensure staff is clinically competent and trained in their roles in patient safety
- To articulate and take action in support of the Joint Commission's National Patient Safety Goals

These imperatives are the necessary building blocks the nurse executive must communicate to foster the development of a culture of proactive patient safety. This vignette will first review the historical background of the evolution of a patient safety proponent. From lessons learned in the redesign of an entire hospital culture, a model "Systemic Mindfulness Model of Proactive Patient Safety" is presented. Using a corkscrew metaphor and systems theory, the model suggests that all levels and professions of the health care culture must become aware and responsible to achieve meaningful medical error reductions. Practical suggestions are then offered, which derive directly from the model for achieving and maintaining a culture of proactive error reduction. The skillful acquisition of the five core competencies and the implementation of the seven patient safety imperatives are necessary for these practical suggestions to be truly effective.

A Culture of Systemic Mindfulness

A systemic mindfulness culture is grounded in professional experience of the vice president of patient care at the University Community Hospital (UCH) in Tampa, Florida, from 1996 to 2002. Prior to this tenure, the sentinel event of wrong-leg amputation in the now-famous case of Willie King occurred in 1995.[2] This patient safety crisis, in concert with the drug overdose death

of Betsy Lehman in Boston in the same year, ignited public and regulatory agencies to question the safety of hospitals.[2] In 1996, the Joint Commission (formerly the Joint Commission for Accreditation of Healthcare Organizations) developed the Accreditation Watch and encouraged the use of root-cause analysis.[3] Subsequently, the Institute of Medicine's 2000 report, *To Err Is Human*, which estimated that 44,000 to 98,000 deaths in hospitals occurred each year due to medical errors, forced the issue of patient safety into public awareness.

The organizational culture of UCH in 1996, 1 year following the Willie King tragedy, was defensive and insular to any outside feedback or systems redesign. Nursing practice was fragmented, and identifying and firing the one employee—usually a nurse—responsible for a medical or nursing error was the way mistakes were handled.

Due to the negative publicity that the wrong-leg amputation created for the hospital, patients were unsure of the care they would be given, and trust by local, State, and Federal health care agencies was at an all-time low. Multiple inspections occurred by the Florida Agency for Health Care Administration, Joint Commission, Health Care Finance Administration, and Federal Drug Administration due to the numerous complaints and accusations. Malpractice claims increased and hospital administrators became adept at giving legal depositions and writing corrective action plans for the above-mentioned regulatory agencies.

Strong beliefs in patient advocacy and safety, in conjunction with a few visionary colleagues, supported the work required to make necessary changes, relying on critical-thinking skills, strong nursing educational background, personal tenacity, and self-reflection. It was not a time to second-guess personal decisions to practice at UCH, but to become part of a culture of change. Doctors, nurses, administrators, and all other employees at UCH seemed truly dedicated to providing safe patient care. Due to the wrong-site event, the culture needed leaders unscathed by the actual 1995 event to assist in reprioritizing basic patient care measures to reestablish the trust of the community. The punitive treatment of the entire hospital community by the regulators and media essentially destroyed the pride and self-confidence of the entire medical and hospital staffs.

To make matters worse, a nurse in the UCH emergency room administered a medication that was contraindicated for a patient with an aspirin allergy, culminating in the patient's death. During this time, the Joint Commission encouraged the use of the root-cause analysis process; hence, UCH was required to conduct one of the first root-cause analyses of a medical error. A root-cause analysis was conducted with key pharmacy personnel and administrators, an approach that was both overwhelming and enlightening. More questions than answers were discovered as a result of the root-cause drill-down process. The Joint Commission provided further direction, and the hospitals' chief operating officer and chief nurse officer were invited to fly to Chicago to discuss questions with the major creator of the root-cause analysis process, Dr. Richard Croteau.

Patient safety science is an important base of knowledge for nursing leadership. Patient safety conferences where Dr. Lucian Leape, Don Berwick, and Michael Cohen and their book, "New Look in Patient Safety," provide important understanding of latent errors and system dynamics in medical errors.[4–7] An important insight into the most salient insight in the journey was that the causes of medical errors were complex and did not occur in any predictable and linear way. Rather, a systems approach to patient safety and the impact of leadership and communication on the safety processes was needed—instead of focusing solely on the one person who presumably made the error. Yet, the scarcity of nursing scholars and executives assuming leadership in the development and design of patient safety science was evident; which may be why physicians, pharmacists, quality officers, administrators, sociologists, and information experts became the pioneers for this new frontier in health care.[8]

The extensive experience gained by the entire UCH multidisciplinary team in the 3 years from 1996 to 1999 culminated in a true success story. The 1999 Joint Commission triennial visit resulted in UCH earning Accreditation with Accommodation with no citations. This achievement remains a career hallmark.

Development of the Systemic Mindfulness Model of Proactive Patient Safety

The experiential journey of managing contradiction, chaos, and complexity in patient safety informed the development of the Systemic Mindfulness Model of Proactive Patient Safety.[9, 10] This model, displayed in Figure 1, resembles a corkscrew and suggests that risk and safety are embedded in all systems of the health care environment, from the blunt end (leadership) to the sharp end (clinical interventions). In addition, the pathway to patient safety risk reduction is not linear. Movement and change in each level of the corkscrew are complex, circular, and continuous.[11, 12] Furthermore, such complex circularity is by nature interdisciplinary in medical systems in which critical safety systems are embedded at each level of the system, and in which each level interacts with other levels, making each turn of the corkscrew an appropriate field of study for the researcher.[10] The goal of the model is to provide a framework for moving a health care culture from a pathological or bureaucratic organization to a generative patient safety culture. Basic definitions are provided for clarification:

- *Systemic mindfulness* is being aware of the current moment-to-moment, lived experience by observing and attending to the changing scope of thoughts, feelings, and sensations. This results in alertness to what is happening in the here and now.[13–16] In the health care genre, systemic mindfulness refers to focused attention at each level of the health care system on how its functions affect patient safety.
- *Blunt end of a system* refers to those people in the organization such as administrators, members of the board of trustees, and health care leaders farthest removed from individual contact with the patient and patient system who nonetheless affect the patient safety processes through policies, technological and economic decisions, and cultural leadership.[5]
- *Sharp end of a system* refers to those who are closest to the moment-by-moment interactions with the patient and the patient's family. Nurses, doctors, pharmacists, technicians of various medical specialties, and support personnel such as dieticians work at the sharp end.[5]
- *Culture* is defined as a system of shared beliefs, values, customs, behaviors, and material objects that interact to produce attitudes and behavioral norms that determine how health care providers do things. Culture includes almost any form of behavior that is learned rather than instinctive or inherited.[17]
- *Generative* or *informed safety culture* exists when bidirectional communication is open and honest, trust exists for all levels of the organization, and messengers are trained and rewarded for improving systems. The system is just in the treatment of employees, reporting of errors is valued, and lifelong learning from mishaps is identified and appreciated.[18–20]
- A *pathological organization* is one in which messengers are reprimanded or ignored, change is extremely difficult, and powerful people are honored.[19, 20]

- A *bureaucratic culture* is highly compartmentalized and failure is known by only a few. Bidirectional communicational processes do not exist.[19, 20]

Figure 1. Systemic Mindfulness Model of Proactive Patient Safety Using a Corkscrew Metaphor

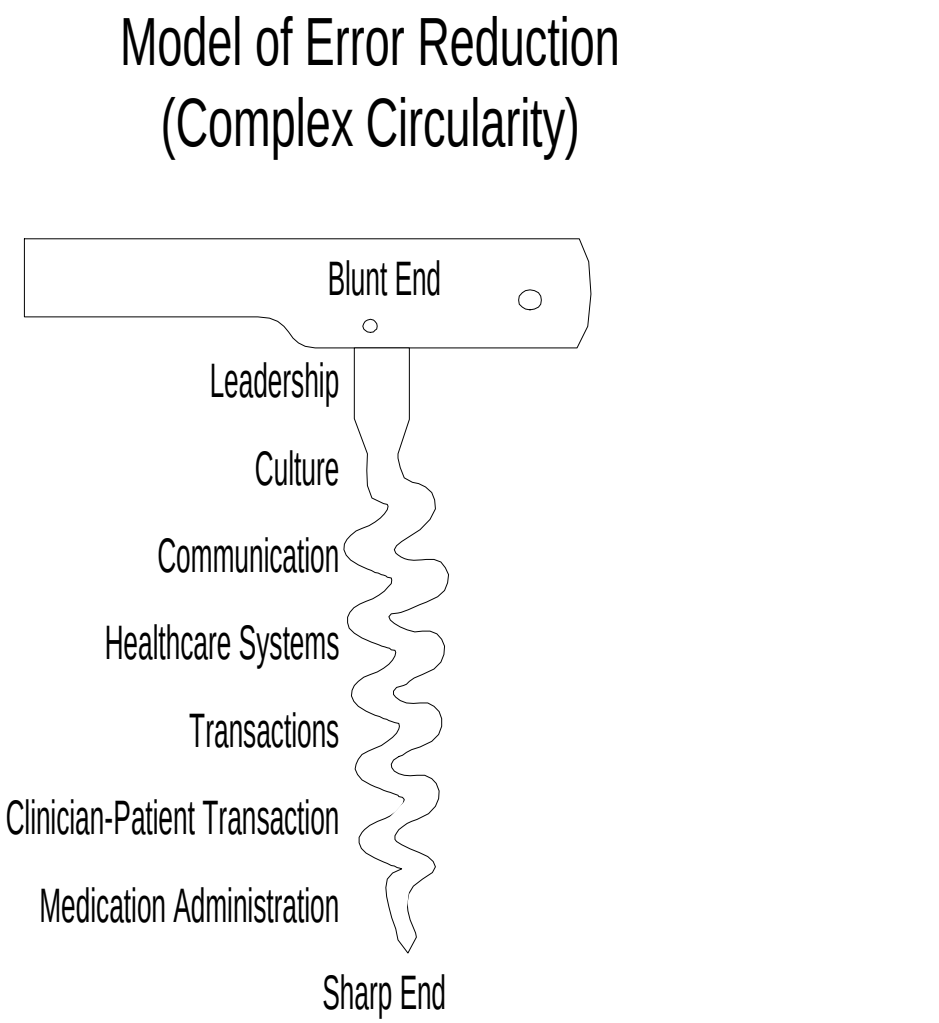

Figure 1. Systemic Mindfulness Model of Proactive Patient Safety Using a Corkscrew Metaphor

The corkscrew metaphor (shown in Figure 1) also signifies that the journey to an error reduction culture is never static, but constantly turning and twisting, and that a steady state of patient safety can never be obtained without a systemic mindfulness value system that holds both the sharp and blunt ends personally and professionally accountable for patient safety. As mentioned, there are seven imperatives that the nurse leader must implement to develop a patient

safety culture.[1] These imperatives must be initiated by the nurse executive leadership and communicated from top to bottom.

However, communication between the blunt and sharp ends of the system must be bidirectional. If nurses feel comfortable reporting near misses in a nonpunitive environment, new communication channels are developed and new practice procedures are put in place by leadership. Moreover, decisions made at one level of the system affect all other levels. For example, a decision to decrease staff made at the leadership level will necessarily affect health care system transactions and nurse–patient interactions by increasing caseloads and responsibilities, and thereby potentially increase medical error risk.[21]

Communication affects health care transactions among health care personnel. For example, it is imperative that the list of a patient's medications that is gathered at admission be communicated effectively to subsequent providers as the patient is transferred between settings and practitioners extending all the way to discharge.[10]

Croteau[22] refers to the general principles of proactive risk reduction necessary at the sharp end of care to mitigate error. Leadership involves staff in the development and implementation of the following principles: (a) retraining and counseling, (b) redoing policies and changing practices, (c) creating redundancy and double checks, (d) putting in fail-safe systems such as backup systems, and (e) purchasing more technological solutions.

In summary, the premise behind the model is that each level identified in the spiral must be addressed and managed to ensure patient safety. A generative culture of systemic mindfulness and professional accountability is imperative at all levels of the system for system-wide effectiveness. This infers that everyone's job is patient safety in all health care system transactions; this safety mission involves the entire health care team, from the nurse and physician to the valet parking attendant.

Handling a Medical Error

A generative culture for nursing is created by the chief nurse executive, mindful of patient safety. Leadership guidelines to adhere to when an error or near miss occurs are as follows:

1. Interview all clinicians involved in the error and be sensitive to not only the overt, explicit information about the experience, but also implicit knowledge such as coping style, fatigue, and personality traits such as attitudes of overconfidence and underconfidence in clinical knowledge.
2. Assess if the error is one of three types: (a) s*kill-based*—occurs when the competency of the nurse is identified as a component of the error, (b) *rule-based*—results from a failure to follow policy and procedure, or (c) *knowledge-based*—due to a knowledge deficit or assumption that known knowledge is correct when it is not.[18]
3. If an error occurs, provide administrative leave with pay during the investigation and offer psychological counseling. Invite the nurse to be involved in the root-cause analysis to express what happened and why. The nurse executive or designee should be present to provide professional support and leadership to all team members. Remember that the involved clinician is often overlooked and can become the second victim. Shame and guilt can become disabling.

The information gained through this process can be used to further explore the latent errors within each level of the system. Nurses learn to use 'work-arounds' and peer support to compensate for poorly designed systems or lack of resources. These 'work-arounds' become

common practice. A hallmark of identifying causes of system errors or near misses is to interview nurse clinicians involved in the mishap about their actual thoughts and resultant behaviors during the time of the event. This process should be accomplished prior to the root-cause analysis so that information obtained can be utilized in remedial actions and self-reflections of the people involved.

Changing and Holding Generative Culture Gains at the Nurse-Patient Transactional Level

There are a number of processes that can be used to retain gains made through the change process that move the culture to one of patient safety. For example, decisions to improve patient safety by leadership must be communicated through each level of the system from leaders in allied professions, to health care transactions among health care professionals, to clinician-patient interactions, to the administration of a specific health care intervention. These changes not only need to be implemented effectively, but also maintained over time in the face of other changes such as staff and nurse manager turnover.

1. Foster a just culture that enables reporting of all errors and rewards actions to proactively avoiding future errors:
    a. Provide opportunities for staff to share near-miss scenarios with one another without breaking patient confidentiality.
    b. Reward nurses who speak up and identify errors or near misses. As a nurse executive leader, it is important to personally meet with staff that speak out and present them with a thank you note and/or a small gift such as movie tickets.
    c. Learn the art of storytelling. Become a raconteur. In nurse executive leadership meetings with staff, tell the story of a root cause, what was discovered and what practice changes are needed. Initiate a bidirectional dialogue with staff to get honest feedback. Validate disparate opinions and explain alternative solutions.
    d. Review, on an annual basis, all root-cause analyses to assure that identified corrective strategies are still in existence and are providing continued safety nets.
    e. Proactively identify unit trends in near misses, nurses' expressed concerns, vacancy and turnover increases, increased patient volume, and acuity. The perfect storm could be brewing.
    f. Administer punishment when willful misconduct, reckless behavior, and unjustified deliberate violation of the rules were significant factors in causing the error.
2. Identify and develop nurses as patient safety experts:
    a. Create employees who function as surveillance and reconnaissance officers who are trained in patient safety principles and are well versed in the Joint Commissions' National Patient Safety Goals. Give these patient safety disciples titles such as "deltas" and provide a formalized structure for ongoing communication, empowerment, and recognition.
    b. Include patient safety functions in everyone's job description.
    c. Consider a patient safety clinical specialist who provides oversight for nurse/patient safety processes such as clinical alarms, code carts, and telemetry outcomes.[23, 24]
3. Ensure staff have the needed tools and resources to improve patient safety:

a. Implement computerized occurrence reporting that is anonymous and easy to complete. Report aggregate data at designated times to determine areas of concern.

b. Spread positive gossip and the rationale for the purchase of new safety equipment or process changes that have been implemented. Include nurses in decisions. Celebrate acquisition of new technologies and changes as key components to creating safe environments for both the patient and nurse.
c. Develop a scorecard for each nursing unit, reporting clinical outcomes and adherence to patient safety goals such as patient identification. Establish achievable targets to share with all staff on a monthly basis.
d. Create evidence-based nurse safety practices that are unit-specific and review and update on a yearly basis with staff.
e. Establish a communication officer for nursing and publish a monthly newsletter that includes patient-nurse safety updates from both internal and external avenues. Circulate to all nursing units the *Institute for Safe Medication Practices* (ISMP) monthly newsletter.[25]
f. Expect new technology to create new, unexpected errors and perform a failure mode and effects analysis prior to implementation or early on in the adoption phase.[26, 27]
g. Invite industry partners to open forum lunches with staff nurses to discuss design and operative concerns of safety devices. Effectuate changes with health care vendors and purchasing agents.

4. Develop clever reminders for nursing staff that validate their importance in safety, both for their patients and themselves. An example is the following message attached to the back of the employee identification badge:

> Mindful Practice
> It doesn't matter how good we are if we are not paying attention.
> - Stop—Stop and become focused on the task at hand.
> - Look—Look and see the uniqueness of the patient.
> - Listen—Listen to what you have been taught about safe patient care.

5. Enable patient safety through effective leadership:
   a. Address in senior leadership lack of professionalism and diminished respect in the workplace. Remember, it takes a village to change a culture.
   b. Provide leadership, direction, and passionate commitment for rapid response team implementation. Communicate successful outcomes to not only nursing and medical staff, but to all stakeholders. Take charge as a nurse executive to promote the successes.[28]
   c. Be the moral conscience for the patient at the senior leadership table, especially if a balance of safety practices and financial imperatives is needed. Sometimes compromise is not acceptable when it concerns patient or nurse safety.
   d. Develop translational research mechanisms and business acumen to effectively articulate the business case for patient safety.

e. Keep informed on technology and innovations in patient safety and support them vehemently if outcomes appear justified.
f. Emulate authentic leadership traits using skilled communication messages of truth, trust, balance, respect, and confidentiality.[29]

6. Enable patients and their families to be part of patient safety improvements:
   a. Invite preselected patients, families, and/or consumers to speak directly to nurses about their perceptions of care given, as well as the lived experience of near misses or medical errors.
   b. Empower patients on admission by giving them safety information regarding issues such as making sure identification bands have correct information, observing and expecting clinicians to wash hands, mark surgery sites, etc.
   c. Remember medical errors are always matters of the heart. Everyone is impacted, not just the patient and family, but the nurse or clinician involved in the error—the second victim.

The development of an informed patient safety culture has evolved since 1995 through the passionate leadership of many stakeholders in both the public and private sectors, including the Joint Commission and the development of its National Safety Goals.[7, 8] However, the health care industry still struggles to gain the trust of patients. Consumer groups are encouraging patients to have a patient advocate accompany them to the hospital.[30]

The patient safety leadership skills identified by the Leadership Alliance for Nurse Executives[1] should be addressed by practicing the strategies described as necessary for creating a generative culture at all levels of the health care system from leadership to the nurse-patient transaction (see Figure 1). Patient safety is dependent upon the safe practices of nurses. Nurse executives must be the moral conscience for the patient and assure that wherever nursing care is practiced, it is practiced with a mindful approach. Nurses must have the time to think critically and not be interrupted or easily distracted. Every newly designed system will never be fail-safe if the nurse does not have time for that final safety net at the sharp end of the care delivery system. The authentic executive nurse leader in the 21st century must lead in spite of contradictions and complexity and build bridges to all stakeholders as we walk on them together.[31]

Research Implications

Despite the advances in the science of patient safety, a significant reduction in the frequency of medical errors has yet to be accomplished.[30] Process enhancements such as double checks, redundancy, and fail-safe procedures, have not led to the elimination of administering the wrong drug or the wrong dose. Research from the field of human factors has shown that attention, perception, and cognition are all fallible. Reality is influenced by expectation. Routines and similarities may result in not being able to recognize differences. Fatigue, stress, and strong emotions such as anger and frustration, affect perceptions and thoughts. The next frontier in patient safety is now researching how human factors affect performance. As such, mindfulness may contribute to preventing common errors of attention and perception, but it is not known whether mindfulness can be a learned skill. Each time a nurse administers a medication, an MRI is performed, and the operating room personnel complete the sponge count, can they learn to bring full awareness to their task?

Another set of questions involves new technology. How will the work of the future nurse be redesigned to assure that barcoding, hand-held devices, bedside computerized documentation,

computerized physician order entry, e-ICUs, smart infusion systems, and voice-activated communication tools are all interconnected to result in a decrease in errors and better patient outcomes? Paradoxically, these strategies may introduce new sources of error.

Conclusion

Well-publicized medical errors during the mid-1990s created a health care crisis involving patient safety. As the public and the profession have become more cognizant of the problem, demands for system redesign to significantly reduce medical errors have occurred. This vignette suggests that it is imperative for all nurse leaders and the chief nurse executive, in particular, to become prime architects in creating a culture of patient safety by employing the core competencies of leadership, communication, professionalism, business skills, and knowledge of the health care environment.

Personal experience in redesigning a hospital safety culture, following a significant medical error, contributed to learning that the science of medical error reduction is complex and involves multiple levels and systems of the health care environment. More specifically, reducing medical errors is not a matter of finding and punishing the one person thought responsible for the error. Rather, chief nurse executives must recognize that medical errors occur because of complex reasons that are not entirely predictable. All departments of the hospital environment with direct or indirect patient contact must be accountable if patient safety goals are to be achieved.

To assist in this process, the Systemic Mindfulness Model of Proactive Patient Safety model suggests using a corkscrew metaphor where each multiple level of the health care system interacts in complex ways to affect patient safety. Decisions made at one level can affect all other levels and alter the dynamics of the patient safety culture. To be effective, all staff need to be aware of their role in the patient safety process and how they can best promote and maintain a patient safety culture.

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Chapter 21. Creating a Safe and High-Quality Health Care Environment

Patricia W. Stone, Ronda Hughes, Maureen Dailey

Background

Maintaining a safe environment reflects a level of compassion and vigilance for patient welfare that is as important as any other aspect of competent health care. The way to improve safety is to learn about causes of error and use this knowledge to design systems of care to "… make errors less common and less harmful when they do occur"[1] (p.78). As a result, researchers, policymakers, and providers have intensified their efforts to understand and change organizational conditions, components, and processes of health care systems as they relate to patient safety.

Health care is the second-fastest growing sector of the U.S. economy, and nursing is the largest occupation within the industry, with more than 2.4 million jobs and the highest projected growth.[2] As noted in recent reports by the International Council of Nursing and the Institute of Medicine, one of the reasons for the current and future shortages of nurses relates to the work environment.[3, 4] Improving the environment in which nurses work may attract new students to nursing as well as engage current professionals in developing innovative models of care delivery that will help retain and nurture future generations of nurses. Most important, improving the work environment may also improve the quality and safety of patient care.

High turnover has been recognized as a problem in many service industries, including health care.[5] In U.S. hospitals, nursing turnover has been reported to range from 15 percent to 36 percent per year.[6] These turnover rates are much higher than those for other health care professionals, which are estimated to average 2.3 percent per year.[7] Past estimates of the cost to replace one medical-surgical registered nurse (RN) range between $30,000 and $50,000; and replacement costs for critical care nurses are closer to $65,000.[8] More recently, Jones[9] estimated the total turnover costs of one hospital-based RN to range from $62,000 to $67,000 depending on the service line. While these cost estimates rely on nurse manager reports of decreased productivity, clearly there are avoidable organizational monetary and human costs related to high turnover of desirable employees. Using multiple databases in an academic medical center, other analysts found the low-end estimate for the cost of employee turnover accounted for greater than 5 percent of the annual operating budget.[10] Clearly, understanding organizational aspects that promote a stable workforce is important.

Besides the obvious harm to patients, preventable adverse health care events related to patient safety have major financial consequences for the patient, the provider, the insurer, and often the family and/or caregivers. Using Agency for Healthcare Research and Quality (AHRQ) patient safety indicators, researchers estimated the excess length of stay for postoperative sepsis to be approximately 11 days at a cost of almost $60,000 per patient.[11] While in some instances there is extra payment made by insurers to hospitals for these adverse events, it has been estimated to be considerably less than the total cost of the resources used.[12] Furthermore, with increased discussions about pay-for-performance and mandatory reporting of certain adverse patient safety events, providers may have increased financial as well as other incentives to

improve patient safety.[13] Therefore, understanding organizational aspects that promote patient safety is also very important.

Throughout the body of patient safety and occupational health literature, authors refer to concepts of organizational climate and culture as well as safety climate and culture. Culture broadly relates to the norms, values, beliefs, and assumptions shared by members of an organization or a distinctive subculture within an organization.[14, 15] Organizational culture is typically thought of as evolving over the course of time and difficult to change. Organizational climate refers to members' shared perceptions of organizational features like decisionmaking, leadership, and norms about work, including opportunities for advancement and collaboration.[16] Organizational climate has been likened to a weather pattern.[17] For example, Clarke[18] pointed out that organizational climate refers to an atmosphere, which is a moveable set of perceptions related to working and practice conditions, many of which can be directly influenced by managers and organizational leaders. There are other microclimates; for example, safety climate is the current landscape of employees' perceptions and attitudes about safety, such as state of current safety initiatives and safety behaviors.[19]

Additionally, a number of safety climate scales have been developed in the fields of occupational health and patient safety. In occupational health, attributes of a safe climate in hospitals have been found to include senior management support for safety programs, absences of hindrances to safe work practices, availability of personal protective equipment, minimal conflict, cleanliness of work site, good communication, and safety-related feedback.[20] A positive safety climate has been significantly correlated to reduced risk of work injury and exposure.[20] In patient safety, attributes of a safe hospital environment have been identified as a positive work environment, supportive supervisor/manager, improved interdisciplinary communications, and increased safety event reporting.[21] Obviously these microclimates overlap. Additionally, they should be synergistic and correlate with the overall organizational climate. Indeed, a positive organizational climate is most likely an essential antecedent to the development of a strong safety climate.

As part of AHRQ's The Effect of Health Care Working Conditions on the Quality of Care research portfolio (RFA HS-01-005), a team of interdisciplinary scholars developed a model depicting aspects of organizational climate and their relationship to worker and patient outcomes.[22] These investigators tested the model in various settings (i.e., ambulatory care, home health, long-term care, Veterans Health Administration facilities, and acute care hospitals) and identified important organizational structures (leadership and infrastructure) and processes (supervision, work design, group behavior, and quality/safety emphasis). Using this model as the organizing framework, this chapter reviews the evidence examining the impact of organizational climate on patient and employee outcomes. It is important to note that we are focusing on the broad concept of organizational climate. Another chapter in this volume focuses specifically on safety culture and climate. Based on the evidence on organizational climate and the relationships with patient outcomes, job satisfaction, and turnover, we have developed a new conceptual model of organizational attributes and outcomes.

Research Evidence

Overall 14 studies were reviewed. In four of the published studies, the researchers focused only on patient outcomes,[23–26] with one of the teams reporting the results related to worker turnover and job satisfaction in other publications.[27, 28] Two of the research teams published

results related to patient outcomes and worker outcomes in single manuscripts.[29, 30] The majority of the manuscripts reviewed focused on worker outcomes. In the following section, the studies focusing on organizational climate and patient outcomes are synthesized, followed by a synthesis of the evidence linking organizational climate with turnover and job satisfaction.

Organizational Climate and Patient Outcomes

Table 1 describes the primary research (six studies) found investigating organizational climate and patient safety outcomes. The attributes of organizational climate measured varied. Some researchers focused on quality,[23] measures of morale, and consensus of depersonalization,[24, 29] while others used a composite organizational climate measure, which focused on nurses' perceptions of the work environment.[25] The patient outcomes were also varied and specific to the setting. For example, in one study the measure of patient safety was nurse-reported medication errors;[24] another research team measured self-report service quality.[29] All other research teams used some form of existing administrative data to measure patient safety outcomes, with one team using clinical and laboratory data elements collected for participation in the Centers for Disease Control and Prevention's National Healthcare Safety Network.[25] The National Safety Network hospitals collect standardized nosocomial infection data. The settings studied also varied across projects and were primary care sites, rural hospitals, outpatient social services, specialized hospital settings (e.g., emergency departments and intensive care units) and the Veterans Health Administration. All studies used cross-sectional designs with the exception of one group reporting on the evaluation of a quality-improvement project.[23] Despite these varying measurement issues, settings and populations, and research designs, positive organizational climates were generally found to improve patient safety.

Organizational Climate, Turnover, and Job Satisfaction

Table 2 provides the results of the current evidence found examining the relationships among organizational climate and worker outcomes (i.e., turnover and job satisfaction). Ten studies were found, half of which included both job satisfaction and turnover. Again, the organizational climate attributes varied from morale to composite measures of organizational climate.[28, 30] The study populations were mainly nurses (60 percent), but outpatient caseworkers and mental health providers were also studied. Most studies (80 percent) were conducted in the United States, but nurses employed in Australia,[31] Begium,[32] and Hong Kong[33] were also studied. The majority of the studies were cross-sectional, with only one pre-post test intervention study.[34] All of the researchers reported that positive organizational climates were related to increased worker satisfaction. The results related to turnover were not quite as strong, and researchers in one study found that job satisfaction mediated the effect of organizational climate on turnover.[35]

Evidence-Based Practice Implications

Overall, there is an emerging evidence base pointing to the need for positive organizational climate. For the most part, the research findings were consistent; patient and employee outcomes were affected by organizational climate. However, the strength of the relationship between organizational climate and job satisfaction was stronger than the relationship between organizational climate and turnover. Furthermore, the evidence base regarding organizational

climate and patient safety outcomes was scant, with only six studies found, and only three of those studies focused on patients in acute care settings. Despite these limitations, the consistency of the findings point to the importance of organizational climate on patient and employee outcomes.

Based on this review and our previous work,[22] we developed the conceptual model displayed in Figure 1. The structural characteristics of the setting may serve as enabling factors for outcomes. These first and foremost include senior leadership. Other important enabling factors are related to the infrastructure (such as technology available) and communication systems. We call these enabling factors structural characteristics because they are not easily changed. These enabling factors influence the settings' microclimates, which may be grouped into three main foci: employee/staff, patient, and organizational. It is important to understand these microclimates are not conceptualized as mutually exclusive or independent. We believe these microclimates interact with each other and are synergistic. For example, a setting that focuses on occupational safety may also focus on evidence-based, patient-centered care; additionally, collaboration and communication among providers and patients may be important shared components of each microclimate. The microclimates influence the actions of the staff, patient, and often the family and/or caregivers, which in turn have an impact on the outcomes. Again, the outcomes are conceptualized at three different levels: the employee, the patient, and the organization. The list of specific outcomes under each category is representative of the category, but it is not exhaustive. For more complete lists of patient safety outcomes, the reader should refer to AHRQ's Patient Safety Indicators and the National Quality Forum's consensus standards for nursing-sensitive care.[36, 37]

Based on the literature reviewed and the conceptual model developed, there are a number of practice recommendations at all levels of nursing (e.g., nursing leaders, nurse managers, staff nurses, and educators). The existence of a relationship between a positive organizational climate and both worker and patient outcomes means that facilities need to be aware of the importance of assessing and periodically reassessing the climate within their organization. There are published reviews of instruments used to assess organizational climate.[38] Additionally, data regarding the climate should be correlated with outcomes along all three of the foci (employee, patient, and organizational).[39] The recommended frequency of conducting these analyses is not clear, but such assessment and reassessment should be part of a continuous quality-improvement process, and it seems reasonable that employee surveys should be conducted at least annually. Nurse educators need to develop and evaluate safety and leadership curriculum.[40, 41] Additionally, as we rapidly increase the information technology available in health care, we must ensure that this infrastructure promotes patient safety, increases efficiency, and contributes to nursing knowledge.[42]

Nursing leaders and managers need to be cognizant of the job satisfaction of all employees on an ongoing basis, specifically as low satisfaction can be linked to burnout, intention to leave, and even higher rates of job turnover or loss to the nursing profession (i.e., early retirement or transfer to another career). With the high costs of nursing turnover, efforts to increase job retention levels are likely to be financially beneficial.[9, 10]

Despite the scant evidence linking organizational climate—broadly defined—and patient safety, the evidence supporting the significant relationship between a climate of safety—a specific component of organizational climate—and patient safety is growing, given increased utilization of safety climate surveys. (This is discussed further in the next chapter.) It is likely then that development and utilization of readily available tools to assess organizational climate

will expand the evidence base and provide key information to leaders and managers to improve job satisfaction, interdisciplinary teamwork, and retention, ultimately improving the quality of health care delivery. Indeed, the usefulness of this information would likely be considerably improved if it were linked with ongoing patient-safety monitoring and quality-improvement activities within the organization. Organizational climate is more malleable and open to change than the more-entrenched aspects of culture. Thus, data-driven leaders can be proactive by assessing both worker perceptions and outcomes to ensure safety processes are adhered to more consistently (i.e., less violations or work-arounds); this should improve all outcomes. For staff and future staff, nurses' job satisfaction is key to not only providing quality care, but to having lower levels of occupational stress and higher levels of occupational safety, both of which are discussed in other chapters within this book.

Research Implications

This review identified a number of gaps in the research evidence. First and foremost, as interventions are developed to improve the organizational climate, rigorous research and evaluation studies need to be conducted. It is important to note, however, that this type of research will not often lend itself to randomized controlled trials. Other epidemiological designs that control for confounding variables and ensure comparability between groups will most likely be needed. Second, future research aimed at understanding the impact of human capital variables (i.e., stability of the workforce, education, etc.) on patient outcomes and system efficiencies is warranted. Furthermore, consistency in measurement tools would help advance the field and assure that study results are more consistent and comparable.

Lastly, more cost analyses need to be conducted to make the business case for improving the organizational climate in nurses' work environment and improving patient, employee, and organizational outcomes. The model provided presents various aspects of organizational climate that may be measured in different research projects, across a research portfolio, and in various settings. It is doubtful that any one study would include all aspects presented in this model. Rather, the researcher may use this model to select the organizational aspects and outcomes most appropriate to their research aims.

Organizational climate is one of the overarching aspects found in the work environment. However, it is not the only aspect related to patient safety and worker satisfaction and turnover. Other environmental aspects include actual workload, such as nurse-to-patient ratios in acute and long-term care and caseloads in outpatient settings; scheduled work hours (e.g., shift length, nights versus days); mandatory overtime; information systems for decision support to prevent errors of commission and omission; and human factor engineering solutions. The impact of these other aspects of the work environment is discussed elsewhere in this volume.

There are both strengths and limitations to this review. In our search for evidence we attempted to be comprehensive. However, we may have missed some studies. Additionally, only primary studies published in English after the year 2000 were audited.

Conclusion

Gradually, evidence is accumulating that links work environments to behavior, attitudes, and motivations among clinicians. These behaviors and orientations can, in turn, affect quality processes and outcomes. A growing number of studies in health care show that members of

organizations are more satisfied when they work in climates that have more supportive and empowering leadership and organizational arrangements, along with more positive group environments (often reflecting elements of group support and collaboration). Moreover, although the research base is not as strong, there is emerging evidence that these same organizational attributes impact employee turnover and, most important, patient safety. Improving the organizational climate is likely to improve patient safety and decrease overall health care costs. However, future research studying specific interventions and their cost effectiveness is needed.

Search Strategy

A systematic review of the literature was conducted focusing on relationships among organizational climate and three outcomes: patient safety, nurse turnover, and job satisfaction. Medline and AHRQ's Patient Safety Network (PSNET: www.psnet.ahrq.gov) searches were conducted using the key word "organizational climate," then cross-referenced with "patient safety" and "patient outcomes," "satisfaction," as well as "turnover" and "intention to leave." More than 200 titles were examined. Abstracts were examined by two nurse researchers if the article was published in 2000 or after, written in English, and pertained to health care organizations. Manuscripts were obtained and reviewed if they were primary reports of research findings. Editorials were excluded. Reference lists were also reviewed for key articles.

Publications that presented primary research findings and had sample sizes of greater than 30 respondents were organized into two tables presenting evidence on the relationships between organizational climate and (1) patient outcomes, and (2) worker satisfaction and retention of workers. Each study was audited for the following elements: the organizational climate attributes studied, the design type, the outcome measures (patient or worker), study setting and population, study intervention, and key findings. All studies were reviewed by two authors. Following the guidelines put forth by AHRQ, the study design types were categorized using the "type of evidence" criteria.

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Evidence Table 1. Organizational Climate and Patient Outcomes

Source	Organizational Climate Attributes	Design Type	Patient Safety Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cretin 2001[23]	Importance of improving quality of care, current status in quality improvement, climate for guideline implementation, attitude toward practice guidelines, and motivation for guideline implementation	Quality improvement projects/ research	Primary care followup, physical therapy or chiropractic care, specialist care	U.S. Army Medical Department: 4 facilities in the Great Plains Region served as demonstration sites, and there were 5 comparison facilities. 31,273 new low-back pain patients	Integrated model guideline implementation system: Evidence-based practice guidelines, education/training, toolkit, and interdisciplinary team approach	Significant downward trend in the percentage of the patients referred to physical therapy/chiropractic care (10.7%–7.2%) at demonstration sites as compared to comparison sites. No discernable reduction in specialty care referrals or primary care followup visits at the demonstration sites as compared to comparison sites.
Fogarty & McKeon 2006[24]	Workplace morale, supervisor leadership, participative decisionmaking, role clarity, professional interaction, appraisal and recognition, professional growth, goal congruence, workplace distress, and excessive work demands	Cross-sectional study	Medication error index	11 rural hospitals in Australia 176 nurses	Not applicable	Self-report medication errors positively correlated to composite measure of organizational climate ($r = 0.75$, $P \leq 0.01$). However, this relationship was mediated by health care worker psychological well-being, and distressed employees were more likely to report medication errors.
Glisson & James 2002[29]	Employee consensus of depersonalization, emotional exhaustion, and role conflict	Cross-sectional study	Service quality measured by perceptions of case managers	33 child welfare and juvenile case management teams in 30 counties (4 urban and 26 rural) in 1 southeastern State in the U.S.	Not applicable	Case managers and teams with more constructive cultures reported a higher service quality ($P \leq 0.05$); organizational climate was not significantly related to service quality.

Source	Organizational Climate Attributes	Design Type	Patient Safety Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Stone 2007[25]	Composite measure of organizational climate	Cross-sectional study	Central line bloodstream infections (CLBI), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infections (CAUTI), 30-day mortality and decubiti (pressure ulcers)	51 adult intensive care units in 31 U.S. hospitals 15,902 patients 1,095 nurses	Not applicable	Results were inconsistent. Organizational climate was significantly positively related to CLBI and significantly negatively related to CAUTI ($P \leq 0.05$).
Warren 2007[30]	Organizational climate as measured by 4 metafactors: employee focus, support, professional demands, and pay satisfaction	Cross-sectional study	1. Management of 2 chronic diseases (diabetes and chronic obstructive pulmonary disease [COPD]) 2. Prevention Index (PI): Summary of prevention care delivery (vaccination, tobacco prevention, disease, and risk factors screening) 3. Surgical outcomes using the National Surgical Quality Improvement Program (NSQIP) measures postsurgical morbidity and mortality	74,662 employees from the U.S. Veterans Health Administration	Not applicable	Positive associations between employee focus and COPD, diabetes, and prevention index ($P \leq 0.05$).

Source	Organizational Climate Attributes	Design Type	Patient Safety Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wright 2003[43]	Fairness and equity, role ambiguity, role overload, role conflict, workgroup cooperation and facilitation, growth and advancement, job satisfaction, emotional exhaustion, personal accomplishment, and depersonalization	Cross-sectional study	Frequency of staff members' clinical work with patients with psychiatric problems	1 general hospital emergency department (ED) in a U.S. urban Midwest location 131 ED staff (medial, nursing, and psychiatric workers)	Not applicable	Workgroup cooperation and facilitation is positively associated ($P \leq 0.05$) with frequency of clinical work with patients.

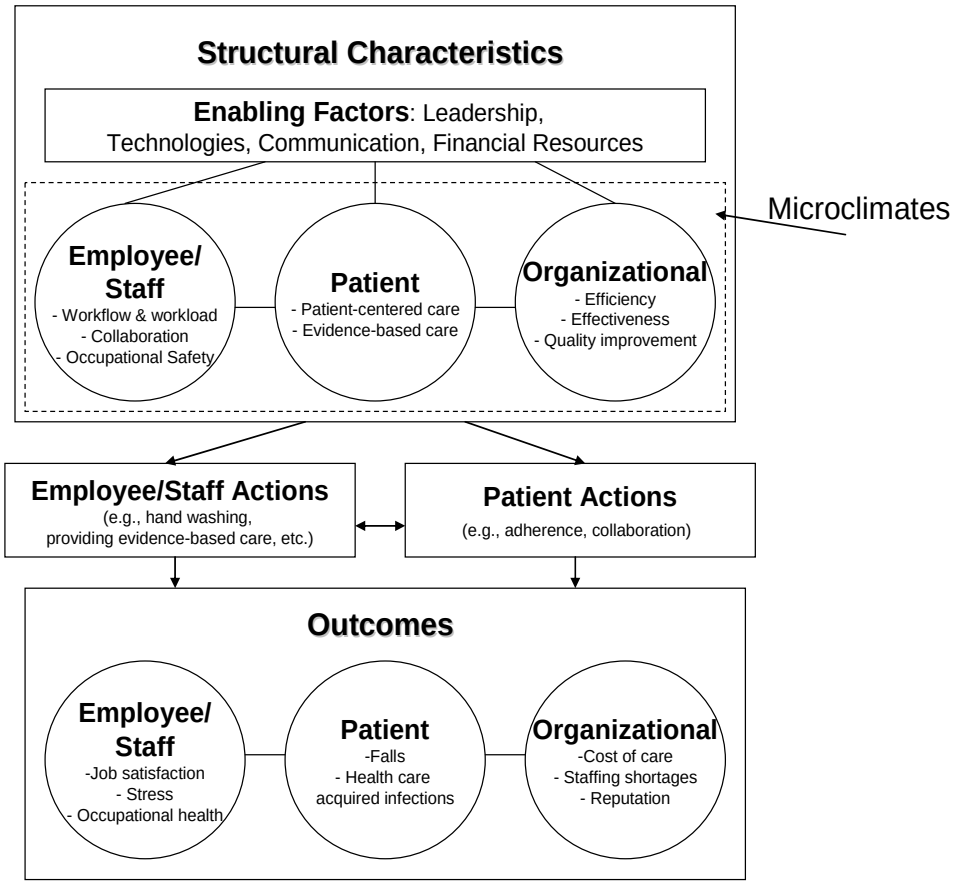
Evidence Table 2. Organizational Climate and Worker Outcomes

Source	Organizational Climate Attributes	Design Type	Worker Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Aarons & Sawitzky 2006[35]	Demoralizing climate	8	Job satisfaction, 1-year turnover	322 pediatric, adolescent, and family mental health providers in 49 public sector programs in California	Not applicable	The effect of organizational culture on job satisfaction and other work attitudes was partially mediated by the organizational climate in structural equation modeling. Worker attitudes significantly predicted turnover 1 year later.
Albion 2003[44]	Workplace morale, supervisor leadership, participative decisionmaking, role clarity, professional interaction, appraisal and recognition, professional growth, goal congruence, workplace distress, and excessive work demands	4	Job satisfaction, intention to leave	1,097 regional Health Service District employees in Australia	Not applicable	Nurses reported lower organizational climates on all scales except professional interaction ($P < 0.05$). Nurses reported significantly lower job satisfaction than administrators, medical professionals, or operational staff. Nurses working in large hospital reported significantly lower job satisfaction and higher intention to leave ($P < 0.05$).
Dunham-Taylor 2000[45]	Transactional leadership, laissez-faire leadership	4	Staff satisfaction	396 nurse executives and 1,115 staff who report to them	Not applicable	Staff satisfaction in the workplace was correlated with transformational leadership ($r = 0.79$, $P < 0.0001$). Staff satisfaction decreased as staff rated the leader as being more transactional ($r = 0.37$, $P < 0.0001$) or using a more laissez-faire leadership style ($r = 0.71$, $P < 0.0001$).
Glisson 2006[34]	Depersonalization, emotional exhaustion, role conflict, and role overload	6	Turnover	235 caseworkers and 26 case management teams that provide child welfare and juvenile justice services	Availability, responsiveness, and continuity (ARC) intervention	In hierarchical linear models analyses, it was found that the ARC intervention reduced turnover by 2/3 and improved organizational climate.

Source	Organizational Climate Attributes	Design Type	Worker Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Glisson & James 2002[29]	Employee consensus of depersonalization, emotional exhaustion, and role conflict	4	Job satisfaction, 1 year turnover	33 child welfare and juvenile case management teams in 30 counties (4 urban and 26 rural) in 1 southeastern State in the U.S.	Not applicable	Case managers and teams with more constructive cultures experienced lower turnover rates ($P \leq 0.05$); organizational climate was not significantly related to turnover. Organizational climate was significantly positively related to job satisfaction.
Siu 2002[33]	Organization, immediate upper level, coworkers, involvement, flexibility, work environment, and well-being	4	Job satisfaction	Two separate samples of Hong Kong nurses sample 1: 144 nurses sample 2: 114 nurses	Not applicable	Findings were not consistent across samples. In sample 1, environment was significantly correlated with satisfaction. In sample 2, well-being was a significant predictor of job satisfaction.
Stone 2006[27]	Professional practice, staffing/resource adequacy, nurse management, nursing process, nurse/physician collaboration, nurse competence, and positive scheduling climate	4	Intention to leave	2,323 registered nurses from 66 hospitals and 110 critical care units	Not applicable	Organizational climate factors that had an independent effect on ICU nurse intention to leave due to working conditions were professional practice, nurse competence, and tenure ($P < 0.05$).
Stone 2007[28]	Composite measure	4	Intention to leave	837 nurses employed in 39 adult critical care units from 23 hospitals		Organizational climate is an important determinant of intention to leave. Higher wages did not reduce these intentions; therefore, it was concluded that increased pay alone without attention to organizational climate is likely insufficient to reduce nurse turnover.

Source	Organizational Climate Attributes	Design Type	Worker Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Stordeur 2006[32]	Meaning of work, relationships with nursing management, relationships with team, relationships with doctors, relationships with administration, quality of leadership, social support from superior, social support from colleagues, days dedicated for professional development, satisfaction with handover shifts	4	Intention to leave, job satisfaction	2,065 registered nurses in 12 Belgian hospitals	Hospitals with high and low turnover were compared	Relationships with nursing management; work ability; and satisfaction with working time, handover shifts, and schedules were also better in attractive hospitals ($P < 0.001$). Job satisfaction and commitment were higher in attractive hospitals, whereas intention to leave was lower ($P < 0.001$).
Warren 2007[30]	Organizational climate as measured by 4 metafactors: employee focus, support, professional demands, and pay satisfaction	4	Intention to leave, job satisfaction	74,662 employees from the Veterans Health Administration	Not applicable	Employee focus was most strongly associated with job satisfaction, and support was negatively associated with turnover intention ($P < 0.05$).

Figure 1. Conceptual Model of Organizational Attributes and Outcomes



Chapter 22. Practice Implications of *Keeping Patients Safe*

Ann E. K. Page

Background

Improving patient safety and other dimensions of health care quality requires change at all four levels of the health care system: (1) the experience of patients during their interactions with individual clinicians; (2) the functioning of small units (microsystems) of care delivery such as surgical teams or nursing units; (3) the practices of organizations that house the microsystems; and (4) the environments of policy, payment, regulation, accreditation, and other factors external to the actual delivery of care that shape the context in which health care organizations deliver care.[1] Several groundbreaking Institute of Medicine (IOM) reports have spurred substantial actions at each of these levels to bring about improvements in patient safety and overall quality.

These IOM reports began as the product of the unique Committee on the Quality of Health Care in America created by the IOM in 1998 in response to the accumulating number of studies documenting that the way in which health care has been delivered has not kept pace with the advances in medical technology and our growing knowledge about diseases and how to effectively treat them. The committee's first report, *To Err Is Human*, was stunning. This report documented that not only was health care often of poor quality, it was actually unsafe. The report said that between 44,000 and 98,000 deaths every year (more than deaths from breast cancer, AIDS, or motor vehicle accidents) were caused by problems in the way the health care system was designed, not from "bad" doctors, nurses, or other health care workers.[2]

The report's message and recommendations for building safer systems of care delivery across the entire U.S. health care system primarily addressed the changes needed at the fourth level of the health care system—where policy, payment, regulation, accreditation, and similar external factors shape the delivery of health care.[a] Within weeks of the report's release, the Senate Committee on Appropriations began hearings on medical errors and patient safety.

As a result of those hearings, Congress directed the Agency for Healthcare Research and Quality (AHRQ) to lead a national effort to combat medical errors and improve patient safety. AHRQ subsequently established a research and demonstration program to fund research to determine the causes of medical errors and to develop models that minimize the frequency and severity of errors; mechanisms that encourage reporting, prompt review, and corrective action; and methods to minimize paperwork.[3]

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[a] The Committee's second report, *Crossing the Quality Chasm—A New Health System for the 21st Century*, addressed health care quality in all its dimensions: effectiveness, timeliness, patient centeredness, efficiency, and equity (in addition to safety). *Crossing the Quality Chasm* generally spoke to the first and second levels of the health care systems—the experiences of patients with their individual clinicians and the microsystems of care delivery. *To Err Is Human* and *Crossing the Quality Chasm* both directed less attention to the third level—health care organizations.

Nurse Working Conditions

Nursing personnel represent the largest component of the health care workforce. Licensed nurses and unlicensed nursing assistants represent approximately 54 percent of all U.S. health care workers (e.g., physicians, nurses, dentists, allied health professionals, technicians and technologists, and other health care assistants).[4] Registered nurses (RNs) alone constitute approximately 23 percent of the entire health care workforce—the largest portion among all health care workers. These 2.2 million RNs provide health care to individuals in virtually all locations in which health care is delivered—hospitals; long-term care facilities; ambulatory care settings, such as clinics or physicians' offices; and other settings, including the private homes of individuals, schools, and workplaces. In U.S. hospitals, approximately one of every four hospital employees is a licensed nurse.[5] Although constituting the largest contingent in the health care workforce, nurses are in short supply and competition for them is strong.

As part of its portfolio of research and demonstrations, AHRQ contracted with the IOM to study key aspects of the work environment of nurses that likely impact patient safety and identify potential improvements that would likely increase patient safety. AHRQ further directed the IOM to address three issues that have received much attention in Federal and State policy arenas: extended work hours and fatigue, mandatory overtime, and regulation of nurse staffing levels.

The report produced by the IOM in response to this charge, *Keeping Patients Safe: Transforming the Work Environment of Nurses*,[6] is significant for three reasons:

1. It documents the key role that nurses (the largest component of the health care workforce) play in patient safety and makes specific recommendations for changing their work environments to improve patient safety.
2. It highlights the role that an organization's governing boards, executive leadership, other management personnel, and practices play in patient safety by shaping organizational work environments.
3. It identifies generic workplace processes and characteristics that threaten or protect patient safety, not just with respect to nurses' actions, but by affecting the actions of all health care practitioners.

Keeping Patients Safe's recommendations are addressed to those parties that most directly shape work environments: health care organizations, Federal and State regulators, labor organizations, as well as other leaders in health care and nursing education. (The recommendations are reproduced in the section below, "Recommendations for Promoting Patient Safety in the Work Environments of Nurses.") However, individual nurses can also use the recommendations of this report to improve work environments in ways that keep patients safe from errors in their health care. The evidence presented in *Keeping Patients Safe* identifies factors that all nurses should take into consideration in selecting the health care organization in which to be employed, in participating in labor-management discussions, and in interacting in their employing organizations' efforts to reduce health care errors.

Practice Implications

Keeping Patients Safe identifies eight overarching safeguards to protect patient safety that need to be in place within all health care organizations in which nurses work: (1) organizational governing boards that focus on safety; (2) the practice of evidence-based management and leadership; (3) effective nursing leadership; (4) adequate staffing; (5) provision of ongoing

learning and clinical decisionmaking support to nursing staff; (6) mechanisms that promote interdisciplinary collaboration; (7) work design practices that defend against fatigue and unsafe work; and (8) a fair and just error reporting, analysis, and feedback system with training and rewards for patient safety (see Table 1).

Table 1. Necessary Patient Safeguards in the Work Environment of Nurses

Governing Boards That Focus on Safety
- Are knowledgeable about the link between management practices and patient safety.
- Emphasize patient safety to the same extent as financial and productivity goals.

Leadership and Evidence-Based Management Structures and Processes
- Provide ongoing vigilance in balancing efficiency and patient safety.
- Demonstrate and promote trust in and by nursing staff.
- Actively manage the process of change.
- Engage nursing staff in nonhierarchical decisionmaking and work design.
- Establish the organization as a "learning organization."

Effective Nursing Leadership
- Participates in executive decisionmaking.
- Represents nursing staff to management.
- Achieves effective communication between nurses and other clinical leadership.
- Facilitates input from direct-care nursing staff into decisionmaking.
- Commands organizational resources for nursing knowledge acquisition and clinical decisionmaking.

Adequate Staffing
- Is established by sound methodologies as determined by nursing staff.
- Provides mechanisms to accommodate unplanned variations in patient care workload.
- Enables nursing staff to regulate nursing unit workflow.
- Is consistent with best available evidence on safe staffing thresholds.

Organizational Support for Ongoing Learning and Decision Support
- Uses preceptors for novice nurses.
- Provides ongoing educational support and resources to nursing staff.
- Provides training in new technology.
- Provides decision support at the point of care.

Mechanisms That Promote Interdisciplinary Collaboration
- Use interdisciplinary practice mechanisms, such as interdisciplinary patient care rounds.
- Provide formal education and training in interdisciplinary collaboration for all health care providers.

Work Design That Promotes Safety
- Defends against fatigue and unsafe and inefficient work design.
- Tackles medication administration, handwashing, documentation, and other high-priority practices.

Organizational Culture That Continuously Strengthens Patient Safety
- Regularly reviews organizational success in achieving formally specified safety objectives.
- Fosters a fair and just error-reporting, analysis, and feedback system.
- Trains and rewards workers for safety.

Source: Committee on the Work Environment for Nurses and Patient Safety, 2004[6]**:** pages 16-17. Reprinted with Permission.

Keeping Patients Safe's 18 recommendations describe actions health care organizations, governmental policymakers, labor organizations, and other leaders in health care and nursing should take to promote patient safety in nurse work environments. While not directed principally

to individual nurses in clinical practice, the recommendations also can be used by nurses to leverage improvements in patient safety. Specifically, the recommendations have corollary questions (presented in Table 2) that nurses should ask of prospective and current employers.

Table 2. Questions Nurses Should Ask Prospective (and Current) Employers About Patient Safety

Governing Boards That Focus on Safety

1. What are the organization's most recent statistics on patient care errors, near misses, and adverse events?
2. How long has the organization been measuring these, and what do the trends show?
3. What activities does the organization have underway to improve patient safety, and what are the quantitative results of these initiatives to date?
4. Does the governing board review results of measurement of patient safety? How frequently?

Evidence-Based Management Structures and Processes

5. What mechanisms does the organization have in place to enable it to function as a "learning organization," i.e., to internally create and acquire from external sources new knowledge of better health care practices, distribute this knowledge throughout the organization, and change its policies and practices to reflect this new knowledge?

Effective Nursing Leadership

6. What person in the organization represents clinical nursing staff to the organization's governing board and management? What percent of this person's time is dedicated to improving clinical nursing care? Is this person a nurse? Of what senior management structures is this person a part?
7. How much funding and other organizational resources does nursing leadership have in its budget to support nurses' acquisition of knowledge?
8. To what nursing manager will the position in question report? What are the responsibilities of this nurse manager, and what portion of the nurse manager's time is generally spent in each of these responsibilities? What proportion of the nurse manager's time is spent providing supervisory and managerial support to clinical staff? How much time does the nurse manager spend providing direct patient care to his or her assigned caseload?

Adequate Staffing

9. What methods does the organization use to determine safe nurse staffing levels? Can you get a copy of the methodology?
10. What input do clinical nurse staff have in reviewing and modifying the staffing methodology? How frequently are the methodology and its assumptions reviewed?
11. Does the organization count admissions, discharges, and "less than full-day" patients (in addition to a census of patients at a point in time) in its estimates of patient volume for projecting staffing needs?
12. What mechanisms does the organization use to quickly secure additional staffing when need for nurse staffing is higher than anticipated—e.g., an internal float pool, use of staff from external agencies, staffing at higher levels to provide "slack" in the system, other mechanisms? Does the organization avoid use of nurses from external agencies?
13. What roles does clinical nursing staff have in determining admissions and discharges to the unit?
14. What is the nurse turnover rate for the organization? How is this calculated?
15. If an acute care hospital, what are the nurse-patient staffing levels in the intensive care units (ICUs)?
16. If a long-term care facility, is there at least one RN in the facility around the clock, seven days a week?

Organizational Support for Ongoing Learning and Decision Support

17. How does the organization support new graduate nurses and nurses new to the organization? Does it assign preceptors? How long is orientation?
18. What percent of the organization's nursing payroll is dedicated to the ongoing acquisition and maintenance of knowledge of the nursing staff?
19. To what extent does the organization annually ensure that each licensed nurse and nurse assistant has an individualized plan and resources for their educational development?
20. What types of decision support technology does the organization provide to nursing staff?
21. Does the organization use an electronic health record (EHR)? Does the EHR include decision support?

Mechanisms That Promote Interdisciplinary Collaboration

22. What mechanisms (such as interdisciplinary patient care rounds) does the organization have in place to promote interdisciplinary collaboration?
23. Does the organization provide formal education and training in interdisciplinary collaboration for all health care providers?

Work Design That Promotes Safety

24. What are the organization's policies with respect to nursing work hours? Do they prevent direct-care nurses from working longer than 12 hours in a 24-hour period and in excess of 60 hours per 7-day period under both voluntary and mandatory work hours?
25. Has the organization undertaken initiatives to design or redesign the work environment and care processes to reduce errors? What care processes did these initiatives address? Did the design of these efforts directly involve direct-care nurses?
26. Has the organization undertaken initiatives to improve hand washing and the safety of medication administration? When were they conducted and what were the results?

Organizational Culture That Continuously Strengthens Patient Safety

27. What are the organization's short- and long-term safety objectives?
28. How and how frequently does the organization review its success in meeting these?
29. What are the organization's policies and procedures for reporting errors, near misses, and adverse events in care?
30. Does the organization assure a de-identified, fair, and just reporting system for errors and near misses? How does it do this?
31. What are the organization's procedures for analyzing errors and providing feedback to direct-care workers?
32. Does the organization conduct an annual, confidential survey of nursing and other health care workers to assess the extent to which a culture of safety exists?
33. To what extent does the organization provide employee training in error detection, analysis, and reduction?
34. What rewards and incentives does the organization use to reduce health care errors?

Recommendations for Promoting Patient Safety in the Work Environments of Nurses[b]

Recommendations for Transformational Leadership and Evidence-Based Management

Creating work environments for nurses that are most conducive to patient safety will require fundamental changes throughout many health care organizations (HCOs) in terms of how work is designed, how personnel are deployed, and how the very culture of the organization understands and acts on the science of safety. These changes require leadership capable of transforming not just physical environments, but also the beliefs and practices of both nurses and other health care workers providing patient care and those in the HCO who establish the policies and practices that shape those environments—the individuals who constitute the management of the organization.

[b] Reprinted, with permission, from *Keeping Patients Safe: Transforming the Work Environment of Nurses*.[6] ©2004 National Academy of Sciences.

Leadership will need to assure the effective use of practices that (1) balance the tension between production efficiency and reliability (safety), (2) create and sustain trust throughout the organization, (3) actively manage the process of change, (4) involve workers in decisionmaking pertaining to work design and work flow, and (5) use knowledge management practices to establish the organization as a "learning organization." To this end, the committee makes the following recommendations:

Recommendation 4-1.[c] HCOs should acquire nurse leaders for all levels of management (e.g., at the organization-wide and patient care unit levels) who will:

- Participate in executive decisions within the HCO.
- Represent nursing staff to organization management and facilitate their mutual trust.
- Achieve effective communication between nursing and other clinical leadership.
- Facilitate input of direct-care nursing staff into operational decisionmaking and the design of work processes and work flow.
- Be provided with organizational resources to support the acquisition, management, and dissemination to nursing staff of the knowledge needed to support their clinical decisionmaking and actions.

Recommendation 4-2. Leaders of HCOs should take action to identify and minimize the potential adverse effects of their decisions on patient safety by:

- Educating board members and senior, midlevel, and line managers about the link between management practices and safety.
- Emphasizing safety to the same extent as productivity and financial goals in internal management planning and reports and in public reports to stakeholders.

Recommendation 4-3. HCOs should employ management structures and processes throughout the organization that:

- Provide ongoing vigilance in balancing efficiency and safety.
- Demonstrate trust in workers and promote trust by workers.
- Actively manage the process of change.
- Engage workers in nonhierarchical decisionmaking and in the design of work processes and work flow.
- Establish the organization as a "learning organization."

Because HCOs vary in the extent to which they currently employ the above practices and in their available resources, the committee also makes the following recommendation:

Recommendation 4-4. Professional associations, philanthropic organizations, and other organizational leaders within the health care industry should sponsor collaboratives that incorporate multiple academic and other research-based organizations to support HCOs in the identification and adoption of evidence-based management practices.

Maximizing Workforce Capability

Monitoring patient health status, performing therapeutic treatments, and integrating patient care to avoid health care gaps are nursing functions that directly affect patient safety. Accomplishing these activities requires an adequate number of nursing staff with the clinical

[c] For ease of reference, the committee's recommendations are numbered according to the chapter of the main text in which they appear.

knowledge and skills needed to carry out these interventions and the ability to effectively communicate findings and coordinate care with the interventions of other members of the patient's health care team. Nurse staffing levels, the knowledge and skill level of nursing staff, and the extent to which workers collaborate in sharing their knowledge and skills all affect patient outcomes and safety.

Regulatory, internal HCO, and marketplace (consumer-driven) approaches are traditionally advocated as methods to achieve appropriate staffing levels. The committee determined that each of these approaches has limitations as well as strengths; their coordinated and combined use holds the most promise for achieving safe staffing levels. The committee also took particular note of the need for more accurate and reliable staffing data for hospitals and nursing homes to help make these efforts more effective and to facilitate additional needed research on staffing. Finally, the committee identified a need for more research on hospital staffing for specific types of patient care units, such as medical-surgical and labor and delivery units. The committee therefore makes the following recommendations:

Recommendation 5-1. The U.S. Department of Health and Human Services (DHHS) should update existing regulations established in 1990 that specify minimum standards for registered and licensed nurse staffing in nursing homes. Updated minimum standards should:

- Require the presence of at least one RN within the facility at all times.
- Specify staffing levels that increase as the number of patients increase, and that are based on the findings and recommendations of the DHHS report to Congress, *Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes – Phase II Final Report*.[7]
- Address staffing levels for nurse assistants, who provide the majority of patient care.

Recommendation 5-2. Hospitals and nursing homes should employ nurse staffing practices that identify needed nurse staffing for each patient care unit per shift. These practices should:

- Incorporate estimates of patient volume that count admissions, discharges, and "less than full-day" patients in addition to a census of patients at a point in time.
- Involve direct-care nursing staff in determining and evaluating the approaches used to determine appropriate unit staffing levels for each shift.
- Provide for staffing "elasticity" or "slack" within each shift's scheduling to accommodate unpredicted variations in patient volume and acuity and resulting workload. Methods used to provide slack should give preference to scheduling excess staff and creating cross-trained float pools within the HCO. Use of nurses from external agencies should be avoided.
- Empower nursing unit staff to regulate unit work flow and set criteria for unit closures to new admissions and transfers as nursing workload and staffing necessitate.
- Involve direct-care nursing staff in identifying the causes of nursing staff turnover and in developing methods to improve nursing staff retention.

Recommendation 5-3. Hospitals and nursing homes should perform ongoing evaluation of the effectiveness of their nurse staffing practices with respect to patient safety, and increase internal oversight of their staffing methods, levels, and effects on patient safety whenever staffing falls below the following levels for a 24-hour day:

- In hospital ICUs—one licensed nurse for every two patients (12 hours of licensed nursing staff per patient day).
- In nursing homes, for long-stay residents—one RN for every 32 patients (.75 hours per resident day), one licensed nurse for every 18 patients (1.3 hours per resident day), and one nurse assistant for every 8.5 patients (2.8 hours per resident day).

Recommendation 5-4. DHHS should implement a nationwide, publicly accessible system for collecting and managing valid and reliable staffing and turnover data from hospitals and nursing homes. Information on individual hospital and nursing home staffing at the level of individual nursing units and the facility in the aggregate should be disclosed routinely to the public.

- Federal and State nursing home report cards should include standardized, case-mix–adjusted information on the average hours per patient day of RN, licensed, and nurse assistant care provided to residents and a comparison with Federal and State standards.
- During the next 3 years, public and private sponsors of the new hospital report card to be located on the Federal government website should undertake an initiative—in collaboration with experts in acute hospital care, nurse staffing, and consumer information—to develop, test, and implement measures of hospital nurse staffing levels for the public.

Moreover, the knowledge base on effective clinical care and new health care technologies is increasing rapidly, making it impossible for nurses (and other clinicians) to incorporate this information into their clinical decisionmaking and practice without organizational support. Organizational studies and research on exemplary work environments indicate the importance of investment in ongoing employee learning by employers. The committee therefore makes the following recommendation:

Recommendation 5-5. HCOs should dedicate budgetary resources equal to a defined percentage of nursing payroll to support nursing staff in their ongoing acquisition and maintenance of knowledge and skills. These resources should be sufficient for and used to implement policies and practices that:

- Assign experienced nursing staff to precept nurses newly practicing in a clinical area to address knowledge and skill gaps.
- Annually ensure that each licensed nurse and nurse assistant has an individualized plan and resources for educational development within health care.
- Provide education and training of staff as new technology or changes in the workplace are introduced.
- Provide decision support technology identified with the active involvement of direct-care nursing staff to enable point-of-care learning.
- Disseminate to individual staff organizational learning as captured in clinical tools, algorithms, and pathways.

Finally, in response to evidence on inconsistent interprofessional collaboration among nursing staff and other health care providers, the committee makes the following recommendation:

Recommendation 5-6. HCOs should take action to support interdisciplinary collaboration by adopting such interdisciplinary practice mechanisms as interdisciplinary rounds, and by providing ongoing formal education and training in interdisciplinary

collaboration for all health care providers on a regularly scheduled, continuous basis (e.g., monthly, quarterly, or semiannually).

Design of Work and Workspace To Prevent and Mitigate Errors

Nurses' work processes and workspaces need to be designed to make them more efficient, less conducive to the commission of errors, and more amenable to detecting and remedying errors when they occur. The work hours of a minority of nurses, in particular, are identified as a serious threat to the safety of patients. The effects of fatigue include slowed reaction time, lapses of attention to detail, errors of omission, compromised problem solving, reduced motivation, and decreased energy for successful completion of required tasks. Other safety-sensitive industries have acknowledged and taken action to defend against these effects by limiting the number of shifts or hours worked in a week.

Changing work patterns will require attention from HCOs, regulatory bodies, State boards of nursing, schools of nursing, and nurses themselves. Accordingly, the committee makes the following recommendation:

Recommendation 6-1. To reduce error-producing fatigue, State regulatory bodies should prohibit nursing staff from providing patient care in any combination of scheduled shifts, mandatory overtime, or voluntary overtime in excess of 12 hours in any given 24-hour period and in excess of 60 hours per 7-day period. To this end:

- HCOs and labor organizations representing nursing staff should establish policies and practices designed to prevent nurses who provide direct patient care from working longer than 12 hours in a 24-hour period and in excess of 60 hours per 7-day period.
- Schools of nursing, State boards of nursing, and HCOs should educate nurses about the threats to patient safety caused by fatigue.

Enabling nursing staff to collaborate with other health care personnel in identifying high-risk and inefficient work processes and workspaces and (re)designing them for patient safety and efficiency is also essential. Moreover, documentation practices are in great need of redesign. However, this cannot be accomplished solely by nursing staff and internal HCO efforts. As many documentation practices are driven by external parties, such as regulators and oversight organizations, these entities will need to assist in the redesign of documentation practices. To address these needs, the committee makes the following recommendations:

Recommendation 6-2. HCOs should provide nursing leadership with resources that enable them to design the nursing work environment and care processes to reduce errors. These efforts must directly involve direct-care nurses throughout all phases of the work design and should concentrate on errors associated with:

- Surveillance of patient health status.
- Patient transfers and other patient hand-offs.
- Complex patient care processes.
- Non–value-added activities performed by nurses, such as locating and obtaining supplies, looking for personnel, completing redundant and unnecessary documentation, and compensating for poor communication systems.

Recommendation 6-3. HCOs should address handwashing and medication administration among their first work design initiatives.

Recommendation 6-4. Regulators, leaders in health care; and experts in nursing, law, informatics, and related disciplines should jointly convene to identify strategies for safely reducing the burden associated with patient and work-related documentation.

Creating and Sustaining a Culture of Safety

Employing a nursing workforce strong in numbers and capabilities and designing their work to prevent errors will not be sufficient to fully safeguard patients. The largest and most capable workforce is still fallible, and the best-designed work processes are still designed by fallible individuals. Patient safety also requires an organizational commitment to vigilance to prevent potential errors, and to the detection, analysis, and redress of errors when they occur.

A variety of safety-conscious industries have made such a commitment and achieved substantially lower rates of errors by doing so. These organizations place as high a priority on safety as they do on production; all employees are fully engaged in the process of detecting high-risk situations before an error occurs. Management is so responsive to employees' detection of risk that it dedicates time, personnel, budget, and training resources to bring about changes needed to make work processes safer. Employees also are empowered to act in dangerous situations to reduce the likelihood of adverse events. These attitudes and employee engagement are so pervasive and observable in the behaviors of these organizations and their employees that an actual *culture of safety* exists within the organization. These organizational cultures are effective because they (1) recognize that the majority of errors are created by systemic organizational defects in work processes, not by blameworthy individuals; (2) support staff; and (3) foster continuous learning by the organization as a whole and its employees.

HCOs should redouble their efforts to create such cultures of safety within their work environments. Such efforts require a long-term commitment because they necessitate changes in the attitudes and behaviors of both organizations and people. Time is needed to enact an initial change, evaluate, refine, and enact further change. Strong organizational leadership is also essential. The safety of patients needs to be a stated and visible priority, with every organizational member understanding that each is fallible, even with the best of intentions, as are the processes used. Moreover, establishing a fair and just culture in responding to errors reduces workers' fear and disincentives to report errors and near misses. As a result, nursing staff is more inclined to be vigilant for errors and near misses, with a view toward learning from each event and strengthening the culture of safety accordingly. Action also is needed from State boards of nursing and Congress to enable strong and effective cultures of safety to exist. To these ends, the committee makes the following recommendations:

Recommendation 7-1. HCO boards of directors, managerial leadership, and labor partners should create and sustain cultures of safety by implementing the recommendations presented previously and by:

- Specifying short- and long-term safety objectives.
- Continuously reviewing success in meeting these objectives and providing feedback at all levels.
- Conducting an annual, confidential survey of nursing and other health care workers to assess the extent to which a culture of safety exists.
- Instituting a de-identified, fair, and just reporting system for errors and near misses.
- Engaging in ongoing employee training in error detection, analysis, and reduction.

- Implementing procedures for analyzing errors and providing feedback to direct-care workers.
- Instituting rewards and incentives for error reduction.

Recommendation 7-2. The National Council of State Boards of Nursing, in consultation with patient safety experts and health care leaders, should undertake an initiative to design uniform processes across States for better distinguishing human errors from willful negligence and intentional misconduct, along with guidelines for their application by State boards of nursing and other State regulatory bodies having authority over nursing.

Recommendation 7-3. Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by HCOs for internal use or shared with others solely for purposes of improving safety and quality.

Research Implications

Finally, the committee notes that changing health care delivery practices to increase patient safety must be an ongoing process. Research findings and dissemination of practices that other HCOs have found successful in improving patient safety will help HCOs as learning organizations add to their repertoire of patient safety practices. This report calls attention to several areas in which, at present, information is limited about how to design nurses' work and work environments to make them safer for patients. Research is needed to provide better information on nursing-related errors, means of achieving safer work processes and workspace design, a standardized approach to measuring patient acuity, information on safe staffing levels for different types of patient care units, effective methods to help night shift workers compensate for fatigue, information on what limits should be imposed on successive days of working sustained work hours, and collaborative models of care. Accordingly, the committee makes the following recommendation:

Recommendation 8-1. Federal agencies and private foundations should support research in the following areas to provide HCOs with the additional information they need to continue to strengthen nurse work environments for patient safety:

- Studies and development of methods to better describe, both qualitatively and quantitatively, the work nurses perform in different care settings.
- Descriptive studies of nursing-related errors.
- Design, application, and evaluation (including financial costs and savings) of safer and more efficient work processes and workspace, including the application of information technology.
- Development and testing of a standardized approach to measuring patient acuity.
- Determination of safe staffing levels within different types of nursing units.
- Development and testing of methods to help night shift workers compensate for fatigue.
- Research on the effects of successive work days and sustained work hours on patient safety.
- Development and evaluation of models of collaborative care, including care by teams.[d]

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Conclusion

Nurses are in a key position to improve patient safety, not just through their individual patient care actions as clinicians, but by exercising their leverage as much-desired employees in the labor marketplace. If nurses ask the above questions of their prospective employers, and incorporate the responses they receive into their selection of their place of employment, they will be able to exert significant influence within the health care system, as health care organizations come to appreciate the ability to recruit nurses as an additional important reason for making the types of organizational changes needed to provide safe patient care.

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Chapter 23. Patient Acuity

Bonnie M. Jennings

Background

For more than 50 years, researchers have worked to develop staffing methodologies to accurately indicate the number of nurses needed to give good care to patients.[1] By the 1980s, patient classification systems (PCSs) were in common use to predict patient requirements for nursing care. These requirements, or patient acuity, could then be used to manage nursing personnel resources, costs, and quality.[2, 3]

PCSs have numerous limitations, however. Paramount among these are (a) validity and reliability are infrequently monitored;[4, 5] (b) the tools are often complex and require considerable time to complete;[4] (c) they lack credibility among staff nurses and administrators;[5, 6] (d) they are not designed to detect census variability throughout the day from patient movement due to admissions, discharges, transfers, and short-stays;[7, 8] and (e) their focus on tasks shortchanges the cognitive work and knowledge inherent to expert nursing care and sophisticated surveillance.[9, 10]

As restructuring and mergers escalated in the 1990s, issues of patient acuity once again moved to the foreground. Patients were said to be sicker and leaving health care facilities more quickly. Concerns about rising patient acuity continue into the new millennium because of the relentless change that is now common in health care. Moreover, acuity is one of many elements that comprise the often used but not yet well specified concept of workload.[11, 12]

Research Evidence

In assessing the research conducted between 1995 and 2005 about patient acuity, three things stand out. First, most of the research reports are about developing or comparing instruments to measure patient acuity. Unlike early PCSs that were designed for medical-surgical patients in acute care facilities, these instruments are tapping into other care settings such as long-term care,[13–17] home care,[18, 19] emergency departments (EDs),[20–28] and neurological rehabilitation centers,[29–33] to name but a few. There is little evidence, however, regarding the extent to which these tools are being used.

Second, most reports simply mention that patient acuity is increasing without supporting data. Only four studies actually examined trends in patient acuity to empirically substantiate perceptions that acuity is rising. Interestingly, these investigations were all conducted outside the United States. PCS scores were compared over 3 months in 1996 and the same period in 1999 for critical care patients in one Australian hospital.[34] Acuity varied by shift (day, evening, night), with the evening shift demonstrating the highest patient acuity. Although the PCS scores followed similar patterns in 1996 and 1999, the PCS scores were higher for all shifts in 1999.

Monthly PCS data from 17 units in a Swedish hospital indicated that average scores in each of four acuity categories increased from 1995 to 1996.[35] The investigators concluded that patients were sicker and their treatments more time consuming. However, they also demonstrated discrepancies between actual and required staff, with the actual staff consistently lower than required. This gap has also been observed in U.S. hospitals.[6] In a Canadian study from Ontario, case-mix data were examined for all acute care hospitals from 1997 to 2002.[36] After controlling

for age, it was evident that the average inpatient case-mix index (CMI) increased by 17 percent over the 5 years of data that were examined. The least complex patients declined by 24 percent, and the most complex patients increased by 144 percent, representing an overall increase of 211 percent for the most complex patients. The fourth study examined care needs for long-term-care (LTC) residents in Alberta, Canada, between 1988 and 1999.[37] The data demonstrated an increase in residents needing greater help with activities of daily living and more intervention for difficult behaviors such as dementia.

Finally, studies were rarely designed to assess patient acuity in relation to patient outcomes. Of those shown in Table 1, three evaluated heterogeneous groupings of patients in acute care settings.[38–40] An additional three studies examined acuity in more homogeneous patient populations. One study focused exclusively on critical care patients,[41] and another considered only obstetrical care for teenagers.[42] Acuity was also examined in relation to patient outcomes in the ED.[43]

Evidence-Based Practice Implications

There is little empirical evidence about the relationship between acuity and patient safety, making the practice implications from these studies modest. Although three studies showed a positive association between acuity and adult mortality,[38, 40, 41] findings were more equivocal for the relationship between acuity and neonatal mortality rates.[42] This latter study illustrated that factors other than acuity were more predictive of outcomes, particularly weekend births and ethnicity or race. The investigators who studied critical care patients concluded that variations in mortality might be partially explained by excess workload.[40]

Findings from the studies involving a variety of inpatients were not consistent. As expected, the two studies using the same dataset[38, 40] both showed similar results—a positive relationship between acuity and adverse outcomes such as infections and decubiti, but not medication errors and falls. The third study was conducted on 32 units in a different hospital.[39] Data were collected for a full year. Although the association between hours of nursing per patient day was statistically significant ($r = .60$; $P < .05$), the relationship between acuity and adverse outcomes was not examined. Rather, acuity was a significant predictor of various self-care measures such as symptom management.

The ED study assessed patient satisfaction as the outcome measure.[43] Although this work did not provide evidence about outcomes related to patient safety, it did illustrate how patient perceptions come into play regarding features of care delivery. Patients whose acuity placed them in the ‘emergent’ category were more satisfied with their care than patients in either the ‘urgent’ or ‘routine’ acuity groups. However, when perceived throughput time was controlled, acuity did not predict satisfaction with ED care. The importance of patient perceptions was clearly in effect in determining satisfaction.

Research Implications

At present, very little is known about the relationship between acuity and outcomes. The lack of a standardized approach to measuring acuity has broad research implications. For investigations using PCSs, reports need to include information about the psychometric properties of the tools. It would also be helpful to examine the relationship of PCS acuity to clinical outcomes using more homogeneous patient groupings.

Perhaps the most important research issues concern greater clarity about the larger concept—workload. There is an urgent need to develop a conceptual model illustrating the relationships of the various elements comprising workload as well as a standardized definition of workload. Empirical testing of the model might then better elucidate how acuity, as one aspect of workload, relates to patient safety.

It would also be very helpful if U.S. studies were conducted to ascertain whether the perceptions of increased acuity are verifiable. It would be most beneficial if these studies looked not just at acuity in the aggregate, but also at acuity for homogeneous patient populations. This could help clarify whether acuity for medical-surgical patients has escalated. Finally, it would be useful to have a sense of acuity in the outpatient setting, given how patient care has shifted. Although outpatient acuity is particularly difficult to capture, it remains a research challenge for the future.

Conclusion

Patient acuity is a concept that is very important to patient safety. Presumably, as acuity rises, more nursing resources are needed to provide safe care. Very little research has actually been conducted, however, to verify this premise. Moreover, findings from the research that has been conducted are largely inconsistent. Design issues account for these differences. In addition, it is possible that factors other than patient acuity may contribute more to patient outcomes. It remains important to derive a much better grasp of the relationship between patient acuity, outcomes, and patient safety. At present, little can be said with confidence about this association.

Search Strategy

The literature for this review was identified by searching the MEDLINE® and CINAHL® databases from 1995 to 2005 for research-based articles published in the English language. A reference librarian assisted in choosing the search terms. In the CINAHL® search, the terms were "patient acuity" or "patient classification." This yielded 345 citations. The MEDLINE® search was tried four times using various combinations of terms such as "patient acuity," "patient classification," "severity of illness index," "acute disease classification" and "diagnosis related groups." The combined efforts of the four searches resulted in identifying 98 references.

The abstracts for all 443 citations were reviewed. Of these, 104 were considered to be potential candidates for use in this review. The references that were excluded from this assessment included a wide array of topics that were irrelevant to patient acuity. The diversity of these articles is too great to provide a complete view of them, but a few examples include quality of life, menstrual cycle abnormalities, blood pressure variability, and fever management for children.

After reading the 104 candidate articles in their entirety, an additional 72 papers were omitted from the remainder of the analysis. Papers were excluded because they were more tangentially related to patient acuity (e.g., indicators of patient dependency), they were reviews of literature, or they did not focus on patients per se (e.g., a way to classify school-age children with disabilities). As a result, this review was based on findings from 32 research reports.

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Table 1. Evidence on Patient Acuity

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Blegen 1998[38]	Inpatient outcomes (acuity was measured by the monthly reports derived from the hospital's acuity system)	Cross-sectional	Design: Level 3 Patient outcomes: deaths, rates of falls, medication errors, decubiti, urinary tract and respiratory infections (Level 1), complaints	42 inpatient units in an 880-bed hospital during FY 1993 (prior to restructuring); 21,783 discharged patients; 1,074 full-time equivalent nursing staff members, 832 of whom were RNs		In bivariate correlations, acuity was negatively associated with medication errors and falls, and positively correlated with infections, decubiti, complaints, and death.
Boudreaux 2004[43]	ED patients (acuity was measured by triage categories assigned by trained nurses—emergent, urgent, routine)	Cross-sectional	Design: Level 3 Patient outcomes: satisfaction (Level 4)	1,865 patients over 1 month at a large inner-city hospital ED Patients: average age 30 years; 53% female		Patients with higher acuity were more satisfied with care and perceived their throughput time more favorably; satisfaction was more closely linked to perceived throughput times than to actual throughput times or acuity.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hamilton and Restrepo 2003[42]	Neonatal deaths preventable in the perinatal period (acuity was measured using maternal medical risk factors such as hypertension, anemia, previous birth of an infant who was preterm or small for gestational age)	Cross-sectional	Design: Level 3 Patient outcomes: mortality (Level 1)	All births to teenage mothers (< 20 years of age) in Texas in 1999 and 2000 (N = 11,749) with a focus on neonatal deaths (prior to the 28th day of life) (n = 397); mean neonatal mortality/1,000 live births = 3.6; Hispanic (56%), White (27%), African American (15%), other (2%)		Neonatal mortality rates differed significantly between weekdays and weekends (odds ratio [OR] = 1.42, 95% CI = 1.14–1.76, *P* = 0.001). When ethnicity and or race were examined with day of the week, a statistically significant difference was found for births to Hispanic teens (OR = 1.728, 95% CI = 1.275–2.342, *P* < 0.001). Differences in acuity did not fully explain higher weekend neonatal mortality rates.
Potter 2003[39]	Patient outcomes (after adjusting for acuity)	Cross-sectional	Design: Level 3 Patient outcomes: fall and medication error index (Level 1); self-reports of symptom management, self-care, health status; patient satisfaction	32 inpatient units in one hospital from 2000 to 2001; 3,418 patients		Unit data were aggregated to create yearly data due to small numbers for some variables. Acuity was a significant predictor of the self-care measures of importance and understanding, and indexes of self-care symptom management.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Reed 1998[40]	Adverse occurrences among inpatients (acuity was measured by an institutionally standardized measure; average daily acuity/month was used)	Cross-sectional	Design: Level 3 Patient outcomes: deaths, pressure ulcers, nosocomial infections, medication administration errors (Level 1), complaints	42 inpatient units in an 880-bed hospital during FY 1993 (prior to restructuring). This was a secondary data analysis of a mix of units: 5 surgical; 10 medical; 3 obstetrical; 8 pediatric; 4 critical care; 4 psychiatric; 2 eye, ear, nose; 6 orthopedic and neuroscience.		Deaths, pressure ulcers, infections, patient complaints were positively intercorrelated and positively correlated to patient acuity. When patient acuity was controlled, these adverse outcomes seemed to share a common underlying characteristic indicating something other than acuity, such as the quality of care.
Tarnow-Mordi 2000[41]	Staff workload (after adjusting for risk using the APACHE II; workload was defined by average nursing requirement per occupied bed and peak occupancy)	Prospective cohort	Design: Level 3 Patient outcome: hospital mortality (Level 1)	1,050 patients admitted to an adult ICU in Scotland between January 1, 1992, and December 31, 1995. Patients: Age, 16 to $\geq$70, with 43% of the patients in the $\geq$ 70 age group58% male		Predicted mortality was calculated using the APACHE II. The 337 hospital deaths were 49 more than predicted by APACHE II (95% CI = 34–65). Adjusted mortality was more than two times higher (OR = 3.1, 95%CI = 1.9–5.0) for patients exposed to high ICU workload.

Chapter 24. Restructuring and Mergers

Bonnie M. Jennings

Background

During the first half of the 20th century, there was a huge increase in the number of free-standing general hospitals in the United States.[1] At that time, registered nurses (RNs) typically practiced in hospitals. Consequently, there are strong parallels between the evolution of the nursing profession and the growth of hospitals as the central structure in the U.S. health care system.[2] By the 1980s, however, a variety of initiatives were implemented for the purpose of curtailing the rapid rise in health care costs.[3, 4] Based upon the assumption that hospital care was very expensive, cutting inpatient care was a central strategy in the attempt to control the cost of health care.[5] Moreover, the focus on fiscal challenges shifted the health care industry into a business mode that substantially altered the experiences of patients, as well as the roles of health care personnel.[6]

Cost-cutting initiatives over the past 20-odd years contributed to tremendous turmoil in health care. The initiatives were often introduced concurrently and without empirical evaluations to determine their effectiveness. Among the early initiatives was a prospective payment system based upon Diagnosis Related Groups (DRGs), which differed from the historical system of retrospective payments that covered all services rendered. DRGs established fixed prices for care based on set criteria, such as diagnosis, therapy, and discharge status. These fixed prices altered hospital reimbursements, which in turn changed their incentives. As a result, for example, lengths of stay were shortened. Patients with complex care needs moved through the inpatient care setting much more rapidly than in the past, giving rise to the phrase “sicker and quicker” to reflect this dramatic change. In addition, preauthorization was implemented to reduce hospital use. Together, DRGs and preauthorization provided the impetus to shift care from the hospital to the outpatient setting and the home.

Fewer inpatients required fewer staff. Reductions in hospital personnel helped to reduce labor costs; they also raised concerns about the effects of staffing on quality of care and nurses’ job satisfaction.[7] By the year 2000, although the hospital remained the primary place of employment for RNs, 40 percent of RNs worked in other settings.[8] This represented a significant shift over 25 years.

Also contributing to the turmoil in health care during the 1980s was the rapid growth in managed care. All types of managed care programs attempted to control costs by decreasing unnecessary use of health care. To support this goal, primary care physicians assumed a more dominant role in health care by becoming “gatekeepers,” allocating health care resources such as referrals to specialists.

Managed care also prompted the integration of health services and providers. Through horizontal integration, free-standing hospitals merged into multihospital systems owned by central organizations (e.g., Humana), and physicians in private practices joined group practices. Through vertical integration, a broad array of services covering the care continuum—from ambulatory care to long-term care—were pulled together into comprehensive delivery systems.[4] Ideally, these mergers helped to streamline functions, reduce administrative redundancy, and negotiate reduced rates when purchasing supplies, equipment, and pharmaceutical products.

These often radical changes proceeded, however, with little empirical evidence to guide them. Evaluations were uncommon, and those that were conducted could not keep pace with the speed of changes resulting from restructuring and mergers. A report from the Institute of Medicine[9] concluded that despite enormous organizational turmoil, little progress was made toward restructuring health care systems in ways that meaningfully addressed quality and cost concerns. Likewise, a critical review of restructuring studies found mixed signals about what was accomplished through these organizational changes.[3] According to Aiken and colleagues[10] (p. 463), "What we know about changes in organization and structure and the potential for those changes to affect patient outcomes pales by comparison to what we do not know."

Assessments about how restructuring and mergers affected patients and staff are more a look through the rearview mirror because they occurred after the fact. Nonetheless, the findings are informative, especially when considered in the context of current changes such as recent growth in hospital construction.[11] Today, ongoing change, not stability, is the order of the day for health care. Lessons from the past can be used as a platform for more proactive responses to future changes.

Research Evidence

The findings from studies of restructuring can be grouped in numerous ways. A summary of the findings is presented in Table 1. These studies represent work conducted internationally, but predominantly in the United States and Canada. Most of the evidence came from assessments of restructuring in acute care settings.[10, 12–48] Although hospital restructuring altered care delivered in other settings, little research was found that looked outside acute inpatient care. Exceptions were assessments of outpatient care following restructuring in the Department of Veterans Affairs (VA),[49, 50] an evaluation of increasing home care needs in Canada,[51] and an examination of overcrowding in an emergency department following restructuring.[52]

Studies typically addressed employee perceptions of restructuring. Overall, the changes that occurred through restructuring processes were viewed unfavorably. Most studies considered the effect of restructuring on staff nurses.[10, 12–21, 23, 25–27, 29–31, 34, 35, 38–44, 47, 48] Other health care professions such as physical therapists[33] and social workers[36] also explored how restructuring affected their respective roles. A few investigations considered restructuring from the perspective of nurses in administrative positions at the patient unit and executive levels.[12, 22, 24, 32, 38, 43] One investigation examined the views of top and middle managers from various disciplines at one VA hospital, as well as physicians and patients.[53] A pair of related investigations considered restructuring as viewed by chief executive officers.[45, 46] An important finding among these studies was that although strong leadership is essential in times of change, staff nurses' assessment of nurse managers' abilities declined considerably between 1986 and 1998, as did the perception of nurse executive power.[10]

Few studies explored ways to mitigate the deleterious effects of restructuring. There is beginning evidence, however, that empowerment[32] and leadership style[20] may reduce burnout and increase job satisfaction. One study explicitly examined rebuilding after restructuring.[24] Staffing changes were central to the rebuilding efforts, especially increases in licensed personnel and senior support staff, and decreases in part-time, temporary, agency, and contract nurses. In three studies that examined cost, results reflected increased costs at both the unit level[13] and the hospital level[45, 46] suggesting that restructuring did not achieve its intended purpose.

The majority of studies examined the relationship between restructuring and job satisfaction. Regardless of professional discipline, there was a decline in job satisfaction after restructuring.[13, 15, 18–21, 23, 30, 32, 33, 36, 45] Aspects of burnout were also frequently explored.[19–21, 32, 48] Findings consistently showed burnout was increasing, particularly emotional exhaustion, which is viewed as the core feature of burnout. Along with evaluating psychological health, studies began to detect a relationship between restructuring and increased musculoskeletal injuries.[14, 29, 42]

Restructuring can occur within a single institution, while mergers involve integrating two or more institutions. A cluster of studies explicitly addressed various aspects of mergers.[54–62] Findings from three studies verified that the success of mergers was enhanced by engaging staff from the merging institutions in the process.[54, 56, 57] Other investigations evaluated various responses of nursing staff to mergers.[58–60] In a merger involving three hospitals, for example, Jones[59] found that uncertainty about job status and feeling unappreciated minimized nurses' organizational commitment. Other studies examined mergers from the standpoint of factors effecting financial performance,[61] midwifery practice,[62] and the integration of two emergency departments.[55]

A number of investigations relied exclusively on qualitative methods to explore restructuring and mergers.[16, 17, 25, 27–29, 32, 34, 40, 53, 54, 60, 62] Themes across these studies help to edify potential sources of job dissatisfaction and burnout. For example, participants commented that restructuring altered work relations in undesirable ways,[16, 25, 27, 53, 62] including relations with management,[32] that contributed to staff distrust of the employing organization.[25, 54] Participants also identified changes in work life related to increased responsibilities, decreased resources, and overall busyness.[25, 27, 29, 32, 34, 62]

In two studies, themes emerged indicating that staff viewed restructuring as detrimental to the quality of care.[27, 32] In another two investigations, in which both patients and health care professionals were interviewed, findings indicated that patients had fewer complaints about the changes than did the hospital staff.[34, 53]

A few studies considered the effects of restructuring on quantifiable patient outcomes;[10, 13, 18, 30, 37, 42, 49, 50] two of these investigations related to outpatient care.[49, 50] The paucity of studies exploring patient outcomes related to restructuring illustrates that staff response has been the focus of most restructuring and merger studies. Although no causal connections have been demonstrated, beliefs and assertions hold that staff characteristics do affect patient outcomes. For example, recent findings show emotional exhaustion among nurses is associated with higher patient morality.[63]

Nevertheless, the staff-focused studies do not help to inform patient care per se. Moreover, the concerns addressed a decade ago by Ingersoll[26] persist—many studies are reported in journals geared to audiences that are more interested in application than scientific rigor. There is a continued need for studies with more sophisticated designs to better inform the science of patient safety. These needs expose the potential for better informing practice by combining health services research techniques with nursing research inquiries.

Table: Summary of Research Evidence Related to Restructuring and Mergers

Care setting	• Most studies evaluated restructuring and mergers in acute care settings.
Effect on costs	• Increased unit level costs. • Increased hospital level costs.
Effect on staff nurses	• Decreased job satisfaction. • Increased burnout, especially emotional exhaustion. • Increased musculoskeletal injuries.
Common sources of job dissatisfaction and burnout	• Undesirable changes in work relations, including relations with administrators, that fostered organizational mistrust. • Increased work responsibilities. • Decreased resources.
Ways to reduce the undesirable effects of restructuring and mergers	• Empowerment. • Empathetic leadership style. • Staffing changes—more licensed personnel and senior support staff; fewer part-time, temporary, agency, and contract nurses.
Effect on patient outcomes	• Results are conflicting about patient mortality. • Indicator data (e.g., falls, nosocomial infections, medication errors) vary over time, making it important to track trends. • Indicator data differ when assessed at the hospital level, the unit level, and by unit type (e.g., medical or surgical). • Overall, the evidence is scattered and inconsistent.

Evidence-Based Practice Implications

The 11 studies in Table 2 illustrate findings pertinent to patients as well as staff regarding likely connections between restructuring and patient safety. The setting for studies that met inclusion criteria was most often acute care,[10, 18, 20, 21, 32, 43, 46, 48] with research focused on outpatients[40, 50] and home care[51] also represented. Overall, however, the evidence is scattered and, at times, inconsistent. As a consequence, there are few solid implications for practice.

Patient mortality showed conflicting results. Increases in mortality were found in aggregated data from hospitals throughout the United States,[10] and decreases were found based on data from more than 2,000 patients at a single hospital.[18] A study of VA outpatients showed no statistically significant differences in mortality between patients who saw a physician for symptoms and patients who were not seen.[50]

Indicator data for falls, medication errors, nosocomial infections, and intravenous complications were examined in an 18-month longitudinal study of four medical-surgical units at one hospital.[18] The four indicators were assessed for more than 2,500 patients at four points in time. Although descriptive data reflected patternless variations in the indicators, all indicators were increasing at 18 months. The investigators noted, however, that when indexed by rate of occurrence per 100 patients, all four indicators either improved or remained unchanged.

Sovie[43] collected data from 29 university teaching hospitals in eight of the nine U.S. census regions. More than findings about the individual patient outcomes, this study illustrated important variations depending upon how data were aggregated. That is, data aggregated at the hospital level differed from data at the unit level. More striking, findings varied by unit type—medical or surgical. For falls, pressure ulcers, and urinary tract infections (UTIs), the rates were always lower on surgical units than medical units. This may have important implications for practice related to staffing considerations.

Berlowitz[49] led a study of pressure ulcers among residents of long-term care units at 150 VA medical centers nationwide. This study illustrated that, as care shifted from a focus on hospital-based specialty care to outpatient primary care, pressure ulcers increased, even after risk adjustment. Conversely, in a study from a single VA facility in California, Rubenstein and colleagues[50] demonstrated that the shift to outpatient care yielded improvements in continuity of care and preventive care related to smoking, exercise, detection of depression, and the number of individuals with hypertension receiving treatment.

The final study involving a patient focus examined home care needs for patients after hospitals closed beds.[51] Not only did more patients need care after discharge, but service intensity also increased. The intensity diminished in the second week after discharge. Although findings from single studies do not warrant practice changes, the effects of restructuring on home care needs remains an important consideration for patient safety.

The studies that evaluated various staff response to restructuring displayed a much clearer pattern to their findings—restructuring was associated with negative effects on staff.[21, 32, 48] Interested in mitigating these effects, Cummings and colleagues[20] tested a model that examined leadership style. Empathy was a critical leadership competency that served to offset the negative effects of restructuring. It was characterized by individuals who listened and responded to employee concerns.

Finally, Walston and colleagues[46] evaluated changes in hospital costs during restructuring efforts. They found that restructuring altered work processes by changing the workflow and job responsibilities. This exerted a negative influence by increasing hospital costs relative to competitors.

Research Implications

Given the current evidence, we know that reducing inpatient care as the central strategy for controlling the cost of health care has not succeeded. We know that staff report being dissatisfied with their job conditions. We also know there is no consistent pattern in the few studies that have examined the effect of organizational change on patient outcomes. Furthermore, we know that change in health care organizations is likely to continue.

Consequently, there are large gaps in knowledge about restructuring and mergers. It is not feasible to provide a comprehensive list of areas for future study. However some general notions can be outlined. A fundamental premise is that health care leaders must seriously consider which changes to implement and the best processes for introducing changes into their organizations. In addition, they need to evaluate changes—not just implement them. The evaluations need to be sufficiently comprehensive so that organizational goals (e.g., costs) do not overshadow examination of the effects of change on staff and patients. These studies also need to be longitudinal, to track the effects of restructuring over time. This strategy will help to fill the void about the effects of restructuring on patient safety.

Moreover, if existing care delivery structures are not effective, then a central question concerns how best to organize care. For example, if the Institute of Medicine's aims for the 21st-century health care system are still appropriate,[9] then what structures will lead to care that is safe, effective, patient-centered, timely, efficient, and equitable? Continuity of care before and after restructuring and mergers is an aspect of care that could benefit from in-depth exploration because it could contribute to improvements in each of the desired aims. Acute care, outpatient

care, and home care have all been affected by restructuring. What mechanisms could be introduced to enhance continuity from unit to unit and across the care continuum?

Many studies of restructuring follow a sociological view of organizations; a psychological framework has been used less often. Human relations—among both staff and patients—are central to caregiving organizations. Kahn[64] asserts that interpersonal transactions are at the core of caregiving organizations. He believes that resilient organizations have members who are able to learn and grow, even in difficult environments. Resilient organizations are better able to absorb stress and maintain the capacity to function effectively. Therefore, regardless of the structure, health care organizations would benefit from investigations that examine interpersonal conditions at work. Interventions could then be developed to help staff improve relationships with one another and work together more effectively. To date, studies have not examined the effects of restructuring on the dynamics among caregivers and between caregivers and patients. In addition, leadership as a linchpin of relationships between staff and administrators begs to be better understood.

From the perspective of patient outcomes, however, we know very little. There is no discernible pattern in existing findings; there is no meaningful statement that can be made. The impact of restructuring on patient safety remains unknown. Measurement and methods questions are important considerations to enhance that understanding—which indicators to use, how they are defined, how they are measured, what the unit of analysis is. Decreased resources, including sufficient staff, surfaced as a concern in studies of restructuring. It would be beneficial to assess different care structures, determine the work that needs to be done, determine who needs to do it, provide the proper type and number of staff to do the work, and then assess which organizational structures yield the best opportunity for providing safe care to patients.

It would also be extremely useful to pursue a series of qualitative studies to better depict the current state of health care organizations. Data could be collected from staff at all levels of individual organizations as well as vertically and horizontally integrated systems of care. Data could also be collected from patients getting care in different venues, including the home. Family member perspectives would be valuable, too. Such studies would be very complex and difficult, but they could elucidate key issues and concerns. These could then be used to construct interventions or guide future restructuring efforts.

This is just the beginning of an almost endless list of ideas that could be studied to advance the understanding of restructuring and mergers. Future endeavors need to be more proactive in assessing organizational change early in the change process. They also need to approach questions over time, using a comprehensive set of variables, as well as sophisticated methodological and statistical techniques, to truly advance the understanding of restructuring on the staff as well as patient safety.

Conclusion

As reflected in the Table (see above), most studies of restructuring and mergers have been conducted in acute care settings. Many of these studies have examined the effects of restructuring and mergers on cost, staff nurses, and patient outcomes. In the aggregate, restructuring and mergers did not achieve the desired reductions in cost. However the upheaval accompanying restructuring efforts and mergers can be related to lower job satisfaction among nurses and increased burnout. The effects of restructuring and mergers on patient care, however,

are more difficult to understand because the evidence varies over time, by hospital or unit, and by unit type.

There is convergence in findings about sources of job dissatisfaction and burnout related to restructuring and mergers. Organizational and unit leaders would be wise to carefully assess work relations, work responsibilities, and the availability of resources, all of which may be sources of dissatisfaction and burnout. It would also behoove the leaders to consider the evidence that illustrates ways to minimize the undesirable effects of restructuring and mergers. These include empowerment, empathetic leadership, and staffing changes that increase the number of licensed nurses who are employed by the institution.

Search Strategy

A reference librarian assisted in running database searches in both MEDLINE® and CINAHL® to identify literature for this review. Both databases were searched from 1995 to 2005, using the same two MESH headings: hospital restructuring and health facility mergers. The searches were limited to research reports published in the English language. A total of 149 potential publications were identified, 56 in MEDLINE® and 93 in CINAHL®. Based upon an assessment of the abstracts, 67 of the publications were regarded as being suitable for inclusion in this review. The 82 papers that were omitted were a combination of brief reports or abstracts, topics not suitable to this review (i.e., mental health triage tools), and doctoral dissertations.

After reading the 67 publications in their entirety, 14 were omitted from further consideration. Some of these papers, for example, were only tangentially related to restructuring and mergers, a few were redundant publications, and others were about instrument development. This review is therefore based on 53 research reports.

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Evidence Table: Restructuring and Mergers

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Aiken 2000[10]	Staffing	Cross-sectional	Design: Level 4; Patient outcomes: mortality (Level 1)	Hospitals throughout the United States, 646 CEOs, 2,000 nurses, patient data from American Hospital Association and Health Care Financing Administration databases	Restructuring: personnel reductions via attrition (69%), cross-training (84%), skill mix reductions (60%), reassignment of support services (60%), redistribution of patients on nursing units (42%); reduction of management positions (54% by layoffs, 70% by attrition)	57% of hospitals had restructured; 12 magnet hospitals showed more declines than improvements in the nursing practice environment between 1986 and 1998; RN staffing and mortality were negatively correlated (r = –0.49, P = 0.02 based on 1997 data from 22 magnet hospitals; r = –0.18, P = 0.02 for 314 hospitals).
Berlowitz 2001[49]	Outpatient care	Retrospective cohort	Design: Level 4, Patient outcomes: risk-adjusted development of stage 3 or 4 pressure ulcers (Level 1)	Department of Veterans Affairs (VA) long-term care units at about 150 VA medical centers nationwide between 1990 and 1997; 274,919 observations of 103,499 VA residents who were without a pressure ulcer (PU) at an index assessment: 97% were men, average age was 71 years	Reorganization beginning in 1995 to shift from a hospital-based, specialty-focused system to one based on primary care delivered in outpatient settings	Before the change (1990–1994), risk-adjusted rates of PUs declined by 27%. Rates began increasing in 1997. By 1997 rates were similar to those in 1990. The proportion of new PUs that were severe increased significantly from 1995 to 1997 (P = 0.01, average 45%). 11 patient characteristics were significantly associated with PU development (e.g., mobility, dependency on transferring, toileting; P < 0.001).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bryan 1998[18]	Patient-centered care	Cross-sectional, Same variables measured at 4 points in time using different patients (preimplement-ation, 6, 12, and 18 months after)	Design: Level 3, Patient outcomes: mortality, falls, medication errors, nosocomial infections, IV-related complications (Level 1), patient satisfaction	Four medical-surgical units in one Pennsylvania hospital: patients at baseline = 2,700 6 months = 2,500 12 months = 2,756 18 months = 2,672	Hospital redesign using patient-centered concepts—facility changes (e.g., alter location and number of work stations and supply areas), enhanced information systems (e.g., redesigned patient call system), total redesign of work processes (e.g., redesigned staff roles to use multiskilled personnel)	Mortality ratios declined from baseline, although an increase was evident in the last year of reported data; rate of occurrence per 100 patients for falls, medication errors, nosocomial infections, and IV-related complications improved or remained unchanged since restructuring (0.4-3/100 patients before and 0.2-2/100 after); patient satisfaction improved on 3 of the 4 units, but the pattern of change differed among all units.
Cummings 2005[20]	Leadership	Cross-sectional	Design: Level 3, 15 nursing outcomes: e.g., emotional health; physician-nurse teamwork; nurse workgroup collaboration; satisfaction with time to spend with patients, supervision, financial rewards, one's job; perceived quality of care as measured by unmet patient needs (Level 3)	Acute care hospitals in Alberta, Canada; 6,526 registered nurses (53% response rate)	Leadership styles: resonant (visionary, coaching, affiliative, democratic), dissonant (pace setting, commanding), mixed.	Hospital restructuring led to reported increases in unmet patient needs among all nurses surveyed. Resonant leadership lessened the intensity of the impact of restructuring on unmet care needs, emotional exhaustion, emotional health, and workgroup collaboration. Dissonant leadership intensified the effects of restructuring. Other causal relationships were discovered among nursing outcome variables that were mitigated by resonant leadership.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cummings 2003[21]	Effects on nurses who remained employed while others lost their jobs	Systematic literature review	Design: Level 1, effects of restructuring on nurses remaining employed in hospitals (Level 3)	Published research—84 papers were screened for inclusion criteria: 22 papers were included in the review (18 of 24 quantitative papers and 4 of 9 qualitative papers)	Hospital restructuring effects on nurses (RNs and LPNs)	Decreased job satisfaction complicated recruiting and retaining nursing staff; increased emotional exhaustion and work absences; perceived and actual increased workload; perceived increase in patient acuity; impaired ability to communicate important patient information; loss of work group cohesion.
Keller 2004[51]	Hospital bed closures	Cross-sectional	Design: Level 4; outcomes: rate of home care, service intensity	Kingston, Ontario, Canada; closure of 134 acute care beds in 2 tertiary teaching hospitals in 1997; hospital patients ages 45 and older, discharged to a home setting between 1996 and 2000, covered by the provincial health insurance plan and admitted to the local Community Care Access Center within 5 days before or after hospital discharge (*n* = 1,651)	Delivery of home care by registered nurses (RNs) and registered practical nurses (RPNs)	Patients needed continued care after discharge. Age-gender standardized rates for home care showed a 10% increase between 1996 and 1997, with people 13% more likely to receive home care in 1997 (OR 1.13, 95% CI 1.05–1.22). Between 1996 and 2000, there was a 4% net increase in the age-gender standardized rate of admission to home care services. Service intensity and volume were measured at weeks 1, 2 & 1 month—total visits and visits/patient increased from 1996 to 1999; the total volume of nurse visits was highest in 2000; the intensity of nursing care eased in the second week after discharge.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Laschinger 2004[32]	Nurse managers' health	Cross-sectional	Design: Level 3, outcomes: empowerment, burnout (emotional exhaustion [EE]), job satisfaction, mental and physical health (Level 3)	Acute care hospitals in Ontario, Canada; random sample of 500 nurse managers; 286 usable surveys were returned (62%); first-line managers (*n* = 202), 95% female, average age 48, average years nursing experience 25, average years managerial experience 10, 42%, were baccalaureate prepared; middle managers (*n* = 84), 96% female, average age 49, average years nursing experience 27, average years managerial experience 14, 43%, were master's prepared	Restructuring	First-line and middle nurse managers perceived their work environments as being only modestly empowering but reported high levels of psychological empowerment. EE was high (reflecting burnout), energy levels were low, physical and depressive symptoms were infrequent. Predictive models showed structural empowerment was a significant predictor of EE in both groups of managers. Managers are at risk of developing EE, the core component of burnout, if they do not have needed information, resources, and support to perform their roles.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rubenstein 1996[50]	Outpatient care	Cross-sectional with data collected at 3 points in time—1989, before implementation; 1992, early in implementation; and 1993 after implementation	Design: Level 3, outcomes: mortality (Level 1), continuity, preventive care, access, workload (Level 3)	A VA medical center in California; data for practice-based comparisons came from 1,262 veterans in 1992 and 1,373 in 1993 (697 were from a new cross-sectional sample and 676 were from the original cohort); data for visit-based comparisons came from 1,407 veterans in 1992 and 643 in 1993 (92.3% of the new clinic cross-section). Patient survey responses were linked to computerized utilization and mortality data.	Implementation of the Primary Ambulatory Care and Education (PACE) program, a medical-center-wide interdisciplinary matrix management system and training program; put in place in 1990–1991.	There were no statistical differences in mortality between patients who saw a physician for symptoms vs. patients who did not. From 1992 to 1993, improvements were found for continuity of care, preventive care related to smoking and exercise ($P < 0.05$), and detection of depression ($P < 0.001$). Hypertensive patients receiving antihyperten-sives increased as well (8.6%, $P < 0.01$). Access diminished—21% of patients with serious symptoms did not see a physician in 1992, rising to 42% in 1993. Time to talk with patients and explain health problems and medications improved ($P < 0.05$).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sovie 2001[43]	Nursing structure and processes	Cross-sectional	Design: Level 3, outcomes: *structure* (full-time equivalents for each type of nursing staff; skill mix, hours worked per patient day [HPPD] for all staff); *process* (management practices and organizational processes, e.g., autonomy, decisionmaking); *outcomes* (annual rates for nosocomial pressure ulcers [NPUs], urinary tract infections [UTIs], falls, (Level 1); patient satisfaction with pain management, education, attention to needs, nursing and the hospital, preparation for discharge (Level 3)	29 university teaching hospitals with > 300 acute operating beds in 8 of 9 U.S. census regions; chief nurse executives (CNEs) at each hospital (all were women with graduate degrees, 15 had doctorates), patients and nursing staff (registered nurses [RNs], licensed practical nurses [LPNs], unlicensed assistive personnel [UAP]) from a medical unit and a surgical unit at each hospital (RN participants: *n* = 1,687 in 1997, 1,256 in 1998; 92–93% female, 57–58% married, 53% BSN degrees, mean age 37, mean years in nursing 11)	Restructuring had been in progress in 50% of the hospitals for over 4 years prior to data collection. The goal of restructuring was to achieve reductions in operating costs.	Less management support was available to patient care staff: expanded CNE responsibilities (97%), nursing departments downsized (82%), nurse manager positions reduced in 91% of the hospitals and span of control increased to more than one nursing unit. There were fewer RNs and more UAPs; outcomes were affected by RN HPPD and HPPD by all staff; increased RN HPPD were associated with lower falls and higher patient satisfaction with pain management; increased HPPD by all staff were associated with lower UTI rates; no single staffing pattern resulted in best value; outcomes differences for medical and surgical units reflected the importance of unit-level evaluations.
Walston 2000[46]	Changed work processes and design	Cross-sectional	Design: Level 3, outcomes: changes in hospital cost per adjusted patient day relative to the hospital's market area (controlling for bed size and other factors) (Level 3)	All U.S. general medical/ surgical hospitals in urban areas with > 100 beds (*N* = 2,306); CEOs surveyed November 1996 through July 1997	Reengineering (60% rate of adoption in sample)	Negative influence on a hospital's competitive position (hospital costs were increased relative to competitors); use of integrative strategies (e.g., project teams, deep CEO involvement) may moderate the negative effects of reengineering.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Woodward 1999[48]		Cross-sectional at 3 points in time over 2 years	Design: Level 3, outcomes: work environment, emotional distress, personal resources, perceptions of patient care and the hospital as an employer (Level 3)	One large teaching hospital in Ontario; 900 randomly sampled employees, 881 of whom were eligible, 730 of whom were employed 2 years later, 47% responded in all time periods. Respondents to all 3 surveys included 220 health care professionals, 40 service/technical staff, 66 secretarial personnel, 20 business staff.	Re-engineering	Statistically significant changes ($P \leq 0.001$) were found for job demands (increased), coworker and supervisor support (decreased), less role clarity and teamwork, and more job insecurity. Psychological distress as measured by anxiety, depression, and emotional exhaustion showed an overall increase ($P < 0.001$). Perceptions of care quality and the hospital's work environment also diminished ($P \leq 0.001$).

Chapter 25. Nurse Staffing and Patient Care Quality and Safety

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The importance of nurse staffing to the delivery of high-quality patient care was a principle finding in the landmark report of the Institute of Medicine's (IOM) Committee on the Adequacy of Nurse Staffing in Hospitals and Nursing Homes: "Nursing is a critical factor in determining the quality of care in hospitals and the nature of patient outcomes"[1] (p. 92). Nurse staffing is a crucial health policy issue on which there is a great deal of consensus on an abstract level (that nurses are an important component of the health care delivery system and that nurse staffing has impacts on safety), much less agreement on exactly what research data have and have not established, and active disagreement about the appropriate policy directions to protect public safety.

The purpose of this chapter is to summarize and discuss the state of the science examining the impact of nurse staffing in hospitals and other health care organizations on patient care quality, as well as safety-focused outcomes. To address some of the inconsistencies and limitations in existing studies, design issues and limitations of current methods and measures will be presented. The chapter concludes with a discussion of implications for future research, the management of patient care and public policy.

Background

For several decades, health services researchers have reported associations between nurse staffing and the outcomes of hospital care.[2–4] However, in many of these studies, nursing care and nurse staffing were primarily background variables and not the primary focus of study.[5] In the 1990s, the National Center for Nursing Research, the precursor to the National Institute of Nursing Research, convened an invitational conference on patient outcomes research from the perspective of the effectiveness of nursing practice.[6] It was hoped that as methods for capturing the quality of patient care quantitatively became more sophisticated, evidence linking the structure of nurse staffing (i.e., hours of care, skill mix) to patient care quality and safety would grow. However, 5 years later, the 1996 IOM report articulating the importance of nurses and nurse staffing on outcomes concluded that, at that time, there was essentially no evidence that staffing exerted an effect on acute care hospital patients' outcomes and limited evidence of its impact on long-term care outcomes.[1]

There has been remarkable growth in this body of literature since the 1996 IOM report. Over the course of the last decade, hospital restructuring, spurred in part by a move to managed care payment structures and development of market competition among health care delivery organizations, led to aggressive cost cutting. Human resources, historically a major cost center for hospitals, and nurse staffing in particular, were often the focus of work redesign and workforce reduction efforts. Cuts in nursing staff led to heavier workloads, which heightened concern about the adequacy of staffing levels in hospitals.[7, 8] Concurrently, public and professional concerns regarding the quality and safety of patient care were sparked by research and policy reports (among them, the IOM's *To Err is Human*[9]), and then fueled by the popular

media. A few years ago, reports began documenting a new, unprecedented shortage of nurses linked to growing demand for services, as well as drops in both graduations from prelicensure nursing education programs and workforce participation by licensed nurses, linked by at least some researchers to deteriorating working conditions in hospitals.[10, 11] These converging health care finance, labor market, and professional and public policy forces stimulated a new focus of study within health services research examining the impact of nurse staffing on the quality and safety of patient care. An expected deepening of the shortage in coming years[12] has increased the urgency of understanding the staffing-outcomes relationship and offering nurses and health care leaders evidence about the impacts of providing care under variable nurse staffing conditions. This chapter includes a review of related literature from early 2007.

Identifying Nurse-Sensitive Outcomes

The availability of data on measures of quality that can be reasonably attributed to nurses, nursing care, and the environments in which care is delivered has constrained research studying the link between staffing and outcomes. While nurse leaders have been discussing the need to measure outcomes sensitive to nursing practice back to at least the 1960s, widespread use of the terms "nurse/nursing-sensitive outcomes" and "patient outcomes potentially sensitive to nursing" is a relatively recent development. Nurse-sensitive measures have been defined as "processes and outcomes that are affected, provided, and/or influenced by nursing personnel, but for which nursing is not exclusively responsible."[13, 14] While some scholars feel the term "nurse-sensitive measure" is fundamentally incorrect because patient outcomes are influenced by so many factors, health care is practiced in a multidisciplinary context, and few aspects of patient care are the sole purview of nurses, there is a broad recognition that some outcomes reflect differences in the quality of nursing care patients receive and therefore presumably respond to the characteristics of the environments in which care is provided (including staffing levels).

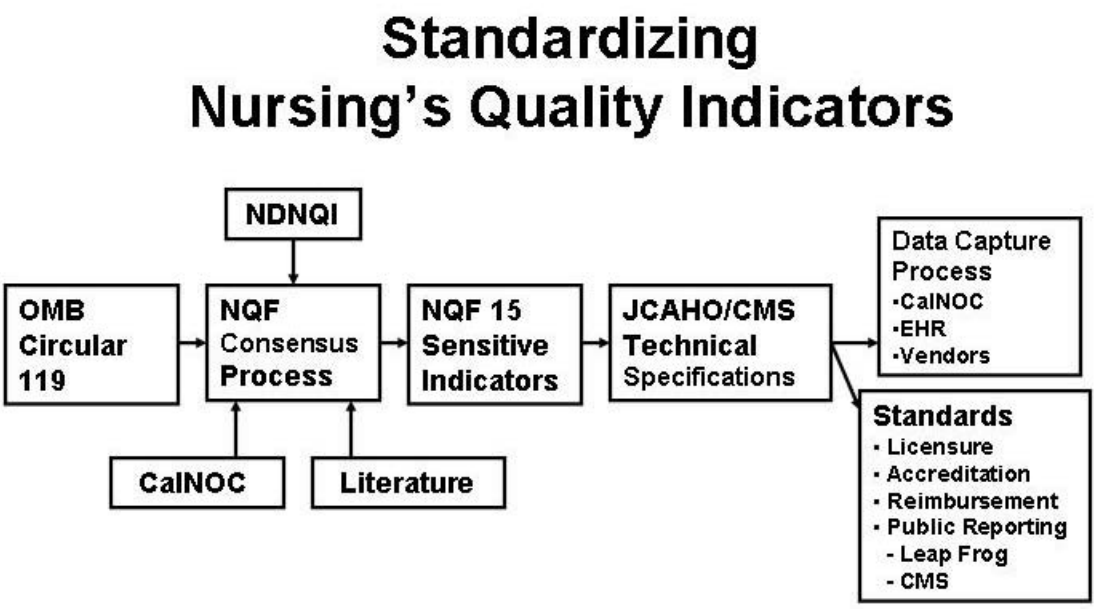
No matter what label these measures are given, measures that have conceptual and clinical links to the practice of nursing and are sensitive to variations in the structure and processes of nursing care are an essential ingredient in this area of research. Data sources from which to construct these measures must be identified, and exact definitions indicating how measures are to be calculated must be drafted. This is particularly critical if different individuals or groups are involved in compiling quality measures. There have been calls for standardization of measures of the quality of health care for some time,[1, 15] along with outcome measures related to the quality of nursing care. Inconsistent definitions have slowed progress in research and interfered with comparability of results across studies. A paper, now under review, examines and compares common measures of adult, acute care nurse staffing, including unit-level hospital-generated data gleaned from the California Nursing Outcomes dataset, hospital-level payroll accounting data obtained from the California Office of Statewide Health Planning and Development, hospital-level personnel data submitted to the American Hospital Association, and investigator research data obtained from the California Workforce Initiative Survey. Findings reveal important differences between measures that may explain at least some inconsistencies in results across the literature (Spetz, Donaldson, Aydin, personal communication February, 2007).

Efforts to address the standardization imperative began with the American Nurses Association's (ANA) first national nursing quality report card initiative. This initiative began with a literature search to identify potential nurse-sensitive quality indicators. Next, expert reviewers examined and validated a smaller, selected group of indicators and measures from

among these.[16] The ANA then funded six initial nursing quality report card indicator feasibility studies, which developed and refined these first sets of measures, documenting the quality of nursing care in acute care settings. The California Nursing Outcomes Coalition (CalNOC) was among the first State-based feasibility projects conducted by the ANA that ultimately served as the basis for the National Database for Nursing Quality Indicators (NDNQI) established in 1997. Maintaining an informal collaboration with the NDNQI, CalNOC continues to function as a regional nursing quality database, and more recently, CalNOC methods have been adapted by both the emerging Military Nursing Outcomes Database and VA Nursing Outcomes Database projects. All four groups currently collect and analyze unit-level data related to the associations between nurse staffing and the quality and safety of patient care. Together, they have formed an unofficial collaborative of nursing quality database projects.[17–21]

The most recent initiative in standardizing staffing and outcomes measures for quality improvement and research purposes was undertaken by the National Quality Forum (NQF). The mission of the NQF is to improve American health care through consensus-based standards for quality measurement and public reporting related to whether health care services are safe, timely, beneficial, patient centered, equitable, and efficient. To advance standardization of nurse-sensitive quality measures and respond to authoritative recommendations from multiple IOM and Federal reports,[9, 15, 22] the NQF convened an expert panel and established a rigorous consensus process to generate the Nation's first panel of nursing-sensitive measures for public reporting. The aim of the expert panel was to explicate and endorse national voluntary consensus standards as a framework for measuring nursing-sensitive care and to inform related research. Potential nursing-sensitive performance measures were subjected to a rigorous and systematic vetting under the terms of the NQF Consensus Development Process, which included a thorough examination of evidence substantiating each measure's sensitivity to nursing factors, alignment with existing requirements being made of providers, and validation/recommendations of advisory bodies to Federal agencies. As illustrated in Figure 1, the resulting first 15 NQF nursing-sensitive measurement standards were informed by earlier work by the NDNQI and CalNOC, as well as measures arising from formal research studies.

Figure 1. Standardizing Nursing's Quality Indicators



Notes: CMS = Centers for Medicare and Medicaid Services; EHR = electronic health record; JCAHO = Joint Commission on Accreditation of Healthcare Organizations, now known as the Joint Commission; OMB = Office of Management and Budget.

These measures represent a first (but by no means final) attempt to make nurse-sensitive outcomes visible to the broader community of payers and policymakers. The first 15 voluntary consensus standards for nursing-sensitive care intended for use in public reporting and policy initiatives included[23]

1. Failure to rescue
2. Pressure ulcer prevalence
3. Falls
4. Falls with injury
5. Restraint (vest and limb) prevalence
6. Urinary catheter-associated urinary tract infections (intensive care unit, ICU)
7. Central line catheter-associated bloodstream infections (ICU)
8. Ventilator-associated pneumonia (ICU)
9. Smoking cessation counseling for acute myocardial infarction
10. Smoking cessation counseling for pneumonia
11. Smoking cessation counseling for heart failure
12. Skill mix
13. Nursing hours per patient day
14. Practice Environment Scale-Nursing Work Index
15. Voluntary turnover

A Framework Relating Nurse Staffing to Patient Care Quality and Safety

Figure 2 illustrates a set of conceptual relationships between the key variables in this review, including influences on staffing levels and factors influencing outcomes. These relationships form a set of interrelated pathways that link nurse staffing to patient care quality, safety, and outcomes. Notable is that each of the elements enclosed in a box—specifically administrative decisions, quality of nursing care, care needs, and safety and clinical outcomes—is influenced by a host of factors that are not detailed in the diagram and could each be the subject of its own literature review.

Figure 2. Nurse Staffing, Quality of Care, and Outcomes

- Staffing levels are set by administrators and are affected by forces that include budgetary considerations and features of local nurse labor markets. Administrative practices result in a structure of the nursing staff of an agency (nature of supervision) and staff or staff hours assigned to different subunits in a facility. These practices also affect the mix and characteristics of the nurse workforce, the model of care used in assigning staff and in providing care, and a wide range of workplace environments that affect how nurses practice. Other characteristics of the workplace environments noted in the literature included the physical environment, communication systems and collaboration, information systems, and relevant support services. All of these factors ultimately influence the "dose" or quantity of nursing time, as well as the quality of nursing care.
- Variables included in the category of care needs of the patient include the acuity and complexity of the patient's health status, as well as the patient's comorbid medical conditions, functional status, family needs/resources, and capacity for self-care. The vulnerabilities of patients for adverse events varies and changes over the course of a hospital stay or episode of care.
- The quality of nursing care relates to the appropriate execution of assessments and interventions intended to optimize patient outcomes and prevent adverse events. For

example, the extent to which nurses assess the risk for falls in hospital patients upon admission, implement evidence-based fall-prevention protocols, and sustain such preventive interventions could each be developed into measures of nursing care quality. The quality of nursing care also includes attention to safety issues, for example, the accuracy of medication administration. Safe care also entails consistent monitoring tailored to patients' conditions to guarantee early recognition of patient deterioration and, if problems are identified, benefit from a rapid, appropriate interdisciplinary team response to these issues.[24]

The quality of care that nurses provide is influenced by individual nurse characteristics such as knowledge and experience, as well as human factors such as fatigue. The quality of care is also influenced by the systems nurses work in, which involve not only staffing levels, but also the needs of all the patients a nurse or nursing staff is responsible for, the availability and organization of other staff and support services, and the climate and culture created by leaders in that setting. The same nurse may provide care of differing quality to patients with similar needs under variable staffing conditions and in different work environments.

- Safety outcomes include rates of errors in care as well as potentially preventable complications in at-risk patients. Safe practices that avoid errors and foreseeable complications of care can be thought of as either a basic element of or a precondition for delivering high-quality care, but are generally thought of as only one component of quality.
- Clinical outcomes (endpoints) of importance vary from patient to patient or by clinical population and include mortality, length of stay, self-care ability, adherence to treatment plans, and maintenance or improvement in functional status. Serious errors or complications often lead to poor clinical outcomes. So far, very few positive clinical outcomes have been studied by staffing-outcomes researchers, probably because of limited measures and data sources.

The sheer number of variables and myriad linkages depicted suggest why precise evidence-based formulas for deploying nursing staff to ensure safe, high-quality patient care are impossible based on the knowledge on hand. In fact, such prescriptions may never be possible. Certainly, evidence-based guidelines for allocating resources to ensure optimal outcomes in acute care and other health care settings cannot be offered until working environments, staffing (beyond head counts and skill mix), patient needs, processes, and outcomes of care can be measured with precision.

Research investigating links between hospital nurse staffing and patient outcomes began with studies examining patient mortality. Reviews now include research examining a broad range of outcomes, including specific adverse events other than mortality. Although many studies support a link between lower nurse staffing and higher rates of negative nurse-sensitive safety outcomes,[25–27] reviews of two decades of research revealed inconsistent results across studies.[25–30]

State of Science on the Relationship Between Nurse Staffing and Patient Outcomes

Before examining the state of the scientific literature on the relationship between nurse staffing and clinical outcomes, it is important to consider common challenges of research in this arena. Investigators face at least two fundamental problems when designing staffing-outcomes studies: first, finding suitable data sources and measures for staffing and patient outcomes, and

second, linking the two types of variables to reach valid conclusions. As noted earlier in this chapter, because of limitations in measures, data sources, and analytic methods, researchers generally ask a different question in their studies (Is there a correlation between staffing and patient care outcomes?) than the questions that are of primary concern to patients, clinicians, managers, and policymakers (What staffing levels are safe under a specific set of circumstances?).[31] Nonetheless, researchers in this field deserve a great deal of credit for making creative use of a variety of data sources not originally developed for research (or research on staffing and outcomes) to generate a great deal of evidence that has fueled discussion in the practice, management, and policy communities.

Data Sources, Measures, and Challenges

As clinical trials or controlled experiments are difficult if not impossible to conduct in this area, observational designs must be optimized as much as possible. When outcomes are compared across hospitals or other health care organizations as a whole or their clinical units or microsystems, frequently the research design that results from data linkages and analyses is cross-sectional and correlational in nature. Staffing levels and patient outcomes from approximately the same time are analyzed to determine whether a correlation exists between the two. As all students of research methods know, correlational designs are more limited than experiments for determining the extent to which causal links exist between staffing levels and outcomes. Factors other than nurse staffing can vary alongside staffing levels, so whether or not certain different staffing levels directly lead to better or worse outcomes cannot be determined with certainty from correlational designs. Such factors include other aspects of the environment in which care is provided (for example the availability of supplies, quality of physician care and/or other services and supports). Statistical methods can control for obvious factors that influence or are otherwise associated with staffing levels (such as hospital size, academic affiliation, or rural-urban location). Nonetheless, it is impossible to measure and account for all possible confounding variables (or competing explanations for findings) in the typical designs of these studies. Maximizing returns on correlational research designs involving staffing requires careful selection of variables and clearly articulating the theoretical and/or empirical bases for choosing them.

Tables 1 and 2 provide brief overviews of types of measures and the questions consumers of staffing outcomes research might consider in appraising individual studies. The discussion that follows is intended to emphasize a few fundamental points before turning to the findings in the literature itself.

Table 1. A Typology of Measures in the Staffing-Outcomes Literature

Variable	Sources of Data	Types
Staffing	• Records from health care facility operations (assignment sheets, scheduling grids) • Data submitted to regulatory bodies • Surveys of staff regarding staffing levels and/or workload	**Major types** • Staff/staffed hours divided by patient/service volume • Credentials/qualifications of nursing staff (higher or lower in relation to total): licensed vs. unlicensed; level of licensure; highest degree, professional certification; years of experience • Voluntary turnover • Use of contract or agency staff **Important distinctions** • Level of measurement within the organization (whole facility/department vs. unit) • Roles of staff measured (such as staff involved in "direct patient care" vs. all nursing staff) • Time frame (shift/day/week/month/quarter/year)
Outcome	• Patient records, discharge abstracts, incident reports, or other byproducts of care delivery (including reimbursement) • Prospective surveillance for specific events (such as falls and pressure ulcers) • Surveys of patients/families and providers	Occurrence of events suggestive of poor (or less commonly, high) quality of care or nurse work-related outcomes **Level of measurement** • Individual patients/nurses • Subunits (e.g., nursing units) of organizations • Entire facilities

Table 2. Major Methodological Considerations in This Literature

Design Feature	Questions to Ask
Measurement of staffing	Do the staffing measures reflect the type and "dose" of staff actually caring for the patients being studied? Were the staffing measures collected in a consistent manner (using common definitions) across the organizational units/time periods?
Measurement of outcomes	Were outcomes assessed in comparable ways across patients and across settings (units or institutions or time periods)? Do data sources allow a distinction between complicating conditions present when care was undertaken (which should be considered in the analyses in risk adjustment (below)) from conditions that appeared during care (that are potentially outcomes of nursing care during the hospitalization)? Were outcomes assessed completely/comprehensively for all patients? What evidence is there regarding the consistency of documentation for the outcomes in question in the data sources? Does the outcome in question have a plausible association with nursing practice, or is it primarily/entirely associated with factors outside the control of providers?
Risk adjustment	Have the authors conducted fair comparisons between rates of adverse events across hospitals units or time periods by considering potentially important differences in the patients treated across those settings and/or over time?

Design Feature	Questions to Ask
Data linkage	To what extent do staffing measures represent conditions at the times and places where nursing care affecting the outcomes and measured for this study is given? Are outcomes attributed to the locations of care where nursing services actually influence the outcome, or do they also reflect the place where detection of the outcome occurs?
Control for confounding factors	Have other aspects of the environments in which patients are cared for that might affect the outcomes been measured and analyzed? E.g., availability of equipment/supplies, quality of physician care, other types of facility personnel, hospital size, academic affiliation, rural-urban location
Statistical modeling	If the study examines an outcome that is rare in the patient population, has this been considered in any modeling? How is skewness of the data managed? If the subjects of the study are grouped or nested within larger organizational units (e.g., patients within nursing units within hospitals), has this been handled by the analytic strategy? Do at least some of the analyses presented depict the complexity of associations between the factors involved through some type of statistical modeling that evaluates impacts of variables simultaneously?

Staffing

Staffing levels can be reported or calculated for an entire health care organization or for an operational level within an organization (a specific unit, department, or division). Specific time frames (at the shift level and as a daily, weekly, or yearly average) must be identified to ensure common meaning among collectors of the data, those analyzing it, and individuals attempting to interpret results of analyses.

In many cases, staffing measures are calculated for entire hospitals over a 1-year period. It is fairly common to average (or aggregate) staffing across all shifts, for instance, or across all day shifts in a month, quarter, or year and sometimes also across all the units of hospitals. The resulting measures, while giving an imprecise idea of what specific conditions nurses and patients experienced at particular points, are general indicators of facilities' investments in staffing. However, staffing levels on different units reflect differences in patient populations and illness severity (the most striking of which are seen between general care and critical care units). Furthermore, in practice, staffing is managed on a unit-by-unit, day-by-day, and shift-by-shift basis, with budgeting obviously done on a longer time horizon. For these reasons, some researchers argue that at least some research should be conducted where staffing is measured on a shift-specific and unit-specific basis instead of on a yearly, hospitalwide basis. A distinct, but growing, group of studies examined staffing conditions in subunits or microsystems of organizations (such as nursing units within hospitals) over shorter periods of time (for example, monthly or quarterly).[17, 32–34]

In addition to three sources of staffing data, there are also two basic types of staffing measures or variables. The first type divides a volume of nurses or nursing services by a quantity of patient care services. Common examples include patient-to-nurse ratios, hours of nursing care delivered by various subtypes of personnel per patient day (HPPD), and full-time equivalent (FTE) positions worked in relation to average patient census (ADC) over a particular time period. Patient-to-nurse ratios, HPPD figures, or FTE:ADC measures have the potential to both

systematically overestimate or underestimate nurse workloads and the attention given to specific patients in relation to those patients' needs, conditions, and clinical trajectories across units or institutions or over time.[31]

The second major type of measure examines the credentials or qualifications of those staff members and expresses them as a proportion of staff with more versus less training (or vice-versa). Commonly, the composition of the nursing staff employed on a unit or in a hospital in terms of unlicensed personnel, practical or vocational nurses, and registered nurses (RNs) is calculated. The specific types of educational preparation held by RNs (baccalaureate degrees versus associate degrees and diplomas) have also begun to be studied. Additional staffing-related characteristics studied include years of experience and professional certification. The incidence of voluntary turnover and the extent to which contract or agency staff provide care have also been studied. As will be discussed, the majority of the evidence related to hospital nurse staffing focuses on RNs rather than other types of personnel.

For the most common measures, ratios and skill-mix, determining which staff members should be included in the calculations is important, given the diversity of staffing models in hospitals. Most researchers feel these statistics should reflect personnel who deliver direct care relevant to the patient outcomes studied. Whether or not to count charge nurses, nurse educators involved in bedside care, and nurses not assigned a patient load (but who nevertheless deliver important clinical services) can present problems, if not in principle, then in the reality of data that institutions actually collect. Outcomes research examining the use of advanced practice nurses in acute care—for instance, nurse practitioners and nurse anesthetists—to provide types of care traditionally delivered by medical staff and medical trainees has been done in a different tradition (analyzing the experiences of individual patients cared for by specific providers) and does not tend to focus on outcomes relevant to staff nurse practice; therefore these studies are not reviewed here. No studies were found that examined advanced practice nurse-to-patient ratios or skill mix in predicting acute care patient outcomes. There have been calls to examine advanced practice nurses supporting frontline nurses in resource roles (for instance, clinical nurse specialists who consult and assist in daily nursing care, staff development, and quality assurance) and their potential impact on patient outcomes. No empirical evidence of this type was found.

Outcomes

Clearly, capturing data about patient outcomes prospectively (i.e., as care is delivered) is the best option for obtaining precise, comprehensive, consistently collected data. This approach is the most challenging because of practical, ethical, and financial considerations. However, researchers can sometimes capitalize on prospective data collections already in progress. For instance, hospital-associated pressure ulcer prevalence surveys and patient falls incidence are commonly collected as part of standard patient care quality and safety activities at the level of individual nursing units in many institutions.[18, 32] Many, but by no means all, studies in this area use secondary data not specifically intended for research purposes, such as patient medical records. Outcomes researchers often use condensed or abstracted versions of hospital patients' records in the form of discharge abstracts, which contain data extracted from health care records about clinical diagnoses, comorbidities, procedures, and the disposition of patients at discharge.[35] As there are concerns that the quality and reliability of clinical documentation varies widely,[35] one author suggested that only a form of electronic medical record that forces contemporaneous recording of assessment data and interventions will permit true performance measurement in

health care.[36] Wider application of information technology in health care settings, anticipated to facilitate care delivery and improve quality and safety, is also expected to provide richer, higher-quality data sources for strategic performance improvement that can be leveraged by outcomes researchers.

Patients are not all at equal risk of experiencing negative outcomes. Elderly, chronically ill, and physiologically unstable patients, as well as those undergoing lengthy or complex treatment, are at much greater risk of experiencing various types of adverse events in care. For instance, data on falls may be consistently collected for all hospitalized patients but may not be particularly meaningful for obstetrical patients. Accurately interpreting differences in rates across health care settings or over time requires understanding the baseline risks patients have for various negative outcomes that are beyond the control of the health care providers. Ultimately this understanding is incorporated into research and evaluation efforts through risk adjustment methods, usually in two phases: (1) carefully defining the patient populations at risk—the denominator in rates; and (2) gathering reliable and valid data about baseline risk factors and analyzing them. Without sound risk adjustment, any associations between staffing and outcomes may be spurious; what may appear to be favorable or unfavorable rates of outcomes in different institutions may no longer seem so once the complexity or frailty of the patients being treated is considered.[35]

The focus of this review is on staffing and safety outcomes. However, as was noted earlier, quality of care and clinical outcomes (and by extension, the larger domain of nursing-sensitive outcomes) include not only processes and outcomes related to avoiding negative health states, but also a broad category of positive impacts of sound nursing care. Knowledge about positive outcomes of care that are less likely to occur under low staffing conditions (or are more likely under higher levels) is extremely limited. The findings linking functional status, psychosocial adaptation to illness, and self-care capacities in acute care patients are at a very early stage[37] but eventually will become an important part of this literature and the business case for investments in nurse staffing and care environments.

Linkage

In staffing-outcomes studies, researchers must match information from data sources about the conditions under which patients were cared for with clinical outcomes data on a patient-by-patient basis or in the form of an event rate for an organization or organizational subunit during a specific period of time. Ideally, errors or omissions in care would be observed and accurately tracked to a particular unit on a particular shift for which staffing data were also available. Most, but not all, large-scale studies have been hospital-level analyses of staffing and outcomes on an annual basis and have used large public data sources.

Linkages of staffing with outcomes data involve both a temporal (time) component and a departmental or unit component. Many outcomes (endpoints) examined by staffing researchers are believed to reflect compounded errors and/or omissions over time across different departments of an institutions. These include some types of complications as well as patient deaths. Attribution of outcomes is complicated by the reality that patients are often exposed to more than one area of a hospital. For instance, they are sometimes initially treated in the emergency department, undergo surgery, and either experience postanesthesia care on a specialized unit or stay in an intensive care unit before receiving care on a general unit. If such a patient develops a pressure ulcer, at what point did low staffing and/or poor care lead to the

pressure ulcer? Unfortunately, in hospital-level datasets, it is impossible to pinpoint the times and locations of the errors or omissions most responsible for a clinical endpoint. In the end, if outcomes information is available only for the hospital as a whole (which is the case in discharge abstracts, for instance), data linkage can happen only at the hospital level, even if staffing data were available for each unit in a facility. Similarly, if staffing data are available only as yearly averages, linkage can be done only on an annual basis, even if outcomes data are available daily or weekly. Linkages can be done only at the broadest levels (on the least-detailed basis or at the highest level of the organization) available in a dataset. Many patient outcomes measures (such as potentially preventable mortality) may actually be more meaningful if studied at the hospital level, while others (such as falls) may be appropriately examined at the unit level.

One should recognize that common mismatches between the precision of staffing measures and the precision of outcome measures (i.e., the staffing across an entire year across all units in a hospital used as a predictor of outcomes for a patient treated for a short time in only a fraction of these units) compromise the likelihood that valid statistically significant associations will be found. This finding is particularly relevant when staffing statistics span a long time frame and therefore contain a great deal of noise—information about times other than the ones during which particular patients were being treated. High-quality staffing data, as well as patient assessment and intervention data—all of which are accurately date-stamped and available for many patients, units, and hospitals—will be necessary to overcome these linkage problems. Such advances may come in the next decades with increased automation of staffing functions and the evolution of the electronic medical record.

Recent prospective unit-level analyses, now possible with datasets developed and maintained by the NDNQI, CalNOC, and the military hospital systems, make it possible to overcome some of these issues. These databases, although not risk adjusted, stratify data by unit type and hospital size and have adopted standardized measures of nurse staffing and quality of care. The resulting datasets provide opportunities to study how variations in unit-level staffing characteristics over time can influence patient outcomes (for instance, pressure ulcers and falls, as discussed later). As data sources do not exist for all types of staffing and outcomes measures at all levels of hospital organization (nor will they ever), research at both the unit level and the hospital level will continue, and both types of studies have the potential to inform understanding of the staffing-outcomes relationship.

Research Evidence

Perhaps staffing and outcomes research has such importance and relevance for clinicians and educators as well as for managers and policymakers, staffing-outcomes research is a frequently reviewed area of literature. As was just detailed, a diversity of study designs, data sources, and operational definitions of the key variables is characteristic of this literature, which makes synthesis of results challenging. Many judgments must be made about which studies are comparable, which findings (if any) contribute significantly to a conclusion about what this literature says, and perhaps regarding how to transform similar measures collected differently so they can be read side by side. The review of evidence here builds on a series of recent systematic reviews with well-defined search criteria.[25, 27, 30, 38] At least one group of researchers conducted a formal meta-analysis that integrated the bulk of empirical findings in the hospital staffing literature and summarized effect sizes for specific staffing measures, outcomes, and clinical populations.[30] This review was the most up-to-date identified within this search.

Evidence Related to Acute Care Hospitals

Many researchers have identified higher levels of adverse patient events (mortality and complications, for instance) and negative nurse job outcomes (such as burnout) under poorer staffing conditions (specifically, thinner staffing coverage or fewer nurses per unit of patient care and, somewhat less commonly in these studies, lower skill mix/education level of staff). These findings have appeared in studies conducted using a variety of designs and examining hospital care in different geographical areas and over different time periods. On the whole, while some researchers have identified effects of 20 percent and greater reductions in negative outcomes associated with increased/improved (or the most generous) staffing, most studies in this literature show much smaller reductions in negative outcomes (under 10 percent and often much smaller ones) associated with the most favorable staffing conditions they observe.[30] Given the relative rarity of some outcomes, these are subtle enough changes in outcomes to require observing many thousands, if not hundreds of thousands, of patients to identify staffing effects on the reduction of negative patient outcomes. Again, because of the tremendous number of factors involved in staffing decisions and their effects on patient care, and limitations in assessing patient characteristics, the specific staffing thresholds applicable to managers' decisionmaking below which outcomes are demonstrably worse cannot be identified using this literature—a point emphasized in many reviews.[24, 26]

The evidence table summarizes four major systematic reviews of the literature, approaches, and conclusions regarding the state of the evidence for specific outcomes or outcome types. In these papers, reviewers identify specific measurement types and established criteria for study inclusion in terms of design and reporting and examined a relatively complete group of the studies one by one to provide an overview of the state of findings as an integrated whole.

The contrasts in the conclusions are interesting but are probably less important than the overall trend: research results point persuasively to a correlation of staffing with outcomes, but not all outcomes or datasets show such a connection. An additional important point is that nearly all studies connecting staffing parameters with outcomes have been conducted at the hospital (rather than the unit) level.

Recent results emerging from the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Working Conditions Program (2001–2005) offer some examples of recent unit-level studies of staffing and its impacts on outcomes. In a 2-year AHRQ Working Conditions and Patient Safety study built on the work of CalNOC, Donaldson and colleagues[17] engaged acute care hospitals using ANA nursing indicators for reporting staffing, patient safety, and quality indicators in a research, repository development, and benchmarking project. Data were drawn from 25 acute care, not-for-profit California hospital participants in the regional CalNOC. The sample included urban and rural hospitals with an average daily census from 100 to more than 400 patients. Most patients' principal diagnoses were medical (66 percent). The aims of the study were to test associations between daily nurse staffing on adult medical-surgical units and hospital-acquired pressure ulcers, patient falls, and other significant adverse events, if they were of sufficient volume to analyze. A prospective, descriptive, correlational design tested associations between patient outcome measures and daily unit-level nurse staffing, skill mix, hours of care (along with hours covered by supplemental agency staff), and workload. Falls were defined as "unplanned descents to the floor." RN hours of care were significantly associated with the two focal outcomes. Unit activity index and hospital complexity (measured by bed size) were also significant predictors of falls.

In another analysis, Donaldson and colleagues[39] traced daily, unit-level direct care nurse staffing in 77 units across 25 hospitals over a 2-month period using data on staffing effectiveness (the match between hours of care and hours provided). By law in California, each hospital unit uses an institutionally selected, acuity-based workload measurement system to determine required hours of care for each patient. For each patient-care unit, the ratio of actual to required hours of care, was expressed as both a mean ratio and as a percentage of days on which required hours exceeded actual hours over the 7 days prior to a pressure ulcer prevalence study. Using Spearman rank correlations, the percentage of patients with hospital-associated pressure ulcers was significantly associated with the mean actual/required hours ratio for the prior 7 days (r's = -0.25, 63 df, $P < 0.05$), and with the percent days with the actual/required ratio <100 percent for the prior 7 days (r's = 0.25, 63 df, $P < 0.05$). Larger actual/required ratios and actual/required ratios closer to 100 percent were associated with a lower percentage of patients with hospital-associated pressure ulcers. These analyses linked unit-level staffing and safety-related outcomes data, and measured for time periods at the unit level closely and logically connected (staffing measures relevant to conditions before the outcome occurred). The findings are intriguing and suggest that the impact on patients of "short" staffing appeared a number of days later, as one would expect given the pathophysiology of pressure ulcers (since it takes a number of days of unrelieved pressure on a vulnerable area for tissue damage to occur). Both researchers and research consumers need to reflect on the time frames involved in the evolution of various outcomes when assessing the validity of data linkages across time and units. For instance, in contrast to the lags between quality problems in care and evidence of their impact on outcomes such as infections and pressure ulcers, practice conditions will tend to have more immediately observable impacts on outcomes like falls with injury and most adverse drug reactions.

Recent legislation in California that introduced mandated nurse-to-patient ratios at the unit level provides an interesting context for studying the association of staffing and outcomes. CalNOC has reported early comparisons of staffing and outcomes in 268 medical-surgical and step-down units in 68 California hospitals during two 6-month intervals (Q1 and Q2 of 2002 and Q1 and Q2 of 2004) before and after introduction of the ratios. Data were stratified by hospital size and unit type. On medical-surgical units, mean total RN hours per patient day increased by 20.8 percent, total nursing hours increased by 7.4 percent, the number of patients per licensed nurse decreased by 16.0 percent, and the portion of nonlicensed nursing hours decreased by 20.8 percent. However, there were no statistically significant changes in the rate of patient falls or pressure ulcers on these units.[40] These early data suggested that the introduction of mandated ratios may have led to changes in staffing metrics in California hospitals without yet attaining the goal of improving patient outcomes.

Summary and Comment

Researchers have generally found that lower staffing levels are associated with heightened risks of poor patient outcomes. Staffing levels, particularly those related to nurse workload, also appear related to occupational health issues (like back injuries and needlestick injuries) and psychological states and experiences (like burnout) that may represent precursors for nurse turnover from specific jobs as well as the profession.

Associations are not identified every time they are expected in this area of research. Other aspects of hospital working conditions beyond staffing, as well individual nurse and patient

characteristics, affect outcomes since negative outcomes are relatively uncommon even at the extremes of staffing and do not occur in every circumstance where staffing is low.

A critical mass of studies established that nurse staffing is one of a number of variables worthy of attention in safety practice and research. There is little question that staffing influences at least some patient outcomes under at least some circumstances. Future research will clarify more subtle issues, such as the preferred methods for measuring staffing and the precise mechanisms through which the staffing-outcomes relationship operates in practice.

Areas Where the Evidence Base Is Currently Limited

Nurse executives and frontline managers make decisions about numbers of staff to assign to the various areas of their facilities. They also establish models of care to be used in caring for patients in terms of the constellation of nursing staff and distribution of responsibilities among professional nurses and other types of nursing staff. Patients and their families want assurances that enough staff are on duty to ensure that care is safe and meets patients' needs. Policymakers want assurances that the nursing workforce in their jurisdictions is adequate; they also want to know whether or not regulatory intervention is necessary to ensure acceptable staffing levels and desirable patient outcomes. Staffing researchers are ultimately constrained by the limitations of their data in answering many questions of relevance to the real worlds of health care delivery and public policy. Investigators most commonly examined the correlations of complex patient outcomes with staffing measures derived at some distance from the delivery of care (perhaps aggregated over time). Researchers then asked whether measures of staffing and outcomes were statistically associated with each other. A clear distinction between direct conclusions from research findings and the opinions of particular authors or interest groups must be made.

It is impossible to specify parameters for staffing that will ensure safety based on current evidence without many qualifiers. The adequacy of staffing (the degree to which staffing covers patient needs) even for the same patients and nurses may change from hour to hour, particularly in acute care settings. Nurse-to-patient ratios and skill mixes in specific settings that are too low for safety still cannot be identified on the basis of the research literature, but decisions must be made on the basis of the judgments by frontline staff and their managers. On a related note, the specific nursing care processes that are more likely to be omitted or rendered less safe under different staffing conditions are not well understood, empirically speaking, and deserve further attention.

A number of other areas identified in the staffing literature are relatively underdeveloped. Most research on staffing has been conducted in acute care settings; however, not all clinical areas within acute care have been equally well studied. A number of observers remarked that for the most part, the state of evidence regarding staffing's impact on specialties outside of adult medical-surgical care is very limited. Data regarding settings for the care of children, childbearing families, and patients with mental health problems are currently very thin.[25] Difficulties in collecting reliable, valid outcomes indicators that are potentially sensitive to nursing care in these other settings is probably at least partly to blame.

The majority of nurses working in hospitals in the United States are, of course, registered nurses. Available evidence suggested that patients in hospitals that use more licensed practical nurses (LPNs) or vocational nurses may see worse outcomes.[30, 40] Indeed, at least one cost-benefit analysis of drawing on findings from one of the largest studies in the field[40] suggested that increasing the proportion of RNs (and decreasing the proportion of practical nurses) in the

composition of hospital staffs may be a more cost-effective measure and could have a bigger impact on outcomes than increasing hours of nursing care per patient day.[41] Likewise, most reports in the literature dealing with unlicensed assistive personnel (UAPs) either failed to find associations with this type of staff or suggested worse outcomes in institutions with high levels of such personnel. There is no direct evidence that it is unsafe to employ LPNs in acute care settings,[42, 43] nor is there empirical support that the use of unlicensed personnel is intrinsically related to poor outcomes. Use of practical nurses and UAPs can be driven by any and all of the factors outlined in Figure 2. Nonetheless, anecdotal evidence suggests that inadequately trained and/or supervised personnel of all kinds at times provide unsafe care; that operational problems having related, but distinct, causes and consequences can lead to substituting other types of workers for RNs and to safety problems; and that the savings associated with using lesser-trained workers sometimes prove to be false economies. The models of care under which LPNs and unlicensed care providers are employed (i.e., the exact roles of non-RN personnel and degree of oversight provided by RNs) has not been considered in research. While RNs have the broadest scope of practice of frontline nursing workers, it is far from established that 100 percent RN staffing is effective in all situations. Future research needs to identify the circumstances under which LPNs and UAPs can be used safely. Until then (and even when it does), local labor market realities, experience, and judgment will need to be used by leaders to establish skill mix and to define the models of care under which RNs, LPNs, and UAPs work.

Early studies have offered early, tantalizing insights regarding a number of variables conceptually close to staffing. These findings include the educational preparation of RN staff in hospitals. Two recent studies[44, 45] found that mortality in surgical and medical patients was lower in hospitals where higher proportions of staff nurses held baccalaureate degrees. The AHRQ-sponsored studies of California hospitals discussed above also suggested that a higher percentage of nurses holding bachelor's and higher degrees was associated with lower fall rates. Additionally, in this latter work, units where higher percentages of RNs held specialty certification had lower proportions of restrained patients. Should these findings be borne out in future studies, there are important potential local and national policy implications. There is a clear need for more research. Similarly, while many feel experience and specialty training have logical associations with quality of care and patient safety, empirical data regarding their impact are very limited at present.

Yet another area where data related to patient outcomes are thin relates to the impact of specific types of work environments on nurse-sensitive outcomes, and in particular the impact of the Magnet hospital model, which has been argued to produce superior patient outcomes (and safer care).[46, 47] Such connections would make intuitive sense, since current Magnet criteria require adherence to many best practices in nursing management, including selection of a well-articulated staffing model driven by data. To our knowledge, there are no studies yet to directly support a connection between safety and specific managerial approaches or to link Magnet status with patient outcomes in the current era of certification. However, early findings with respect to questions around the outcomes of the program are expected in the coming years.

Evidence Related to Other Settings

There has been intense interest in identifying staffing-outcomes relationships in long-term care settings. RNs are, of course, in the minority among the nursing staff in long-term care, with unlicensed providers providing the bulk of physical care in these facilities. There are many

challenges in using existing documentation and databases to measure outcomes in long-term care facilities,[48] some of which are shared with outcomes measurement in acute care. Long-term care researchers face special issues, specifically with respect to data reliability and measure stability, skewedness of measures, and selection and ascertainment bias (where types of patients at high risk for poor outcomes or who are more closely observed are concentrated in certain nursing homes).[48]

Despite these problems, a critical mass of studies suggests that long-term care facilities with the lowest licensed and unlicensed staffing levels among their peers show disproportionately worse patient outcomes. A study sponsored by the Centers for Medicare and Medicaid Services (CMS) suggested that among short-stay patients, skilled nursing facilities with the lowest staffing levels were 30 percent more likely to fall in the worst 10 percent of facilities for transfers to acute care for acute heart failure, electrolyte imbalances, sepsis, respiratory infection, and urinary tract infection. Facilities with staffing below thresholds of 2.78 hours of aide time and 0.75 hours of RN time had greater probability of having the worst outcome rates for long-stay patients, including pressure ulcers, skin trauma, and weight loss.[49] Similar conclusions were reached in a secondary analysis of data from a pressure ulcers study. In 1,376 residents of 82 long-term care facilities, patients in facilities with more direct RN time (30–40 minutes per patient day and more) had fewer pressure ulcers, acute care hospitalizations, urinary tract infections, and urinary catheters, and less deterioration in ability to perform activities of daily living.[50] In a national sample of nursing homes from 45 States, those that met CMS guidelines for RN and unlicensed hours per patient-day had statistically lower rates of lawsuits after controlling for a multitude of structural, market, and patient factors.[51] Not all studies report such findings. Rantz and colleagues'[52] analysis of outcomes in 92 nursing homes found that staffing levels did not predict facilities' classification as having generally good, mediocre, or poor outcomes and found that on average, costs were somewhat higher in poor-outcome facilities. These researchers suggested that administrative practices other than staffing may play an important role in determining long-term care quality.

Home health is a growing sector in U.S. health care. Staffing models fall somewhere between acute care hospitals and long-term care in terms of the proportions of unlicensed personnel and practical nurses. Allocation of nursing time to patients presumably influences quality and thoroughness of nursing acts and assessments. There may be skill-mix issues as well. However, to date there have been no studies of home health agency staffing models, nurse workloads, or skill mix. OASIS (Outcomes Assessment and Information Set) data gathered by home health providers by mandate from the Medicare program, skillfully analyzed and interpreted, will offer opportunities to examine safety in home care in relation to staffing decisions.[53] Similar statements can be made about nurse staffing in most other ambulatory and community settings as well.

Summary of Current Best Practices

The general conclusion of these studies conducted in various settings is that differences in outcomes are often observed between situations or institutions where staffing is high and those where it is low. A critical mass of data suggests that staffing at the lower end of the continuum may place patients and nurses at heightened risk of poor outcomes. Therefore, it appears hazardous to patients and staff to staff at the lowest levels relative to peer units and health care organizations.

Limitations of cross-sectional observational designs that predominate in this literature have been reviewed extensively in the chapter. Prominent among these is that there is no guarantee that increasing staffing alone improves the process or outcomes of care. Nonetheless, it would appear wise to continue the widespread practice of adjusting staffing levels for setting, specialty, model of care, client needs, special circumstances, and trends in the frequency of outcomes potentially sensitive to nurse staffing.

Evidence-Based Practice Implications

A key implication arising from this review is that as much as possible, investigators should align their studies with emerging taxonomies and specifications of measures promulgated by authoritative sources (e.g., the Joint Commission). Continued proliferation of measures is slowing progress in this field. Standardized measurement will advance meta-analytic efforts and facilitate aggregation of data across studies. As hospitals and health systems are inundated with data-reporting demands, wise investigators will leverage ongoing measurement efforts by selecting core measures and common metrics already collected by hospitals. There is value for researchers to forge strategic partnerships with professional sponsors of public and private data repositories. Agencies and researchers alike will be served well by study designs that use already de-identified data and make minimal use of protected health information, particularly since the Health Insurance Portability and Accountability Act took effect in 2004.

Likewise, both researchers and clinical administrators must fully harness the potential of new health information systems to capture clinical data. High-quality data on clinical performance will drive both scientific understanding and organizations' strategic quests for excellence. Some authors suggested that competing on the analytics is a characteristic of high-performing organizations.[54]

Leaders at all levels in the health care system must decide how to apply the findings of this literature. It is impossible to read and discuss this area of research without considering whether regulation of nurse staffing is a valid application of the findings, especially in the current climate in health care. As mentioned earlier, there are no evidence-based minimum staffing ratios,[27, 55] although clinicians and managers set operating ratios every day, largely on the basis of their experience and, to a lesser extent, from extrapolations of researchers' findings. As in all aspects of health care management, empirical evidence needs to be interpreted in the context of local data and experience. Although unsatisfying to proponents and opponents of regulation, it bears mentioning that a like or dislike of minimum ratios is often based on one's values and opinions about the capacity and inclination of health care leaders to make responsible staffing decisions autonomously.

Even absent any specific legal mandates to do so, benchmarking staffing and outcomes against peers and attempting to avoid extremes of low staffing and high adverse events, keeping in mind important contextual factors when making comparisons, is undoubtedly the best administrative practice. Keeping in mind that there are many factors affecting the outcomes of care (see Figure 2), a range of efforts needs to be undertaken to increase the quality of clinical practice or reliability, defined by the Institute for Healthcare Improvement as "the number of actions that achieve the intended result divided by the number of actions taken during a target time period."[56]

Executives and managers make a host of decisions beyond those involving staffing that affect the clinical effectiveness of nursing staff. Thought leaders in the arena of patient safety practices

have identified a number of organizational strategies that may constitute better practice in managing the impact of nurse staffing on patient care quality and safety. For example, efforts to optimize clinical, throughput flow and reduce practice variability may reduce threats to staff and patients due to system and personnel overload.[57] Managing supply and demand in health care settings by smoothing peaks and valleys of patient flow,[58] as well as staffing levels, may be effective in modulating workflow extremes that cause staff distress and might pose risks to patients. Implementing systems that enable staff to standardize high-volume common practices (such as patient education, discharge planning, and risk assessments) may be expected to increase efficiency, while enabling staff to customize these highly effective interventions to the unique characteristics of the patient/family. Engaging staff in self-governance related to patient flow has also been cited as a promising best practice. Considered key to safe staffing, professional judgment as the gold standard establishes the threshold for safe patient care in a given clinical setting,[59] as nurses use a systematic decision matrix to determine if the staff on a particular unit can accept responsibility for additional patients. Informed by understanding of scientific conclusions linking staffing and patient outcomes in comparable settings, the self-governing and administrative teams of the future may use internally generated data to support decisions related to staffing adequacy and effectiveness.[60] Through systematic microsystem (unit) assessment, combined with concurrent measurement tracing structure, processes, and outcomes of care, it is possible to calibrate the expertise and dose of the nurse and individualize interventions to the unique characteristics and needs of the patient, optimizing patient care.[61]

As clinicians and administrators in clinical settings gain greater access to real-time data that enable them to explore links between structure, process, and outcomes, increasingly sophisticated tools such as virtual dashboards are promising.[18] Despite a tradition in nursing that has emphasized scientific inquiry as a fundamental source of evidence for practice, there is growing awareness that data that emerge from practice and practitioners (particularly when collected using systematic methods and with high-quality measures) may be a vital source of material for research in this and other areas of policy-relevant inquiry.[62]

Research Implications

There are a great many questions in this field that are still unanswered. There is a clear need to investigate processes of care that are specific to nursing that are associated with safer patient care as well as safer, more efficient interdisciplinary team functioning. Data issues (a lack of measures and of data sources) are a major barrier to work on care delivery. In a discussion of nursing workload measurement tools, the International Council of Nurses noted that "existing tools are unable to capture more than 40 percent of nursing work"[63] (p. 16). Future research must tackle the black box of nursing practice by acknowledging the complexity of nursing assessment, planning, intervention, and evaluation. Addressing variance in the quality of patient care performed by nurses is key to interpreting inconsistencies in the nurse staffing literature and perhaps at the heart of efforts to improve patient care outcomes. Ultimately, it is a priority for future research to explicate links between structure, process, and outcome in nursing practice and patient care.[64]

As indicated before, study of models of care using non-RN staff in acute care, of the impacts of high levels of staffing on health-promoting nursing interventions and nurse-sensitive outcomes, and of staffing and outcomes in understudied specialties in acute care and in nonacute care settings is vital. Ultimately, research in this area is on a track to assist in establishing

evidence-based management[54] that complements the profession's ongoing efforts in evidence-based practice.

Conclusion

From a research tradition in which nurse staffing factors were primarily background variables, the study of nurse staffing and patient outcomes has emerged as a legitimate and strategically crucial field of inquiry. However, despite significant growth in the number and sophistication of studies responding to public policy and provider demand for these findings, results have been inconsistent. This chapter highlights the methodologic challenges inherent in this area of inquiry and explicates how the diversity in measures and units of analyses confound literature synthesis. In the face of myriad pressures to adopt a position for or against mandated nurse-to-patient ratios, the state of the young science does not permit precision in prescribing safe ratios. In fact, it may be concluded that further research is crucial to tease out the nuances in the staffing-outcomes equation. It is essential to advancing the field that future studies replicate, extend, and refine the current body of knowledge, making explicit how characteristics of the workforce, now barely considered (for example, years of experience or professional certification), in addition to the "dose" of the nurse, are linked to processes of care that ultimately result in clinical outcomes (both desirable and adverse). Until then, selected better practices have been noted, with the potential to contribute to pragmatic efforts to improve patient care quality and safety in hospitals.

Search Strategy

The literature on nurse staffing and patient safety is rapidly evolving, very heterogeneous in terms of measures and methods, and equivocal in terms of many of its conclusions regarding specific measures. Our aim was to describe broad trends in this literature, and to this end, we based our work on four systematic, integrated reviews that contained detailed search criteria and clearly-articulated inclusion criteria and provided detailed syntheses of findings. Three of these four reviews were drawn from AHRQ publications, the most recent of which[30] included articles we had identified in our own searches of PubMed® and CINAHL® databases since 2002 and 2003 using the terms "nurse staffing," "safety," and "outcomes."

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Evidence Table. Major Integrative Reviews of the Staffing-Outcomes Literature

Study	Methods	Outcomes Associated With Staffing	Outcomes for Which Data Considered Limited or Mixed
Seago 2001[25]	16 studies dealing with staffing-safety outcomes relationships, 1990–2000 Grading of design and outcome measures	NPR: Length of stay Nosocomial infections (UTI, postoperative infections, pneumonia) Pressure ulcers	NPR: Mortality Unplanned readmissions Failure to rescue Skill mix: Negative patient outcomes
Hickam 2003[38]	26 studies examining nurse workload/staffing ratios and safety outcomes, 1980–2002 (22 published 1996 or later) Grading of design appropriateness and execution	Workload and skill mix: Nonfatal adverse events Workload: Medication errors	Mortality Recognition of errors Probability that errors will affect outcomes
Lang 2004[27]	43 studies examining effects of nurse staffing on patient, nurse, and hospital outcomes, 1980-2003, excluding studies of ICUs and long-term care facilities General comments on methods limitations for all studies; grading of effect sizes	Patient outcomes: Failure to rescue Mortality Shock in medical patients; gastrointestinal hemorrhage Nurse outcomes: Nurse needlestick injuries Burnout Institutional outcomes: Documentation quality Extended length of stay	Patient outcomes: Pneumonia UTIs Falls Nosocomial infections Medication errors Pressure ulcers Patient satisfaction Morbidity Adverse drug events Intravenous errors Cardiac arrests Patient injuries Nurse outcomes: Nurse job satisfaction Absenteeism Institutional outcomes: Assaults on psychiatric units Hospital financial outcomes

Study	Methods	Outcomes Associated With Staffing	Outcomes for Which Data Considered Limited or Mixed
Kane 2007[30]	94 studies examining associations of nurse-to-patient and hours per patient-day on patient outcomes in hospital practice from the United States and Canada, 1987-2005 Formal meta-analysis (calculation of pooled effect sizes across studies and subpopulations) incorporating evaluation of methodological quality	RN NPR: Hospital-related mortality Failure to rescue+ Medical complications Unplanned extubation* Pulmonary failure*+ Hospital-acquired pneumonia* Bloodstream infections+ Cardiopulmonary resuscitation*+ Extended length of stay * Evidence of a stronger effect or more consistent evidence in ICUs + Evidence of a stronger effect or more consistent evidence in surgical patients HPPD (all staff types) Mortality Shock Upper gastrointestinal bleeding Nosocomial infection Extended length of stay	RN HPPD: Limited support LPN and UAP NPR and HPPD: Trend toward association of worse outcomes with higher use/levels

NPR: Nurse-to-patient ratios
ICU: Intensive care unit
RN: Registered nurse
LPN: Licensed practical nurse
UAP: Unlicensed assistive personnel
HPPD: Hours of care per patient-day
UTI: Urinary tract infection

Chapter 26. Work Stress and Burnout Among Nurses: Role of the Work Environment and Working Conditions

Bonnie M. Jennings

Background

Stress has been categorized as an antecedent or stimulus, as a consequence or response, and as an interaction. It has been studied from many different frameworks (or perspectives?). For example, Selye[1] proposed a physiological assessment that supports considering the association between stress and illness. Conversely, Lazarus[2] (p. 19) advocated a psychological view in which stress is "a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being."

Stress is not inherently deleterious, however. Each individual's cognitive appraisal, their perceptions and interpretations, gives meaning to events and determines whether events are viewed as threatening or positive.[2] Personality traits also influence the stress equation because what may be overtaxing to one person may be exhilarating to another.[3]

Nevertheless, stress has been regarded as an occupational hazard since the mid-1950s.[4] In fact, occupational stress has been cited as a significant health problem.[5–7] Work stress in nursing was first assessed in 1960 when Menzies[8] identified four sources of anxiety among nurses: patient care, decisionmaking, taking responsibility, and change. The nurse's role has long been regarded as stress-filled based upon the physical labor, human suffering, work hours, staffing, and interpersonal relationships that are central to the work nurses do. Since the mid-1980s, however, nurses' work stress may be escalating due to the increasing use of technology, continuing rises in health care costs,[9] and turbulence within the work environment.[10]

In 1974, Freudenberger[11] coined the term "burnout" to describe workers' reactions to the chronic stress common in occupations involving numerous direct interactions with people. Burnout is typically conceptualized as a syndrome characterized by emotional exhaustion, depersonalization, and reduced personal accomplishment.[12] Work life, however, is not independent from family life; these domains may even be in conflict.[13, 14] Stress may result from the combined responsibilities of work, marriage, and children.[15–17] The effects of both work and nonwork stress among nurses have been studied infrequently.[18] And yet, nonwork stress may be particularly salient to nursing, a predominantly female profession. Women continue to juggle multiple roles, including those roles related to the home and family, for which the women may have sole or major responsibility.

Nevertheless, work stress and burnout remain significant concerns in nursing, affecting both individuals and organizations. For the individual nurse, regardless of whether stress is perceived positively or negatively, the neuroendocrine response yields physiologic reactions that may ultimately contribute to illness.[1] In the health care organization, work stress may contribute to absenteeism and turnover, both of which detract from the quality of care.[9] Hospitals in particular are facing a workforce crisis. The demand for acute care services is increasing concurrently with changing career expectations among potential health care workers and growing dissatisfaction among existing hospital staff.[19] By turning toxic work environments into healthy workplaces, researchers and nurse leaders believe that improvements can be realized in recruitment and

retention of nurses, job satisfaction for all health care staff, and patient outcomes—particularly those related patient safety.[20]

Research Evidence

Work stress continues to interest researchers, as illustrated by studies identified in this review that focused on occupations other than health care. For example, in a 3-year study of 14,337 middle-aged men, there was no strong evidence that job demands or job strain were predictors of coronary heart disease (CHD).[21] Findings did verify, however, that a supportive work environment helped reduce CHD. The importance of work support was corroborated in a study of 1,786 lower-ranking enlisted Army soldiers where support helped decrease psychological strain from job demands.[22] A study of 472 Air Force personnel illustrated high levels of work stress in 26 percent of the respondents, with 15 percent claiming work-related emotional distress and 8 percent noting work stress negatively affected their emotional health.[23] Finally, in a sample of 25,559 male and female German workers, the combined effects of exposure to work stress and downsizing contributed to more symptoms than either experience alone.[24]

Stress in the Health Care Professions

Numerous recent studies have explored work stress among health care personnel in many countries. Investigators have assessed work stress among medical technicians,[25] radiation therapists,[26] social workers,[27] occupational therapists,[28] physicians,[29–33] and collections of health care staff across disciplines.[34–38] Most of the studies focused on nurses, but the studies were not always clear regarding which types of nursing personnel participated. Registered nurses (RNs) were the dominant focus.[39–83] Other investigations considered licensed practical nurses (LPNs) and nursing aides;[84–86] licensed nurses (e.g., RNs and LPNs);[87–90] RNs, aides, and clerical staff;[91] and generic assessments of nursing staff.[92–104]

Only four of these investigations considered the effect of stress and burnout among nurses on patient outcomes.[40, 56, 90, 99] These studies examined burnout in relation to increased mortality, failure to rescue,[40, 56] and patient dissatisfaction.[90, 99] Similarly, in an investigation of the relationship between personal stress and clinical care, 225 physicians reported 76 incidents in which they believed patient care was adversely affected by their stress.[30]

Most of the investigations explored the effects of work stress and burnout on health care personnel in acute care settings. Staff working in long-term care (LTC)[102] and nursing homes[84, 85, 100] were the focus of four studies, however. Interestingly, two reports from nursing homes found that staff experienced more stress when caring for patients with dementia.[84, 100] In addition, possible differences among types of nursing personnel were illustrated in a study of rural nursing homes where aides reported more job strain than RNs.[100]

Findings are also emerging about differences in work stress based on shift length and generational cohort. Generational differences were explored in a single-site report of 413 RNs, in which baby boomers (43 percent) and Generation Xers (41 percent) had different perceptions of work stress.[78] The investigators expanded their work to four hospitals in the Midwest (N = 694 RNs).[77] Baby boomers comprised 53 percent of the sample; their scores for stress and strain variables were significantly worse than nurses in the older and younger cohorts. The baby boomers also had significantly less social support.

Shift length, 8-hour versus 12-hour, was explored in relation to both burnout[95] and role stress.[60] In a random sample of Michigan nurses, RNs working 12-hour shifts (n = 105) reported significantly higher levels of stress than RNs working 8-hour shifts (n = 99).[60] However, when differences in experience were controlled, stress was similar in both groups. Conversely, a study from Poland illustrated that nurses working 12-hour shifts (n = 96) compared unfavorably in several aspects to nurses working 8-hour shifts (n = 30).[95] Although the type of nursing personnel involved was unclear, the nurses on 12-hour shifts experienced significantly more chronic fatigue, cognitive anxiety, and emotional exhaustion.

Gender and Family Obligations

The complexity of work stress is further illustrated in two studies that considered gender effects. The prevalence of burnout was studied in a convenience sample of hospital-based neonatologists (n = 86) and office-based pediatricians (n = 97).[32] Although the prevalence of burnout was comparable between the specialty groups, burnout was found more frequently in female physicians (79 percent) than male physicians (62 percent). In a study of female physicians, 51 working full-time and 47 working reduced hours, burnout was not related to number of hours worked per se.[29] Rather, burnout was lower if female physicians worked the number of hours they preferred (r = -0.22, P = 0.03). These studies may have particular relevance for nursing because the profession is predominately female.

Findings from studies that explored family-work conflict in relation to stress, burnout, and well-being indicated the importance of considering both work and family spheres.[25, 29, 38, 44, 45, 86, 94] An investigation conducted using a diverse sample of 342 nonprofessional employees (17 percent worked in health care; 70 percent were women) found family-work conflict was a predictor of well-being.[86] A study of a diverse group of health care personnel compared 64 cases with 64 controls.[38] Although the subjects in the case group were more likely to experience more objective stressful situations in and out of work, for both the case group and the control group, both work and nonwork stress contributed to anxiety and depressive disorders.

Work interfering with family had a direct relationship with work exhaustion in a 4-year study of medical technologists, 80 percent of whom were female.[25] Family interfering with work, however, was not studied. A study of 101 female nurses found that work interfered with family more than family interfered with work.[94] The investigators noted, however, that most of the nurses, who were in their mid-40s, were between the demands of child care and elder care. This finding is consistent with findings from a study of 170 Australian nurses: the principal determinant of stress was workload; nurses were unlikely to bring personal stress to work.[45] Conversely, there was no difference between female physicians working full-time or reduced hours in regard to work interfering with family or family interfering with work.[29] In addition, a study of family-work conflict identified personality as an important factor in whether individuals perceive situations as stressful.[44]

Personal Characteristics and Work Relationships

Personality was explored as an important variable in the burnout/work stress equation in a number of investigations.[26, 37, 41, 49, 50, 81, 82, 92] Together, these studies support findings that perceptions of job stress and burnout are not just a product of work conditions because not all

workers, exposed to the same conditions, develop burnout or perceive stress. However, the specific features of personality that affect the perception of stress or burnout remain unclear.

Neuroticism has been associated with exhaustion.[41, 92] External locus of control has demonstrated a positive relationship with burnout[92] and stress.[26] Findings are mixed for hardiness.[37, 50, 81] Evaluations of anxiety reflect a link with stress and burnout.[49, 82] Anxiety is viewed as having two components—state anxiety, the temporary component which manifests when an individual perceives threatening demands or dangers, and trait anxiety, the more stable component which may be regarded as a personality characteristic.[105] In a study of intensive care unit nurses, the investigators concluded that individuals high on state-anxiety were not only at risk for burnout, but also for making medical errors.[82] In another study, higher trait-anxiety predicted psychological distress.[49] In addition, relationships with other staff—coworkers, physicians, head nurses, other departments—were also predictors of psychological distress.

Investigators have also examined the association between interpersonal relationships and burnout and stress. The exact linkages are not yet understood. Problematic relationships among team members were shown to increase burnout.[93] Verbal abuse from physicians was noted to be stressful for staff nurses.[71] In a study of 260 RNs, conflict with physicians was found to be more psychologically damaging than conflict within the nursing profession.[59] However, a study exploring verbal abuse among 213 nursing personnel (95 percent RNs) found the most frequent source of abuse was other nurses (27 percent).[88] Families were the second most frequent source of abuse (25 percent), while physicians ranked third (22 percent).

Management Styles

Relationships between staff nurses and nurse managers are particularly important when examining stress and burnout.[49, 53, 65, 70, 89] Numeric ratings from a survey of 1,780 RNs indicated that supervisor support and quality of supervision were lowest for nurse managers.[53] Handwritten comments from 509 (28.6 percent) of the RNs clarified these ratings by noting the following problems: (a) inadequate unit leadership and the frequent turnover of nurse mangers, (b) insufficient physical presence of the supervisor on the unit, (c) failure to address problems—too much sweeping them aside or not even being aware they exist, and (d) modest awareness of numerous staffing issues.

These ideas were corroborated in a study of 537 RNs from Canada.[65] Using structural equation modeling, the investigators substantiated the importance of manager behavior on employee experiences. Similarly, in a qualitative study of 50 nurses conducted in England, managers were identified as a direct cause of stress.[89] Finally, responses from 611 RNs on 50 inpatient nursing units in four southeastern U.S. hospitals showed that group cohesion was higher and job stress lower when nurse managers used a more participative management style.[70]

In addition to illustrating a likely connection between nurse managers and staff nurse stressors, these studies also reflected the demanding role of today's nurse managers who are often responsible for multiple patient care areas. However, only two studies were identified between 1995 and 2005 in which burnout was assessed in nurse managers and nurse administrators. One study was conducted in the United States[69] and the other study in Canada.[66] Investigators for the Canadian study examined burnout in a random sample of nurses in first-line (n = 202) and middle-management (n = 84) positions.[66] Nurses in both groups reported high levels of emotional exhaustion and average job satisfaction. In the U.S. study, the investigators explored burnout among nurses (N = 78) from rural and urban hospitals in a southeastern State

who held positions in middle-management and higher.[69] Almost half the respondents (49%) reported high levels of emotional exhaustion.

Lessening Stress

Various studies were designed to evaluate ways to mitigate stress. Studies of social support and empowerment dominated these investigations. Although social support is a multifaceted construct, definitions and types of support were not typically found in these more recent investigations. However, the importance of coworker support was verified in one study.[39] In another study, a general construct labeled "organizational support" exhibited the expected negative relationship with work exhaustion.[25] Similarly, social support from supervisors or colleagues demonstrated a negative association with work stress.[31, 72, 96] Stated differently, based on another study, as nurses felt more stress, they relied more on social support.[87] A cluster analysis demonstrated that high social support was found only in the cluster with low burnout and low stress.[59] No buffering effects were discerned in the studies, but there was a direct and beneficial effect of social support on workers' psychological well-being and organizational productivity.[36] Although these findings do not clarify the mechanism for social support, they do indicate that coworkers and supervisors at all levels would be wise to consider the importance of reciprocal interpersonal exchanges that enhance security, mutual respect, and positive feelings.

All but two studies[80, 96] of nurses and workplace empowerment were conducted by teams involving Laschinger.[57, 62, 64–68] Work empowerment showed a strong, negative association with job tension and a strong positive relationship with perceived work effectiveness.[62, 65] Similarly, in other reports, structural empowerment in the workplace (e.g., opportunity, information, support, resources, power) contributed to improved psychological empowerment (e.g., meaning, confidence, autonomy, impact).[64, 67, 68] Psychological empowerment, in turn, had a strong positive effect on job satisfaction and a strong negative influence on job strain. Likewise, as perceptions of empowerment increased, staff nurses reported less emotional exhaustion and depersonalization along with a greater sense of personal accomplishment—the three components of burnout.[57] Empowerment was negatively associated with work stressors in another study as well.[96]

Because empowerment is often viewed as a characteristic of how work environments are structured, it has strong implications for nurse managers' behaviors. However, one study revealed an interpretive side to empowerment that derives from nurses' perceptions of their personal effectiveness and success.[80] Additionally, there is beginning evidence that nurse managers experience empowerment in a way that mirrors staff nurse experiences. That is, nurse manager perceptions of structural empowerment influenced their sense of psychological empowerment, which, in turn, affected the extent to which they experienced burnout.[66]

Evidence-Based Practice Implications

Based on current empirical evidence on stress and burnout in nursing, there is difficulty in making recommendations regarding how to enhance patient safety. Although findings consistently indicated that nurse burnout was negatively related to job satisfaction, only two studies explored the relationship between nurse burnout and patient satisfaction.[90, 99]

Additionally, findings are inconsistent for two studies that examined the relationship between nurse burnout, 30-day mortality, and failure to rescue for surgical patients.[40, 56] Data for one of

these studies were collected from nurses and patients throughout Pennsylvania.[40] Data for the other study were collected from nurses and patients at a single site.[56] Some of the differences can be accounted for by numerous methodological variations between the two studies. Other differences might be attributed to the strong collective bargaining unit at the single-site study that had negotiated staffing based on nurse-patient ratios that were adjusted for patient acuity.[56] Moreover, fewer nurses from the single-site study reported being either dissatisfied or very dissatisfied with their jobs, compared with the Pennsylvania study (8 percent versus 25 percent, respectively).

Practice implications are also unclear regarding the effects of work stress on nursing staff. The lack of clarity derives, in part, from the complexities of the work stress concept. In one study, for example, nurses were grouped into one of four clusters based on their level of stress, affective and physical symptoms, burnout, and unit social support.[59] In another, the nurse ratings of job strain placed them in four groups ranging from high to low strain.[68] This heterogeneity suggests that many dynamics are operational in relation to stress and burnout. The effects of shift length on stress is one of the dynamics that is not yet understood.[60, 95] Likewise, evidence about how verbal abuse[88] and generational differences[77] operate in the stress equation is just beginning to emerge. The role of personality, family-work conflict, and other features of stress require further study.

Evidence is accruing about the utility of empowerment and social support in mitigating stress. Some caution is warranted in regard to empowerment, however, because the work of one investigator dominates the field.[57, 62, 64–68] Findings related to social support indicated that interpersonal exchanges with coworkers and supervisors may enhance security, mutual respect, and positive feelings—which helped to reduce stress.[31, 39, 72, 96] Overall, however, the assessments of social support were often founded on weak conceptualization and relied upon psychometrically weak instruments to measure the concept. Moreover, the analytical models did not always consider the direct, indirect, and interactive effects of social support.

Although the evidence is sparse, the studies have practice implications for nurse managers. First, managerial behaviors were linked to stress and burnout. Managerial support[38] and participative management[70] helped to reduce stress. Similarly, burnout and work stress were reduced when administrators created work environments that provided staff with access to opportunity, information, resources, and support—the features of empowerment.[64, 65] Second, and studied even more infrequently, nurses in supervisory positions may encounter stress[69] and burnout[66] themselves. There is no existing evidence, however, that empirically illustrates how managerial stress affects staff stress or the manager's ability to behave in a way that reduces staff stress. Given the current emphasis on improving the work environment, there is an imperative to carefully investigate both aspects of the nurse administrator in relation to stress and burnout.

Despite lacking absolute clarity, there is a body of research addressing work stress that spans more than 50 years in the nursing profession. Stress is pervasive in nursing and health care. Moreover, working conditions seem to be deteriorating at the same time that a severe and protracted nursing shortage is occurring. Leaders of health care organizations can no longer ignore these findings. Just as institutional leaders need to understand their financial standing, they also need to assess how environmental stress is affecting patients and staff and take action to alter unhealthy situations.

Research Implications

To derive a better understanding of stress and burnout in the workplace, solid conceptualizations are needed that bring together the various pieces of the stress puzzle. At present, research is often conducted absent a solid theoretical and conceptual base. A more comprehensive blueprint of nurse stress and burnout in the work place needs to be developed. Empirical studies could then be conducted to investigate these very complex relationships, prospectively, over time. Once work stress is examined from a more solid theoretical and conceptual basis, then intervention studies can be initiated to assess the most useful ways to mitigate work stress.

Studies need to move beyond the tendency to use descriptive designs. There is sufficient evidence to believe that work stress is a factor among health care personnel. What is less well understood is the effect of stress on patient outcomes. Studies are needed to enhance the understanding of stress and burnout on patient safety. Studies are also needed to better understand stress beyond the acute care setting.

In addition, because nurse administrators are responsible for creating the environment in which nursing is practiced and patient care is given,[106] it is important to explore interventions that will reduce the stress and burnout experienced by nurse administrators. Findings from studies of this nature could have a threefold effect. By reducing the stressful nature of the nurse administrator's work, nurse administrators could be more satisfied in their positions. This role satisfaction, in turn, could lead to enhancing those managerial behaviors that improve the work environment for staff nurses. Finally, improved working conditions for nurse administrators might make the role more appealing and help correct the serious dearth of individuals interested in pursuing administrative positions.[107]

Conclusion

Stress and burnout are concepts that have sustained the interest of nurses and researchers for several decades. These concepts are highly relevant to the workforce in general and nursing in particular. Despite this interest and relevance, the effects of stress and burnout on patient outcomes, patient safety, and quality care are not well defined by evidence. In fact, the link between stress and burnout to patient outcomes has been explored in only four investigations. There is a great need for comprehensive studies that will examine these dynamics in a way that will yield more solid evidence on which to base practice.

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Search Strategy

Both MEDLINE® and CINAHL® databases were searched to locate literature for this review. A reference librarian conducted the searches after working with the author to specify search terms. The search terms for MEDLINE® were psychological stress, professional burnout, work stress, and occupational health. The search terms for CINAHL® were occupational stress, professional burnout, and nursing units. For both databases, the searches were limited to research articles published in the English language between 1995 and 2005.

There were 1,145 articles identified in the CINAHL® search and 392 identified by the MEDLINE® search, with some duplication in the citations identified by the two databases. All 1,537 abstracts were reviewed. Numerous abstracts were eliminated from further consideration. For example, articles about instrument development, stress in specific populations (e.g., children, adolescents, pregnant women, parents, caregivers) and occupations other than health care (e.g., the police force, fishermen, flight crews, farm workers) were omitted from this review. Likewise, dissertations, literature reviews, concept analyses, and physiologic and immunologic studies of stress in general were not included.

Once the unrelated articles were eliminated, 138 articles remained as candidates for this review. A complete copy of each of these papers was acquired and read, following which an additional 53 articles were removed from further consideration. Dominant among the reasons for excluding these papers were that they were not research based or they were short reports that were lacking essential details.

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Evidence Table

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Aiken 2002[40]	Burnout	Cross-sectional (4)	Design: Level 4 Patient outcomes: 30-day mortality, failure to rescue (Level 1) Nurse outcomes: burnout	Pennsylvania; 10,134 RNs (survey data) linked with discharge data for 232,342 surgical patients from 168 hospitals. Nurses: 94% female; 40% BSN or higher; average of 14 years working as a nurse. Patients: 44% male, average age 59, general surgery (44%), orthopedic surgery (51%), vascular surgery (5%).	Staffing	After adjusting for patient and hospital characteristics: Nurse staffing effects on 30-day mortality (odds ratio [OR] = 1.07, 95% confidence interval [CI] = 1.13–1.34, $P < 0.001$) and failure to rescue (OR = 1.07, 95% CI = 1.02–1.11, $P < 0.001$) imply that decreases in mortality rates and failure to rescue could be realized by increasing RN staffing. After adjusting for nurse and hospital characteristics: Nurses who cared for more patients exhibited high emotional exhaustion (OR = 1.23, 95% CI = 1.13–1.34, $P < 0.001$).
Halm 2005[56]	Burnout	Cross-sectional (4)	Design: Level 5 Patient outcomes: mortality and failure to rescue (Level 1) Nurse outcomes: emotional exhaustion	Large Midwestern hospital; 140 RNs (survey data), discharge data for 2,709 surgical patients. Nurses: 96% female; 43% BSN or higher; average 17 years working as a nurse. Patients: 37% male, average age 56, general surgery (50%), orthopedic surgery (46%), and vascular surgery (4%).	Staffing	Absent risk adjustment and with a strong collective bargaining unit that negotiated staffing plans: No statistically significant relationships were found for nurse staffing on 30-day mortality or failure to rescue. Variables significantly related to mortality were age, circulatory diagnoses, admission through the emergency department, and more comorbidities. 25% of the nurse sample had high scores on emotional exhaustion.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hillhouse 1997[59]	Affective and physical symptoms	Cross-sectional (4)	Design: Level 5 Nurse outcomes: affective symptoms, physical symptoms	A large university hospital; 260 nurses: 97% female, average age 34, all college educated, in current positions an average of 5 years with an average of 11 years experience as a nurse.	Data related to stress, burnout, physical and emotional symptoms were grouped using statistical techniques.	Based on cluster analysis, hospital nurses are a heterogeneous population regarding the effects of stress. Cluster 1 (low stressor/low symptom): low affective and physical symptoms, low burnout and perceived stressors, high unit social support (32%). Cluster 2 (high stressor & burnout/moderate symptom): moderate physical and affective symptoms, high burnout and stressors, low unit social support (43%). Cluster 3 (high stressor/ high symptom): high affective and physical symptoms, high burnout and perceived stressors, low unit social support (26%).
Hoffman 2003[60]	Stress	Cross-sectional (4)	Design: Level 4 Nurse outcomes: role stress	Michigan; 208 RNs randomly selected from the Michigan Nurses Association. Nurses: 92% female, average age 43, 95 (46%) had diplomas or associate degrees, 88 (42%) had a BSN, average experience on their units = 9 years. 99 worked mostly 8-hour shifts (48%), 105 (51%) worked a combination of 8-, 10-, and 12-hour shifts	Length of work shift	RNs working 12-hour shifts experienced significantly higher stress than nurses working 8-hour shifts (P = 0.04). When experience was controlled, stress was similar between the two groups.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Laschinger 2001[63]	Burnout	Cross-sectional (4)	Design: Level 5 Staff outcomes: burnout, nurse perception of care quality	Ontario, Canada; 3,016 medical surgical nurses from 135 hospitals. Nurses: average age of 44 years, average experience in nursing 19 years, 84% were diploma prepared, 69% were from small hospitals, 18% were from teaching hospitals, 13% were from community hospitals.	Magnet Hospital characteristics	Standardized path coefficients from a Structural Equation Model indicated that positive work environments were associated with lower burnout (-0.62), which were then associated with higher perceived quality (-0.42). Higher levels of autonomy, control, and collaboration were associated with higher levels of trust in management (0.56), which was associated with higher perceptions of care quality (0.34).
Laschinger, 2001[64]	Job strain	Cross-sectional (4)	Design: Level 3 Nurse outcomes: job strain	Urban tertiary care hospitals in Ontario, Canada; 404 randomly selected staff nurses: 52% female; all worked in large urban teaching hospitals; on average, 40 years old (standard deviation [SD] = 8.07), 16 years nursing experience (SD = 8.5), 8 years experience in current workplace (SD = 5.8); 58% worked full time; 15% had baccalaureate degrees, 85% were diploma graduates.	Empowerment—both structural and psychological	A proposed model was tested using structural equation modeling. Structural empowerment had a direct, positive effect on psychological empowerment (beta = 0.85); psychological empowerment had a direct negative effect on job strain (beta = -0.57).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Laschinger 1999[65]	Empowerment, job stress	Cross-sectional (4)	Design: Level 3 Nurse outcomes: empowerment, job tension, work effectiveness	Two sites of a large, merged urban teaching hospital in Canada. Nurses: 537 staff nurses; 95% female; 84% diploma educated; 69% worked full time; on average 40 years old (SD = 6.5), 17 years nursing experience (SD = 6.9), 10 years experience in current specialty (SD = 5.5).	Leader behavior	A proposed model was tested using structural equation modeling. Path coefficients from the final model indicated that leader-empowering behaviors directly affected power and work empowerment as well as indirectly affecting work empowerment through power. Higher perceived access to empowerment was associated with lower job tension (-0.39) and increased work effectiveness (0.26) (direct effects). Perceived empowerment also indirectly influenced work effectiveness through job tension (-0.29).
Laschinger 2001[67]	Job strain	Cross-sectional (4)	Design: Level 3 Nurse outcomes: job strain, quality of work life	Urban tertiary care hospitals in Ontario, Canada; 404 randomly selected staff nurses: 52% female; on average, 40 years old (SD = 8.07), 16 years nursing experience (SD = 8.5), 8 years experience in current workplace (SD = 5.8); 58% worked full time; 15% had baccalaureate degrees, 85% were diploma graduates.	Quality of work life	Nurse ratings of job strain fell into Karasek's four job categories: high strain (37%), active (33%), passive (21%), and low strain (10%). When categories were collapsed into high strain/low strain groups, 63% of the sample fell into the low strain group. Comparisons of the high strain and low strain groups revealed significant (P = 0.0001) differences for both structural and psychological empowerment as well as organizational commitment.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lee 1996[69]	Burnout	Cross-sectional (4)	Design: Level 3 Nurse outcomes: stress, commitment, social support	Members of a State organization of nurse executives working at 134 rural and urban hospitals in the southeastern U.S. 78 nurse administrators: female (93%); ages 31–40 (35%); positions—chief nurse officers (CNOs) (45%), assistant CNOs (19%), division or department heads (30%), nurses with executive-level roles (6%); education—doctorate (3%), master's (42%), baccalaureate (29%), associate degree (3%), diploma (26%); average administrative experience, 13 years (range 2–32), CNO tenure in current positions 2 years or less (51%).	Commitment	No significant differences were found for burnout or commitment among the four groups of nurse administrators. Phases of burnout were determined with most nurse administrators in the lowest level (37%); 13% were at the highest level. All burnout scale scores and the organization commitment score were related inversely (r = 0.472 – 0.515) and significantly (P ≤0.001). Emotional exhaustion and burnout phase decreased as the coworker trust and support increased, although 49% of respondents reported high levels of emotional exhaustion.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Leiter 1998[99]	Burnout	Cross-sectional (4)	Design: Level 3 Patient outcomes: satisfaction (Level 3)	16 inpatient units from 2 settings at an 800-bed tertiary care hospital in central Canada. Nurses: 711 with an average of 34 respondents from each inpatient unit (range 22–63), 97% female, 18% had worked for the hospital for > 20 years (2% for < 1 year); 83% RNs, 14% registered practical nurses. Patients: 605 with an average of 36 respondents from each inpatient unit (range 3–104); 55% female, most were between 66 and 75 years old (22%); length of stay was most often up to 3 days (35%).	Patient satisfaction	Patient perceptions of overall quality corresponded to nurses' relationships with their work. Patients on units where nursing staff felt more exhausted were less satisfied with their care.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Leveck 1996[70]	Stress	Cross-sectional (4)	Design: Level 3 Nurse outcomes: perceived quality of care, management style, group cohesion	50 inpatient units from 4 acute care hospitals in the southeastern U.S. Nurses: 358 RNs. Patients: retrospective audits of 525 randomly selected charts.	Management style, group cohesion	Although the average job stress score was moderately low, it was a predictor of quality care in a theoretical model tested using structural equation modeling. Units where nurses perceived participative management also perceived higher levels of group cohesion and lower levels of job stress. Lower job stress was associated with increased quality of nursing care. Indirect effects of variables on quality care, including management style, occurred through job stress. Medical-surgical nurses perceived higher job stress than nurses on other units such as intensive care.
Rowe 2005[88]	Stress and verbal abuse nurse-to-nurse	Cross-sectional (4)	Design: Level 5	500-bed teaching hospital in Philadelphia. Nurses: 213 RNs and LPNs (69% response rate, 5% were LPNs); 96% female, most were diploma graduates (33%); 53% worked full time, 85% had > 5 years experience, 88% were staff nurses.	None—descriptive	96% of the participating nurses reported they had been spoken to in a verbally aggressive manner—79% indicated verbal abuse by patients, 75% by other nurses, 74% by attending physicians, 68% by patients' families. The most frequent sources of verbal abuse were other nurses (27%), patients' families (25%), physicians (22%), and patients (17%). A few of the verbally abusive experiences (13%) were related to errors in patient care.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Santos 2003[77]	Stress, strain, coping	Cross-sectional (4)	Design: Level 5	Four Midwestern hospitals. Nurses: 694 RNs representing 3 age cohorts—1909–1945, matures (8%); 1946–1964, baby boomers (53%); 1965–1979, Generation Xers (35%).	None—descriptive	The four major problem areas within each of the three study variables—stress, strain, coping—were identified. *Stress*: physical environment, responsibility, role overload, role boundary; *Strain*: physical, psychological, vocational, interpersonal; *Coping*: self-care, recreation, rational/cognitive, social support. Significant differences were evident among the generations with baby boomers reporting more stress and worse coping than the other 2 cohorts as well as significantly more interpersonal strain.
Simoni 2004[80]	Stress	Cross-sectional (4)	Design: Level 3 Nurse outcomes: empowerment	Two hospitals in a mid-Atlantic State. Nurses (randomly selected, n = 142) RNs with an average age of 35 years (SD = 10.1), 48% had baccalaureate degrees, most had been working <5 years since becoming RNs (42%).	Empowerment	Two of the three individual styles of stress appraisal were significantly correlated with psychological empowerment: skill recognition ($r = 0.52$, $P < 0.001$), and deficiency focusing ($r = -0.24$, $P < 0.01$). Together, these two interpretive styles explained 24% of the variance in empowerment.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Vahey 2004[90]	Burnout	Cross-sectional (4)	Design: Level 3 Patient outcomes: satisfaction (Level 3)	2 units each in 20 urban hospitals across the U.S. using 1991 data. Nurses (n = 820—both RNs and LPNs): 93% male; on average, 35 years old (SD = 10), 10 years in nursing (SD = 9), 4 years on present unit (SD = 4). Patients (with AIDS) (n = 621): 88% male, average age 37 years (SD = 8).	Patient satisfaction	After adjusting for patient characteristics (age, gender, race, risk factors, and illness severity), patients on units where nurses reported higher-than-average levels of emotional exhaustion were only half as likely to be satisfied with nursing care as compared to units where nurses reported lower-than-average emotional exhaustion (OR =0.51, 95% CI = 0.30–0.87, *P* < 0.05). Patients on units where nurses reported higher-than-average personal accomplishment were twice as likely to be satisfied with their nursing care compared to units where nurses reported lower-than-average personal accomplishment (OR = 2.37, 95% CI = 1.37–4.12, *P* < 0.01). The nurses' work environment exerted both direct and indirect effects on patients through its effect on nurse burnout.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weinberg 2000[38]	Stress	Cross-sectional (4)	Design: Level 3 Staff outcomes: psychiatric disorders	City-based hospital. Four groups of staff members (randomly selected): nurses, physicians, administrative, ancillary. Based on scores from survey responses, participants were identified who had minor psychiatric disorders (e.g., definite depressive or anxiety disorders). These 69 cases were matched to controls by occupational group, gender, and age (within 5 years). Each group had 23 nurses, 8 physicians, 23 administrative staff, and 10 ancillary staff. 52 of the 69 individuals in each group were females (75%). Mean age for cases and controls was 39 years (SD = 10).	Psychiatric disorders (especially depression or anxiety)	Cases were less likely to have a confidant and more likely to have a family or past history of psychiatric disorder as well as a severe event and severe chronic difficulty over the previous 12 months. Most chronic difficulties were outside work. There were no significant differences between cases and controls in regard to management responsibilities at work or the proportion who worked shifts. Cases had significantly more objective work problems than controls. Of 20 work problems, 6 were experienced significantly more often by cases—work role conflict, lack of manager support, physical environment problems, poor promotion prospects, job not secure, skills under used (OR = 2.19 – 3.44; p= 0.006-0.10). The greatest difference between cases and controls was lack of managerial support (*P* = 0.006). Work problems (OR = 1.4, *P* = 0.0003) and difficulties outside work (OR = 8.77, *P* = 0.0001) were contributors to stress.

Chapter 27. Temporary, Agency, and Other Contingent Workers

Ann E. K. Page

Background

The Institute of Medicine (IOM) report, *Keeping Patients Safe: Transforming the Work Environment of Nurses*,[1] determined that the use of temporary nursing staff or staff from agencies external to the health care organization to provide care threatens patient safety. Involving personnel with less knowledge of the nursing unit and larger organizational care policies—and interrupting the continuity of patient care—increases the risk to patients' safety. In its report, the IOM recommended that health care organizations avoid using nurses from external agencies.

In 2004, 2.3 percent of registered nurses (RNs) provided their services through a temporary agency, as opposed to being employed by the organization or organizations through which they delivered care.[2] This was an increase from the 1.8 percent of RNs working in their principal nursing position through a temporary employment service in 2000, which itself was a 36 percent increase over that reported in 1996, reversing a declining trend between 1988 and 1996.[3] Although this proportion continues to represent a minority of the nurse workforce, the increase mirrors workforce trends occurring globally across many industries.[4, 5] Temporary workers, contract employees from external agencies, intermittent workers, "casual" workers, and other types of workers without a standard employer-employee relationship with the organization in which they provide services are together referred to in the United States as "contingent workers."[6] In other counties, such arrangements are sometimes referred to as "precarious employment," the terminology used in the European Union, for example.

Although use of nurses from external agencies can increase the number of staff available for patient care, threats to patient safety are theorized to arise, in part, because temporary staff are less familiar with a nursing unit and a health care organization's overall structure, policies, practices, and personnel—including information systems, facility layout, critical pathways, interdependency among work components, ways of coordinating and managing its work, and other work elements.[4, 7] This can be compounded when temporary workers do not receive the same level of orientation and training from the organization in which they provide care as do the organization's employees. Studies in industries outside of health care have found that increased use of contingent workers can result in higher accident rates and other adverse effects.[4] The International Atomic Energy Agency, for example, cites use of contract personnel to replace traditionally hired employees as a symptom of incipient weakness in an organization's safety culture.[8] Health care researchers find similar results.

Research Evidence

Searching health care literature for the effects of contingent nursing staff on patient safety and other quality of care outcomes is difficult because of the various terminologies used to refer to such workers: for example, temporary, float, casual nursing, contingent employment, or precarious employment. Moreover, health care research, unlike research on the impact of

temporary employees across a variety of other industries, typically has not exclusively examined the effects of temporary workers on patient safety and care quality. Findings are typically embedded in studies of more comprehensive issues such as the effects of nurse staffing or health care organization practices.

The search strategy (see below) resulted in finding seven observational studies; of which six studies reported adverse patient outcomes associated with the use of contingent nurses[7, 9–13] (see evidence table). The seventh study, which did not find adverse patient outcomes,[14] did not measure patient outcome directly, but rather examined nurses' documentation of their own performance of activities related to patient safety and better quality of care—the lowest level of outcome measured for all seven studies. The findings of the seventh study also were confounded by the provision of specialized training in the legal ramifications of documentation to only two of the three groups under study—the groups that subsequently performed at the highest level.

Although it is possible that the findings of six of seven studies showing adverse effects of using agency nurses are a manifestation of reporting bias (i.e., multivariable studies that did not find a difference in the use of contingent nurses might not report the finding of no difference), the evidence cited in these studies does not support this possibility. Five of the seven studies examined variables in addition to staffing composition and their effects on bloodstream infection, 30-day mortality, medication errors, and violence committed by psychiatric patients. All five of these identified and reported on variables for which "no difference" in patient care or outcomes was found.

Evidence-Based Practice Implications

The IOM report identified the need for all health care organizations to have in place mechanisms to achieve "flexible" staffing in instances when the patient census, acuity, or both demand staffing at a higher level than anticipated. However, the research included in the aforementioned analysis reaffirms the importance of avoiding the use of nursing staff from external sources as a mechanism to provide such flexible staffing. The IOM recommends using internal nursing "float pools" composed of nurses employed by the health care organization. Although using floating nurses may still result in nurses being assigned to patient care units with which they are less familiar, using an organization's own float pool of employed nurses at least assures that these nurses have received the same orientation and in-house training as other nursing staff permanently assigned to specific nursing units. Float pools would also assure that, even if the floating nurses are not familiar with policies and procedures unique to individual patient care units within the organization, the nurses would be familiar with organization-wide policies and practices pertaining to patient safety, such as an organization's error reporting system, decision-support systems, and information technologies.

Research Implications

Research on temporary and agency nurses could benefit from a meta-analysis to determine how strong the effect may be between using external nurses and patient safety and outcomes. Additional research could be conducted to further build the evidence base pertaining to the effect on patient care outcomes of using contingent nurses to meet staffing demands. However, research is also needed to understand the reasons for the use of contingent workers in health care in the first place. Such research can inform policy decisions by health care organizations and

other entities affecting workforce deployment. Are contingent workers preferred by health care organizations? If so, why? To what extent is increasing use of contingent nursing staff caused by the same factors leading to increased use of contingent workers globally across myriad industries, or are there unique factors at play in nursing? Do nurses employed by temporary agencies prefer this type of employment? If so, why? Can these factors be replicated in health care organizations to bring contingent workers into standard employer–employee relationships with health care organizations? If nursing staff employed by temporary agencies do not prefer this employment, why are nurses so employed in the face of a widely cited nursing shortage?

Conclusions

Whether temporary workers or float pools are used to meet staffing shortfalls, hospital managers and leaders are challenged to ensure patient safety by matching the available skill mix of nurses to the needs of patients. The flexibility offered by temporary workers may address staffing gaps, but it is important to have effective communication, education, and orientation mechanisms to enable comprehensive, safe patient care by outside nursing staff. More research is needed on the effects of contingent nursing staff on patient safety and the reasons for the use of contingent workers.

Search Strategy

A search of MEDLINE®, CINAHL®, the Cochrane Registry of Controlled Trials, and the Cochrane data base of systematic reviews for the period January 1990–March of 2006 using the search terms (temporary OR contingent) AND (staff OR personnel OR nurs$) in all fields for human studies and English-language articles yielded 809 articles. Five of these titles or abstracts described a research study that included measures of the effects of contingent nurses on patient safety or clinical quality outcomes.[7, 9–11, 14] A repeat of this search using (float OR casual) in place of (temporary OR contingent) generated 181 references, which yielded an additional research study with these variables.[12] A similar search within PychoINFO yielded 178 references, of which one was a previously undetected research study examining use of temporary nurse staffing and patient outcomes.[13] All searches were mediated through the OVID search engine. Studies measuring only nurse outcomes (e.g., occupational injuries, job satisfaction, or features of work design) were excluded, although there is literature showing adverse outcomes in these areas as well.

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Evidence Table

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Alonso-Echanove 2003[7]	Use of float nurses – agency nurses or nurses from other hospital areas who had been working in the unit under study for less than a year.	Prospective cohort	Level 3 study design. Level 1 outcome measure: central venous catheter (CVC) bloodstream infections (BSIs)	4,535 adult patients admitted for at least 24 hours in 1997–1999 to eight Intensive care units at six geographically distinct hospitals	Observational study – no intervention	Of more than 60 potential risk factors studied, portion of days cared for by a float nurse was one of only six statistically significant (*P* <.005) variables strongly associated with the development of CVC-BSIs in patients. Risk of CVC-associated BSI was 2.6 times higher for patients cared for by float nurses more than 60% of the time.
Bourbonniere 2006[11]	Use of a high proportion of contract nurses (RNs and LPNs combined) to fill nurse staffing positions. High proportion was defined as 5 percent or more of total full-time equivalent nursing positions.	Cross-sectional, time series	Level 4 study design. Level 3 or higher outcome measures; i.e., study measured health care quality deficiencies detected in nursing homes as part of their State 's annual survey and certification inspection process.	15,717 freestanding nursing homes (facilities) in urban and rural counties in the United States between 1992 and 2002.	Observational study – no intervention	Annually, facilities using 5 percent or more contract RNs and LPNs were disproportionately represented in the top quartile of nursing facilities ranked in each State according to health care deficiencies detected during annual State survey and certification inspections. For each calendar year these differences were statistically significant($P < 0.05$).
Estabrooks 2005[9]	Use of temporary or casual nurses in hospital staffing.	Cross-sectional	Level 4 study design. Level 1 outcome measure: 30-day mortality following admission	18,142 patients discharged from 49 of 109 acute care hospitals in Alberta Province, Canada	Observational study – no intervention	Hospitals with a higher proportion of casual and temporary nurses had higher rates of 30-day patient mortality (odds ratio = 1.26, 95% confidence interval of 1.09 to 1.47).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
James 1990[13]	Use of agency (temporary) nursing staff	Retrospective cohort	Level 4 study design. Levels 1 and 2 outcome measures: any act of violence, defined as physical aggression involving physical contact directed at fellow patients, staff, self, or property.	All acts of violence occurring in a 12-bed "high dependency" ward within a 60-bed psychiatric unit in a district general hospital in London, England, during January 1986 through March 1987 (15 months).	Observational study – no intervention	A greater than three-fold increase in violent incidents over the study period was strongly associated with a decline in the number of permanent nursing staff employed by the hospital and an increase in the use of agency nurses, despite the maintenance of a constant level of nurse staffing. Study found a positive correlation between the number of violent incidents and use of agency nurses ($P = 0.0018$) and agency nursing shifts ($P = 0.0005$), and a negative correlation between the number of violent acts and levels of permanent nursing staff ($P = 0.0007$).
Robert 2000[12]	Use of nurses from an external agency or from a hospital pool compared to nurses permanently assigned to the surgical intensive care unit (SICU)	Case-control study	Level 4 study design. Level 1 outcome measure: nosocomial bloodstream infections (BSIs)	28 patients with BSIs and 99 randomly selected controls in a 20-bed SICU in a 1,000 bed, university-affiliated, inner-city, public teaching hospital. Cases were any patient hospitalized in the SICU for 3 or more days from June 1994 to June 1995 in whom a primary BSI was identified.	Observational study – no intervention	BSIs were significantly ($P < 0.004$) more frequent during the period of high use of nurses from the external agency or hospital float pool and low use of permanently assigned nursing staff. The pool nurse-to-patient ratio was significantly higher for case patients ($P < 0.001$) than for controls. Conversely, the regular nurse-to-patient ratio for the 3 days prior to infection was significantly lower for case patients than control patients) ($P < 0.001$).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Roseman 1995[10]	Use of temporary nurses	Cross-sectional	Level 4 study design. Level 2 outcome measure: medication errors	All medication errors reported in a 140-bed acute care medical center in Alaska from 1984 to1989.	Observational study – no intervention	Number of shifts worked by temporary staff was positively (and statistically significantly) associated with medication errors (odds ratio = 1.15). Errors decreased when permanent nursing staff worked overtime (odds ratio = 0.85).
Strzalka 1996[14]	Use of nurses from external agencies, compared to internal float pool nurses and nurses hired by the organization to staff a specified nursing unit under study (unit-hired nurses)	Prospective cohort	Level 4 study design. Level 3 outcome measure: Nurses' documentation that they performed nine activities determined by the facility as related to patient safety (e.g., side rails raised, assessment of mental status, vital signs, etc.) and related to bowel management.	All agency nurses and two randomly selected comparison groups of internal float and unit-hired nurses providing care on one nursing unit in a large teaching hospital in the United States over an 8-month period.	Observational study – no intervention	Nursing groups' documentation varied from indicator to indicator, with internal float pool nurses generally documenting at the highest level and unit-hired nurses performing at the lowest, with agency nurses falling in between. Differences were often minimal and were statistically significant (at the $P < 0.05$ level) for only five of the nine documentation activities. Agency nurse reporting was significantly lower than float pool nurses on only two measurement items.

Chapter 28. The Impact of Facility Design on Patient Safety

John Reiling, Ronda G. Hughes, Mike R. Murphy

Background

Recent attention in health care has been on the actual architectural design of a hospital facility, including its technology and equipment, and its effect on patient safety. To address the problems of errors in health care and serious safety issues, fundamental changes of health care processes, culture, and the physical environment are necessary and need to be aligned, so that the caregivers and the resources that support them are set up for enabling safe care. The facility design of the hospital, with its equipment and technology, has not historically considered the impact on the quality and safety of patients, yet billions of dollars are and will be invested annually in health care facilities. This provides a unique opportunity to use current and emerging evidence to improve the physical environment in which nurses and other caregivers work, and thus improve both nurse and patient outcomes.

Human Error and Cognitive Functioning by Design

Cognitive psychologists have identified the physical environment as having a significant impact on safety and human performance.[1, 2] Understanding "the interrelationships between humans, the tools they use, and the environment in which they live and work"[3] is basic to any study of the design a health care facility and its effect on the performance of the nurses and other caregivers who interface with the facility and its fixed (e.g., oxygen and suctioning ports on the wall of a patient room) and moveable (e.g., a patient bed) equipment and technology. Humans do not always behave clumsily and humans do not always err, but they are more likely to do so when they work in a badly conceived and designed[4] health care setting.

Organizational/system factors that can potentially create the conditions conducive for errors are called latent conditions. According to Reason,[1] latent conditions are the inevitable "resident pathogens" that "may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defenses. Latent conditions can be identified and remedied before an adverse event occurs." Examples of latent conditions are: poorly designed facilities, including the location of technology and equipment; confusing procedures; training gaps; staff shortages or improper staffing patterns; and poor safety culture. A specific example of a latent condition effecting patient safety would be the impact of low lighting levels in the medication dispensing areas that are associated with some medication errors but not others.[5] These and other conditions occur at what Reason describes as the "blunt end," where administrators, the work environment, and resources determine the processes of care delivery. Latent conditions are present in all organizations and can be unintentionally created by those who are responsible for designing systems, ensuring adequate staffing, creating and enforcing policies, and so on.

The design of a facility/structure with its fixed and moveable components can have a significant impact on human performance, especially on the health and safety of employees,

patients, and families.[6] In a review of more than 600 articles, researchers found that there was a link between the physical environment (i.e., single-bed or multiple-bed patient rooms) and patient (e.g., fewer adverse events and better health care quality) and staff outcomes (e.g., reduced stress and fatigue and increased effectiveness in delivering care).[7] Efforts to improve patient and staff outcomes can target latent conditions for clinicians by using evidence-based designs to decrease distractions, standardize locations of equipment and supplies, and ensure adequate space for documentation and work areas. The research done by Reason[1] and Leape[2] describes the value of practices based on principles designed to compensate for human cognitive failings. Thus, when applied to the health care field, human factors research (i.e., an area of research that includes human performance, technology design, and human-computer interaction; this topic is covered in chapter 5, "A Human Factors Framework," by Henriksen and colleagues), which has emphasized the need for standardization, simplification, and use of protocols and checklists, can be used to improve health care outcomes.

By targeting human factors through facility design and ensuring that latent conditions and cognitive failures that lead to adverse events are minimized, patient safety will improve. This requires a multifaceted approach, including developing a strong safety culture, redesigning systems or facilities with their equipment and technology, focusing on eliminating the conditions of cognitive errors, and helping caregivers correct/stop an error before it leads to harm or mitigate it if it occurs.[1, 2]

Factors Influencing the Built Environment

With human factors in mind, there are several aspects of the built environment that should be considered. In a review of the literature by Henriksen and colleagues,[8] the following design elements were identified as critical in ensuring patient safety and quality care, based on the six quality aims of the Institute of Medicine's report, *Crossing the Quality Chasm: A New Health System for the 21st Century*:[9]

- *Patient-centeredness*, including
  - using variable-acuity rooms and single-bed rooms
  - ensuring sufficient space to accommodate family members
  - enabling access to health care information
  - having clearly marked signs to navigate the hospital
- *Safety*, including
  - applying the design and improving the availability of assistive devices to avert patient falls
  - using ventilation and filtration systems to control and prevent the spread of infections
  - using surfaces that can be easily decontaminated
  - facilitating hand washing with the availability of sinks and alcohol hand rubs
  - preventing patient and provider injury
  - addressing the sensitivities associated with the interdependencies of care, including work spaces and work processes
- *Effectiveness*, including
  - use of lighting to enable visual performance
  - use of natural lighting
  - controlling the effects of noise

- *Efficiency*, including
  - standardizing room layout, location of supplies and medical equipment
  - minimizing potential safety threats and improving patient satisfaction by minimizing patient transfers with variable-acuity rooms
- *Timeliness*, by
  - ensuring rapid response to patient needs
  - eliminating inefficiencies in the processes of care delivery
  - facilitating the clinical work of nurses
- *Equity*, by
  - ensuring the size, layout, and functions of the structure meet the diverse care needs of patients

There have been five other significant reviews of the literature relating to the physical environment and patient outcomes. Nelson and colleagues[10] identified the need to reduce noise pollution and enhance factors that can shorten a patient's length of stay (e.g., natural lighting, care in new/remodeled units, and access to music and views of nature); according to their study, patients can benefit from the skillful utilization of music and artwork. Ulrich and colleagues[7] found research that demonstrated that the design of a hospital can significantly improve patient safety by decreasing health care associated infections and medical errors. They also found that facility design can have a direct impact on patient and staff satisfaction, a patient's stress experience, and organization performance metrics. Three other reviews found that hospital design, particularly when single-bed rooms are employed, can enhance patient safety and create environments that are healthier for patients, families, and staff by preventing injury from falls, infections, and medical errors; minimizing environmental stressors associated with noise and inefficient room and unit layout; and using nature, color, light, and sound to control potential stressors.[11–13]

Nurse staffing levels. Preventable adverse events such as falls and complications have been found to be related to both the design of health care facilities and nurse staffing levels. Patient falls in acute care settings can result from slippery floors, poor placement of handrails, inappropriate door openings, furniture heights,[14] and inadequate nurse staffing.[15, 16] Infection rates have been found to be lower in patients, particularly critically ill patients, when there are higher staffing levels.[17, 18, 19] High rates of postoperative infections, especially related to wounds among patients ages 65 to 70, have been found to be associated with facilities that were overcrowded, had few private rooms, lacked individual bathrooms and toilets, had no isolation facilities, and had deficient ventilation systems.[16] Without effective ventilation systems, efforts to avoid ventilator-associated pneumonia—such as patient positioning, oral health, and airway management[20, 21]—have a greater potential of not being as beneficial. Then again, the greater risk for health care associated infections may be associated with nurses not implementing evidence-based practices,[22] such as aseptic technique or washing hands appropriately[18] to prevent infections, as well as nurse understaffing;[23–26] how much is not known. These are only some of the examples that indicate that there are fewer adverse events when appropriate nurse staffing levels are met, and operational costs are lower because the rates of adverse events are lowered.[27] Thus, adequate staffing must be addressed to enable the benefits of well-designed health care facilities.

Structural obstacles and the nature of work for nurses. Several factors have been identified as physically being in the way of the work of nurses. An assessment of the organization of nurses in medical and surgical units in hospitals in France found that the work of

nurses was dependent upon the spatial configuration of the unit. For purposes of this study, nurses' work areas were divided into four categories: the patients' rooms, the nurses' area, the corridor, and other specialized areas such as a storage room. Nurses were found to have generally followed three paths in their trips: different points of the nurses' area, trips between the patients' rooms and nurses' area, and trips between the patients' rooms. Trips were organized according to spatial and functional logic. The majority of the activities performed by nurses were found to last less than 2 minutes. On the surgical unit, nurses during one shift were found to perform 3,855 trips that lasted approximately 3 minutes and 25 seconds each; this was fewer than the 4,521 trips performed by nurses on the medical units, each lasting approximately 3 minutes and 9 seconds. The constant movement by nurses varied based on the spatial organization of the unit as well as the temporal structure of the tasks. On the surgical unit, nurses were interrupted, an average of once every 20 minutes; on the medical unit, nurses were interrupted an average of once every 12 minutes.[28]

One approach to address these obstacles and to better meet patients' needs is to not have one central nursing station. Instead, there would be several decentralized nursing work stations throughout the unit with supplies, linens, and equipment areas. Appropriately distributed supplies and equipment could reduce fatigue and improve efficiency of nurses[29] by minimizing the time associated with finding supplies and equipment and moving from one location to another. Patients could benefit from more time with nurses and increased surveillance opportunities that require nurses to visually monitor patients—a benefit enhanced further by using single-bed rooms in hospital design.[30]

Single-bed and variable-acuity rooms. Debate continues as to whether hospitals should have single-bed rooms or semiprivate rooms for patients. Research over the past 10 years has compared single to semiprivate rooms and, in so doing, has provided greater insight into cost implications, patient satisfaction, and impact on patient care and outcomes. Several reviews of the literature found that single-bed rooms were more conducive for infection control and patient care,[7, 31, 32] were associated with reduced stress and improved outcomes for patients,[33] and increased privacy and accessibility for patients and families.[34] Noise levels and catheter-related infections have been found to be lower for critically ill infants in single-bed rooms.[35] Comparatively, environmental risk factors for patients in multiple occupancy include lack of privacy[36] and higher noise levels that can affect their comfort and recovery.[37] Environmental noise and light as well as patient interruptions can cause sleep disturbance,[36] especially in intensive care unit patients.[38]

Patients and families tend to be more satisfied with single-bed rooms. In one study, patient satisfaction among low-risk maternity patients was found to be higher with single rooms because of having their privacy respected; patients felt they were in a comfortable environment and felt that they received more support and education.[39] Clinicians have also been found to prefer single rooms for maternity patients[40] and neonatal intensive care patients.[35]

The availability of single-patient rooms has been found to control the spread of infection from patients infected with methicillin-resistant Staphylococcus aureus,[41–43] gram-negative bacteremia in burn patients,[44] and respiratory and enteric infections requiring contact isolation in pediatric units.[45] Single-bed isolation rooms, intended to prevent the spread of infectious agents by using pressure differentials to contain them, are effective only if the room is tightly sealed.[46] Thus, in terms of controlling infection in isolation rooms and other patient rooms, the greater risk may be associated with nurses not implementing evidence-based practices regarding hand washing and aseptic technique to prevent infections.[18]

The design of a patient room that allows flexibility and can be adapted to meet changing acuity and care needs of patients has been found in some institutions to contribute to decreased medication errors and falls.[47, 48] A well-designed patient room has also been found to be a factor in improving care delivery processes for clinicians by providing more private patient consultations,[36] improving patient and clinician satisfaction,[48] decreasing length of stay,[29] and facilitating continuity of care during a hospital stay.[39]

Traditionally, the bed charge has been higher for single rooms and the capital investment greater. Yet research has found that single rooms and flexible/adaptable rooms for maternity care and intermediate and intensive care offered cost savings, particularly because of shorter lengths of stay and a decrease in the number of transfers within the hospital.[40, 49] Such rooms are more likely to be filled[47] and can avoid the costs of transfers when the room is acuity adaptable.[36]

Lessons From Best-Practice Designs

There are several examples of the impact of evidence-based design in acute care settings; a few will be discussed here. Research in the early 1970s found that unit efficiency was determined by the design of the unit, not room size or occupancy.[50] Research conducted since then has continued to emphasize the importance of designs. One study[51] began with a systematic evaluation of best practices in 19 intensive care units (ICUs), built between 1993 and 2003, that received a design award from the Society of Critical Care Medicine, the American Association of Critical Care Nurses, and the American Institute of Architects. The reviewer found positive characteristics of the ICUs to include single-bed rooms for improved patient care, safety, privacy, and comfort; bed locations that provided easy access for clinicians; hand-washing sinks and waste disposal in the patient rooms; and use of natural lighting. Negative characteristics were found to be renovation projects that posed health and safety hazards during the construction; mixed-service units with safety and staffing problems; overall layout—and layout of work areas for staff—that lacked a common design solution; and family space that was often located outside the unit and provided the family with limited access.

The Pebble Project, supported by the Center for Health Design and funded by the Robert Wood Johnson Foundation, includes several hospitals across the country. As part of this project, evidence-based designs are used and empirical evidence is assessed to measure outcomes such as safety (visit the Center for Health Design's Web site at www.healthdesign.org). Findings from the Pebble Project are expected to advance the evidence base by increasing our knowledge of design features that can ensure a safe healing environment where the best quality of care can be provided. The project is intended to have a ripple effect and influence other health care facilities nationwide.[52]

There are several examples of hospitals involved in the Pebble Project, such as Children's Hospital in San Diego, which opened a long-term, convalescent hospital designed to promote the care needs for permanently disabled children. The design included out-of-sight wheelchair storage in patients' rooms, private spaces outside the patient rooms for parents to hold their children, and an improved ventilation system to decrease respiratory infections. The Methodist Hospital in Indianapolis opened a 56-bed cardiovascular critical care unit where patients are admitted directly to their rooms from the emergency room, admitting, physicians' offices, or the Lifeline helicopter. Patient rooms are private and patients are in control of the temperature and light. Each room also has an interior window that can become opaque to increase privacy. The design also enabled nurses to observe patients better, resulting in half as many patient falls, and the need for patient transfers has decreased substantially from 200 per month to an average of 20

per month. Bronson Methodist Hospital in Michigan opened a new facility with private patient rooms and increased patient access to nature (e.g., indoor gardens, natural light, and landscape views) and decreased patient stress using of positive distractions such as music, water sounds, artwork, and daylight. The Barbara Ann Karmanos Cancer Institute renovated several hospital areas to be patient-centered and to provide a more pleasant environment, where patient rooms were made larger and an emphasis was placed on lighting and acoustics. In doing so, administrators and clinicians have seen a decrease in the use of pain medication and medication errors on these units. Thus, by incorporating private rooms into their designs, these four hospitals and patients they have served have experienced successful outcomes in their new and renovated facilities.[53]

Research Evidence

There were 10 original articles that met the inclusion criteria for this review. Four articles described investigations with nurses in relation to the work and built environment, five were about patient's perspectives, and two were about specific built environment projects; one study investigated both staff and patient perceptions of the built environment.

Nurses' Perspective

Four studies assessed hospital nurses' perspectives on factors associated with the built environment using cross-sectional surveys. Two surveys intended to assess the work environment and challenges prior to moving forward with specific changes.[54, 55] When asked about performance obstacles, nurses reported: work environments; distractions from families; hectic and crowded work environments; delays in getting medications from the pharmacy; amount of time spent teaching families; equipment not being available; patient rooms not well stocked; insufficient workspace for completing paperwork; time spent seeking supplies or patients' charts; receiving many phone calls from families; delays in seeing new medical orders; and misplaced equipment.[54] When asked about what physical changes were problematic in the layout of the current unit, including patients' rooms, pediatric nurses reported that they were not satisfied with: the size of residents' closets, showers, and activity room; the actual size, aesthetics, and location of the break room and dining room; the available space for medical equipment; the available space for charting; and the outdoor recreation area. Not only did nurses share similar concerns with parents, the facility aesthetics and work environment were found to be associated with higher satisfaction and better coworker relationships among nurses.[55]

The other two surveys assessed the perceptions of nurses about single versus multiple bed rooms. A very small sample of nurse managers and unit directors (n = 7) in best-practice ICUs reported the benefits of single-bed rooms as enhanced patient safety, ensured privacy for patients, increased access to patient status information, and more space for family members.[56] In the other survey, administrative and nursing staff (n = 77) reported that they favored single-occupancy rooms because of their flexibility, being more appropriate for patient examination, improved quality of patient monitoring and scope of patient surveillance, and improved patient comfort level and patient recovery rate. Helpful characteristics of single-occupancy rooms were reported as: the more favorable layout of the room, including the availability of extra space in the room making arrangement of furniture easier and providing storage for clean and dirty supplies in the room; better privacy for patients and more space for family members; and better lighting

and temperature control and lower noise levels. A little over half of the respondents believed that health care acquired infections were low or very low in single-occupancy rooms, but that there was no difference in the number of patient falls or the need for pain-reducing or sleep-inducing medications between the two types of rooms. Conversely, helpful characteristics of double-occupancy rooms included proximity to the nursing station. However, being able to see patients for monitoring purposes was reported as problematic for both single and multiple occupancy rooms.[57]

Patients' Perspective and Impact

Five of the identified studies assessed the perspective of patients who received care in a purposefully built environment within hospitals. Two studies used focus groups to assess the patients' perspective, one with hospital inpatients,[58] and the other with patients and family members in ambulatory care, acute care, and long-term care settings.[59] A consistent theme among these studies was the preference for an environment that offered quality and comfortable personal space, rather than an environment that addressed only medical needs, but none were without some aspect that was not favorable.

Three studies assessed the perspectives of patients and family members in the United States and the United Kingdom. Patients and family members in the United States, across various settings, reported wanting a health care environment that facilitates connections to clinicians; fosters a sense of well-being; and is not dissociated from the world outside the hospital, outpatient setting, or long-term care setting.[59] Patients in the United Kingdom, hospitalized patients in various units (n = 51) reported feeling a loss of independence and control while hospitalized, but felt safer and at home when they had the TV close by, and were able to walk around. For these patients, the most important factors about the built environment were privacy, a homely environment, considerations for disabilities, and being able to see outside and get outside.[58] Patients in another study in the United Kingdom reported a relationship between the environment and internal areas of the hospital and how that made them feel comfortable, able to keep a sense of normalcy, and as having a positive affect on their feelings of well-being. Patients further reported that they felt that it was important to have good signage, controllable lighting and temperature, privacy, reduced noise levels, access to the natural environment, safety and security in internal and external areas, internal and external children's play areas, accommodations for visitors, shops and personal services, good 24-7 catering facilities, and good landscape designs with seating and garden areas.[60]

Patient perceptions were assessed after implementation of a built environment in a hospital. In one study, there were fewer patients who left against medical advice, aggression levels in patients decreased, and levels of benzodiazepine dosing decreased compared to measured occurrences before the new unit opened. It is not known if there was any assessment of patients' perceptions.[61] Parents (n = 40) in a children's hospital reported more satisfaction with the structure and facility aesthetics**,** but were not satisfied with space for showers/baths, the amount of closet space in the patient room, lack of sufficient private areas to be with their child or for outdoor recreation, location of the nurses station, and the low level of natural lighting.[55]

Acuity-Adaptable Rooms

One study investigated the impact of an evidence-based design of 56 new acuity-adaptable rooms for a combined coronary critical care and step-down unit.[62] Researchers found that two

different levels of acute care (intensive care and step-down care) could effectively be merged together into a single patient room by making the room acuity adaptable to accommodate the changing needs of patients. Once in the new single-bed acuity-adaptable unit, researchers found: a large reduction in clinician handoffs and transfers; a 70 percent reduction in medication errors; a reduction in patient falls; improvements in patient satisfaction; decreases in budgeted nursing hours per patient day; and increases in available nursing time for direct care without additional cost. Yet, clinicians felt more isolated by the increased size of the unit and with decentralized nursing stations; then again, the "isolation" gave nurses greater opportunity for autonomous decisionmaking.

Designed ICU

The implementation of a new neonatal intensive care unit, designed to have a more efficient floor plan, provide space for supportive family-centered care, and to use of natural light, used was assessed using multiple methods.[63] On this new unit, the majority of nurses were positive about the design features. Nurses reported the new unit as enabling efficiency, in part attributable to being able to move about the unit at a greater velocity, enabling them to spend more time with the infants and less time needed to walk about the unit in the course of their work. The nurses also reported that the new unit was more comforting, clean and quieter, and the new lighting was thought to have a positive impact on the patients. Additionally, nurses reported that they felt that families were utilizing the majority of space designated to them.

Addressing the Problem: A Case Study

One new 80-bed community hospital in Wisconsin has been designed to improve patient safety through research-based design. Following the report of the Institute of Medicine (IOM), *To Err Is Human: Designing a Safer Health System*,[64] the management and medical staff at St. Joseph's initially believed that adverse events applied to other institutions and not their own. When it became apparent that St. Joseph's, too, had preventable adverse events, top management authorized the design of a facility with the equipment and technology to lower or eliminate preventable adverse events—a design that could possibly be used as an example by other health care organizations that were building new facilities, remodeling, or expanding existing facilities.

The process began in April 2002, when leadership from SynergyHealth St. Joseph's Hospital met with national leaders representing health care administration, health services research, hospital quality improvement and accreditation, hospital architecture, systems engineering, medicine, nursing, and pharmacy.[65] Using personal experience, human factors principles, health care research, and research from other industries, it was agreed that a National Learning Lab, would be used to develop recommendations for facility design, define and create a roadmap for safety by design, including safe design principles, make recommendations for changes in care processes, and enhance safety culture for hospitals through facility design focused on patient safety. The specific safety design principles, intended to specifically address both latent conditions and active failures, included the following:

1. Automate where possible.
2. Design to prevent adverse events (e.g., patient falls, operative/postoperative complications and infections, and deaths associated with restraint use).
3. Design for scalability, adaptability, and flexibility.

4. Place accessibility of information in close proximity to the patient.
5. Improve visibility of patients to staff.
6. Involve patients in their care.
7. Minimize fatigue of staff.
8. Minimize patient transfers/handoffs.
9. Reduce noise.
10. Standardize.

These principles were substantiated by using failure mode and effects analysis throughout the design process, involving patients/families, and instituting an organizational culture of safety, these principles would enable designs that would support the anticipation, identification, and prevention of adverse events.[65]

Designing for Nursing Care

The first step for the National Learning Lab was an educational program about human error and its causes associated with latent conditions and active failures. The goal of this education was to gain commitment to the need for nurses to be active in the design phase. Then representatives of nursing were elected to a facility design committee. Design teams of nurses were also formed to assure formal input into the design. Mock-ups were also an important feature and prompted more input from the nurses. Many rooms were mocked up, and the medical-surgical room was modified multiple times by the involvement of nurses reviewing every detail to assure a safe design. Nurses' involvement in equipment and technology planning started immediately with the mock-ups. The interplay between the facility (with its equipment and technology) and nurses and patients creates safe or unsafe interactions, and the result is affected in large part by the facility design.

Once the National Learning Lab was over, St. Joseph's Hospital began the important process of implementing the Lab's recommendations. For St. Joseph's to implement the National Learning Lab's recommendations, senior leadership knew they needed to involve nurses in the facility design process because of nursing's essential role in caring for patients, and because nurses interface with all the systems of a hospital at the "sharp end," including equipment, technology, facilities, and patients—more so then any other care provider in a hospital. Not discounting the role of physicians, other clinicians, and health care staff, nurses provide care 24 hours a day, 7 days a week. As such, nurses providing care are most aware of the best way to design a patient room (for example) so the room design minimizes the potential for human error and harm to patients. St. Joseph's organized the design process to maximize the involvement of nurses.

Single-Patient Room

In many instances, including the need for patient isolation measures, double or multiple-occupancy rooms were viewed as not being conducive to patient safety and quality care. The floor plan shown in Figure 1 illustrates how a series of standardized single-patient rooms were laid out on both sides of a hallway in St. Joseph's Hospital. This perspective allows various features of the room to be seen in relation to each other. There are two entrances to the room, one from the hallway (along the lower edge of the picture), and one from the alcove on the right. In that alcove, also entered from the hallway, a desk, computer, and chair are provided for use by

staff. The alcove also contains a standardized storage area, so staff can find everything they need for the care of the patient adjacent to the patient room.

The interior of a single-patient room incorporates many of the recommendations relating to latent conditions and active failures in the design for safety (see Figure 2). The family area of the room is in the right corner of the room, by the window, and includes a couch/pull-out bed, chair, desk with Internet connection, and good natural lighting. The treatment area of the room is on the left side of the bed, with room all around the bed for patient care. It is intentional, also, that the patient is on the nurses' and other caregivers' right as that person enters the room from either door, so care can be more efficiently provided. Note that the bathroom is at the head of the patient's bed, allowing the patient to get to and from the bathroom without impediments, holding onto a rail all the way if necessary. At the head of the bed is the headwall with connections for various gases such as oxygen; on the wall to the left of the bed is a pull-down table the caregiver can use when it is needed. Although it is not shown in the illustration, there will also be a portable cart in each room, with a computer on it. Last but not least, in the lower right-hand corner of the room, between the two doorways, easily visible to the patient, there is a sink—an ever-present and convenient reminder to nurses, all staff, and visitors to wash their hands.

Figure 1. Floor Layout of Single-Patient Rooms in St. Joseph's Hospital

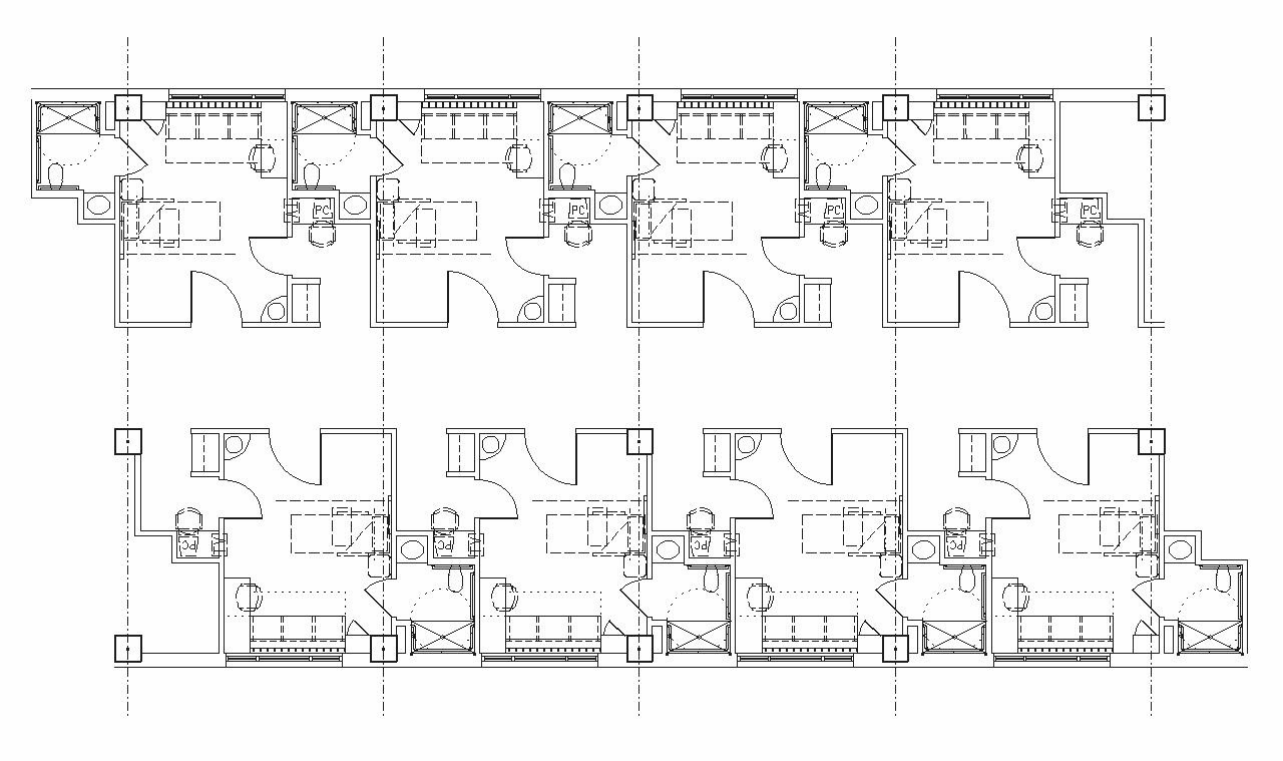

Figure 2. Single-Patient Room in St. Joseph's Hospital

Applying Knowledge of Active Failures and Latent Conditions to Room Design

The design process for St. Joseph's Hospital focused on safety, employing broad participation, including nurses, physicians, board members, administration, National Learning Lab participants, expert consultants, other health systems, health care writers, and design teams. The patient room was selected as a good example of how the design plan for the hospital came together in one location. To show how the room design was reached, each of the applicable latent conditions and active failures will be discussed, to explain how they relate to the plan for a single-patient room.

Noise reduction: Noise interferes with communication, creates distractions, affects cognitive performance and concentration, and contributes to stress and fatigue.[66] Particularly sensitive are mental activities involving working memory.[67] Noise can also adversely impact healing, alter quality of sleep, and reduce overall perceived patient satisfaction, yet the evidence at present is equivocal.[68] Since a standardized patient room has a material effect on noise, the bed in each single room in St. Joseph's is in the same location as the next room. In the traditional patient room style, called back-to-back, patient beds are on the same wall. Back-to-back plans create major transfer noise between rooms, and their use of the same oxygen, compressed room air, and

suction intensifies the transfer noise and vibration. In a truly standardized room, this does not occur. In addition, the walls between rooms are separated and insulated with airspace, minimizing transfer noise. This was designed into the structure early in the building design. In addition, vibration noise between floors and within a floor was minimized through design. The mechanical, electrical, and plumbing systems were designed to use the optimum materials for minimizing noise. This included using vibration isolation/dampening devices wherever vibration could be a factor.

The flooring in the patient room is rubber, second to carpet in sound reduction qualities. The reason carpet was not chosen (it was mocked up and tested) is because spills and mishaps needed to be cleaned up immediately. Carpet requires housekeeping to bring a carpet cleaner, which could take time and also could be embarrassing for the patient. Carpet was chosen, however, for the alcoves and hallways, with a low-nap, special carpet for hospital application. Special ceiling tiles that absorb noise better than regular ceiling tiles were chosen. Triple glazed windows were specified to minimize outside noises. No overhead paging system is used (except for public emergencies such as a tornado warning), and nurse call systems use minimal tone with vibrating features. As specific equipment and technologies were needed, manufacturers of that piece of equipment or technology were contacted and asked how they reduced noise in their products. That became one important criterion for selecting which company's equipment to use.

Scalability, adaptability, flexibility: Many design and construction concepts can be applied to achieve a scalable (e.g., the ability to expand or remodel easily) or adaptable (e.g., the ability to adapt space for different or evolving services) health care facility. At St. Joseph's, all rooms have higher-than-normal ceilings to allow changes to be incorporated in the future. Space around the bed is sized so procedures (e.g., colonoscopies) could be performed in the room in the future.

Visibility of patients to staff: The importance of being able to see patients is inherent to nursing care, a concept that was recognized early by Florence Nightingale, who advocated the design of open, long hospital wards to see all patients. The design of units and patient rooms should allow caregivers to be in visual proximity to patients; a pod structure can allow close proximity and enable quality care by improving efficiency and effectiveness. At St. Joseph's, each alcove door has a glass window with a blind so nurses can work in the alcoves and see the patient or check on the patient. The nurse can also check on the patient in the evening without opening the door and waking the patient. Each room is wired for cameras for observation. All materials, such as medication, linens, IV poles, and a rough-in for icemakers, are delivered to the alcove to allow nurses to spend more time with the patient. The chart will initially be in the room, but shortly after the new hospital opens, it will be replaced by electronic medical records with a workspace so nurses and other caregivers can spend more time with the patient. Furthermore, visibility also means lighting to see the patient. Natural light is maximized by large windows in every patient room. Light sources after hours are as close to natural light as can be achieved cost effectively. Canned lights are located over the patient for assessment. A total of 15 lights are located in every room, including the bathroom and alcoves.

Involving patients in their care: The IOM[9] found that many patients have expressed frustration with their inability to participate in decisionmaking, to obtain information they need, to be heard, and to participate in systems of care that are responsive to their needs. The availability of information for patients increases their knowledge regarding their illness and treatment options, and being informed gives patients the opportunity to participate in shared decisionmaking with clinicians and may help patients better articulate their individual views and preferences.[69–71] This reflects several dimensions of patient-centered care, including respect for

patients' values, preferences, and expressed needs, as well as providing information, communication, and education.[72]

At St. Joseph's, the patient room is designed with a treatment section near the door and a family section near the window. A couch folds outs into a bed; a desk with an Internet connection encourages family members or friends to stay with patients. This is intended to help patients to be more active with their care and better able to protect themselves from errors. A portable computer on a cart (same one used by staff) is located in each room so patients can have appropriate access to their chart.

Standardization: Standardization has been documented as an important human factors-based design strategy [4, 64] that can help lessen the number of errors. Standardization reduces reliance on short-term memory and allows those unfamiliar with a specific process or design to use it safely.[64] With a focus on improving the human-system interface by designing better processes and systems, standardization of patient rooms, treatment areas, equipment, and procedures can substantially reduce errors.[64]

There were many design elements that incorporated standardization as a physical attribute. The patient rooms in St. Joseph's may be the first patient rooms in the country to be standardized. The headwalls are standardized throughout the facility; a seven-drawer configuration was designed into every patient room or alcove to provide consistency of supply locations and to simplify the restocking of those supplies. This provides staff with a known constant, regardless of where they may be caring for a patient throughout the facility due to floating, a patient resuscitation, or some other emergent situation. The electronic medical record, use of bar-coding, computerized provider order entry, and other technologies will be standardized eventually, assisting in the development of standardized protocols and order sets. The facility materials distribution and routine nurse functions can also be standardized to match the facility.

Equipment is not fully standardized yet, but that is the goal, since fully standardized equipment provides the highest level of safety. The complexity and variety in equipment vendors and models is immense, and this complexity creates more errors. This weakness—the lack of equipment standardization—was pointed out continually in using failure and effects mode analysis. So St. Joseph's is evolving toward equipment standardization. The hospital was able to purchase limited new patient monitoring equipment, and took care to assure that new and existing equipment were from the same vendor to give the user a similar feel and functionality, regardless of which equipment they were using. The hospital will continue to utilize this process to guarantee long-term equipment standardization within the facility.

Automation where possible: The IOM identified health information technology solutions as a necessary component to improving patient safety.[9] As discussed in the chapter on health information technology, technologies such as electronic medical records can improve communication and information dissemination between providers.

At St. Joseph's, electronic medical records, bar-coding, physician order entry, a pneumatic tube system, two computers in every room (one in the alcove and one on a cart in the room), a sophisticated nurse call system, new patient beds, and patients lifts for every room are examples of automation. These applications are intended to allow caregivers to give care more efficiently and rely less on short-term memory. Many design features and technology applications have affected multiple latent conditions. This was one of the important criteria used at the matrix exercise to determine which design features to include. Technology applications were deemed to be a critical part of allowing St. Joseph's to design for safety.

Immediate accessibility of information, close to the point of service: In order to provide patients with the most accurate diagnosis and treatment possible, clinicians need to have complete, real-time information about the patient, care needs, and treatment options. Technologies such as the Internet, electronic medical records, and clinical decision-support systems can accomplish this. At St. Joseph's, electronic medical records were seen as the most useful way of making information accessible quickly at the point of service. When the hospital opened, the patient chart was 100 percent paper based. In traditional hospital environments, the patient chart changes location without regard to patient activities. Early mornings, a physician may come around and take the chart to a quiet dictation area to write notes and orders. The chart is often left there until another care provider requires the chart. Or, the chart may be left with the unit secretary to input/transcribe orders.

A transitional plan was developed to meet this guiding principle: When the hospital opened, a mandate was incorporated into the physician and staff orientation that the chart on the medical/surgical unit never leaves the alcove unless the patient leaves. This was surprisingly effective and compliance was unusually high. When an order is written, the physician uses a wall-mounted button labeled "New Order" or "Stat Order" to alert the unit clerk. The unit clerk then transcribes the order and does any necessary computer order entry in the alcove. The chart never leaves the alcove. Anecdotally, the physicians find this process useful to them. They can make rounds more efficiently, since they never have to look for a chart to write their notes or orders. They never have to "batch" their rounding and then look for all of the charts to document. Verbal orders are also reduced. For obvious reasons, this process will cease to be relevant when the electronic medical record is implemented.

Minimizing fatigue: Fatigue has been identified as a contributing factor to human error.[73, 74] While the effects of fatigue on patient safety is not known, fatigue has been found to have a negative impact on alertness, mood, and psychomotor and cognitive performance, which can have an impact on patient safety.[74–76] Some of the effects of long work hours and increasing workload can be mitigated by minimizing the distances staff must travel between patient rooms, and by using health information technology at the bedside to reduce reliance on short-term memory and thought processes. Other considerations in the design of St. Joseph's to minimize fatigue are carpeting and rubber flooring, a chair in the alcove, single rooms, keeping all materials in the alcove so nurses have to take fewer steps, less reliance on short-term memory, less noise, natural light, and strong lighting sources.

Minimizing patient transfers/handoffs: Transferring patients from one unit, room, or floor to another puts both the patient and staff at risk of harm, and it is disruptive to both patients and clinicians. Often these transfers involve handoffs, which, as described in another chapter in this book, also place the patient and clinician at risk for errors. Minimizing patient transfers and handoffs has design implications. Private single rooms with appropriate space around the beds, lifts, and other safety mechanisms allow more procedures to be performed in the room. This is similar to the model in obstetrics with Labor Delivery Recovery Post-Partum (LDRP) rooms, where the mother delivers the child and the child can remain with the mother in the same room for the entire stay. Another example is the physical therapy gym located on the med-surg unit—the patient never leaves the unit to obtain therapy, and their nurse is always in close proximity should a change in patient condition occur. Electronic medical records are another important tool. Bar-coding helps with continually and accurately identifying the patient.

Addressing the Root Causes of Precarious Events

The approaches used by St. Joseph's to address root causes for other types of at risk areas are described as follows:

Operative/postoperative complications and infections: Among the design features that will contribute to the reduction in operative/postoperative complications and infections are private rooms; a sink at the entrance to the medical/surgical patient rooms, which you must pass going in either door (to encourage hand washing); internal window blinds (to reduce accumulation of dust); a housewide air filtration system that includes central HEPA filters; ultraviolet lights in all clinical areas; airflow systems in which clean air passes the patient and is recycled and filtered again; and a radiant heat panel above or below every patient window to eliminate condensation. These are all features that minimize infection. Air supply and return grates that need cleaning have been upgraded to stainless steel so cleaning is more effective. However, the most important design element is the location of the sink, since lack of hand washing is the number one reason for hospital-acquired infections.

Inpatient suicides: Data from the Joint Commission indicate that out of the approximately 1,500 to 1,800 suicides that occur annually in hospitals, about 50 percent of those occur in medical/surgical units. The two most common methods are jumping and hanging. In a medical/surgical room, there are many things patients can use to hang themselves, such as bathroom curtain rods, showerheads, television brackets, or lights. Thus, St. Joseph's decided to use breakaway shower curtain rods and minimize other hanging risks by choosing lights and brackets that met the design needs of the room but would be less likely to be used for a suicide attempt. To minimize jumping, windows cannot be opened, and they are triple-paned, making them much harder to break through. If a suicide-risk patient is identified, that patient is transferred to the mental health unit, but increased visibility in all patient rooms helps staff keep a closer watch, which helps minimize the risk of suicides.

Death of patients in restraints, patient falls: St. Joseph's, like most hospitals, has minimized restraints. The new beds ordered for the hospital have eliminated many of the risks of deaths due to restraints. With less and less restraints, however, the risk of falls rises. Most patients fall at night or while walking with a nurse or other caregiver. Design elements that help reduce falls include fixed night lights in every room, beds that drop down to sixteen inches above the floor, locating the bathroom at the head of the bed with railings to the stool and shower, and utilizing bathroom lights that automatically turn on when anyone enters the bathroom. Besides the above-mentioned strategies, a bed-exit system is being explored using infrared technology. If a patient is identified as he is trying to get out of bed, then lights could turn on, an emergency call to the pager could occur, or a voice could ask the patient to wait for a caregiver. Such a system is in design at St. Joseph's.

Correct tube—correct connector—correct hole placement events, oxygen cylinder hazards: All connectors are a different size for different gases and color-coded. Storage and identification of portable gases employ the same identification program. All gases are in standardized locations to further minimize the risk of a gas-connecting error.

Wrong-site surgery: Operating room suites were standardized, using proper lighting and cable access to digital images and photographs of the surgery site.

Medication and transfusion-related adverse events: Bar-coding, unit doses at point of service, electronic medical records, and physician order entry are critical elements for medication

error reduction. Private rooms with alcoves that include medical records allow nurses to concentrate on one patient and document those efforts, before moving on to the next patient.

Bringing It All Together at St. Joseph's Community Hospital

The use of failure mode and effects analysis, patient focus groups, mock-ups with employee evaluation, and checklist safety design principles (latent conditions and active failures) helped St. Joseph's create the safest room they could envision. The patient room evolved over months of design. Over 27 different designs or refinements were made on the patient room. This room is not the only way a patient room can be designed for safety, but it is believed to be a good way, and it exhibits efficient, thoughtful features that meet National Learning Lab expectations.

The 2002 National Learning Lab had a powerful effect on St. Joseph's and is beginning to influence hospital facility development nationally. St. Joseph's Hospital implemented the recommendations of the Learning Lab, designing around latent conditions and active failures, and enhancing or creating a safety culture through facility design with its technology and equipment. The importance of nursing leadership in the whole process cannot be overstated. Without the commitment, knowledge, and perseverance of the nursing leadership, along with the chief executive officer, board, medical staff, architects, and the rest of the design teams, a safe design would not have occurred.

The effort of St. Joseph's is just the tip of the iceberg of the potential for improving safety of patients in hospitals as a result of facility development. The impact of the National Learning Lab recommendations on processes also offers an immense opportunity to improve the safety of patients in hospitals. The work of St. Joseph's should serve as a model for those health care leaders who share the vision that facilities, including equipment and technology, focused on safety will improve the health and well-being of the patients whom they serve.

The building of the new hospital was completed in 2005, and investigators are currently evaluating the impact of their designs on the frequency of adverse events and patient outcomes. Using innovative architectural and design features to enhance patient safety together with institutionalizing a nonpunitive safety culture can potentially have a greater impact than design features alone. Over the past few years, the National Learning Lab changed St. Joseph's Hospital and has begun to influence hospitals and health care throughout the country.

Leaders and clinicians at St. Joseph's found that the project, with its many safety enhancements, resulted in capital expenditures under budget—an important consideration in the business case. The National Learning Lab's process of identifying and addressing latent conditions was correlated with the Toyota Lean Principles. Standardization, visibility, continuous flow, value stream, minimizing handoffs/transfers will be created as a result of a safely designed facility. This should lead to less human error and potential harm and more efficient operations (process). Yet, one of the major difficulties of translating this efficiency and better outcomes into improved net income is the basic misalignment of financial incentives. Both the fee-for-service and the DRG (diagnosis-related group) introduce perverse incentives. Hospital revenues can actually be reduced as a result of improved safety, and savings can accrue to the insurance companies and not the institutions creating the improvements. Although there is some evidence of changes to improve these misaligned incentives, more dramatic changes are needed to encourage safe process redesign.

Practice Implications

The evidence base is growing in support of evidence-based design for renovations and new building. The new field of evidence-based design has emerged at a time when there is a health care construction boom.[77] There are many factors in the workplace that impact care delivery and work satisfaction, and they should be incorporated into designs. Based on the Gurses and Carayon study,[54] care processes will need to be modified to address inefficiencies caused by distractions (e.g., by family members), overly busy working conditions, delays in getting access to required resources (e.g., medications, patient medical records, supplies, and medical equipment), delays in seeing new medical orders, and misplaced equipment.[54]

Nurses need to be involved and have an active role in evaluating, planning, and testing the layout of patient units and patient rooms to ensure a healing and comfortable environment for both patients and clinicians. Lessons learned should be shared with others to enable improvements across the country, not just on one facility. Current laws and regulations will need to be modified to support new hospital standards and building codes.[10] As single-bed patient rooms are now considered the minimum standard for maternity/postpartum and intensive care units in general hospitals,[78] nurses will need to be involved in planning for transitions and assessing environmental and structural features that will improve the quality of care afforded patient.

Research Implications

The impact of the built environment will most likely be magnified by concurrent efforts to change organization culture and functionality as well as processes of care delivery, but future research would need to so demonstrate. Since the majority of the research on the impact of the built environment has been conducted in specific units in hospital settings, it will be important to investigate whether similar effects can be realized in general medical-surgical units and outpatient settings, including clinics and offices.

In a 2004 report commissioned by the Agency for Healthcare Research and Quality, *The Hospital Built Environment: What Role Might Funders of Health Services Research Play*,[10] the following gaps in the literature were identified: What are the effects of the built environment on the quality of communication and information sharing between clinicians, patients, and families? What is the relationship between environmental factors and the working conditions for clinicians? What are the best mechanisms and designs for facilitating effective hand washing? What is the effect of elements in the built environment that reduce staff fatigue, distractions, and stress? And what is the role of the built environment in decreasing infection rates across patient types? Nurses can have a critical role in addressing these and other research gaps. In this relatively new and exciting area of research in health care, nurses need to and should be actively involved throughout the research and quality improvement processes involving the design of the work environment space.

Conclusions

In the next few years, hospital leaders will be involved in new hospital construction projects to meet the changing marketplace demands associated with the growing demand of an aging population. Many clinicians, architects, and hospital administrators believe that the hospital built

environment can benefit the satisfaction of health care providers as well as patient satisfaction and outcomes. There is some evidence that the built environment may influence patient and family perceptions of the quality of and satisfaction with care received during a hospitalization. There is also some evidence that nurse satisfaction with the built environment was related to general well-being and job satisfaction, two factors that are critical because of their impact on patient care.

The evidence-base is emerging to support the business case that designing for safety and quality can improve patient outcomes and safety, promote healing, increase patient satisfaction, and reduce costs. It is thought that the cost of building or remodeling projects based on design evidence conducive to patient safety can result in organizational savings over time, without adversely impacting revenues.[8] Investigators with the Center for Health Design have been assessing hospitals involved in the Pebbles Project, and have found that the financial incentive for investing in evidence-based design using therapeutic design elements such as single-bed rooms and decentralized nursing stations added close to $12 million in costs to hospital reconstruction—but those costs would be recouped within one year of being operational.[79]

Those building new or remodeling current facilities should consider beginning with transitioning to a culture of safety, then using a safe design as a matter of focusing on maximizing the safety features without expending additional capital resources. While relatively new, evidence is growing in objective assessments of the impact of built environments, particularly around the issue of infection control. Some safety features will cost more than traditionally designed facilities (e.g., HEPA filters and ultraviolet lighting to improve air quality) while other safety features will cost less than a traditionally designed facility, most notably standardization. In all, most of the safety features of a built environment involve a reordering of functions in most "traditionally" designed facilities, minimally affecting capital costs, to improve the quality of care and patient outcomes.

Search Strategy

PubMed® was searched to locate studies and related literature on the built environment. Most of the articles identified in the literature search were primarily descriptive. Search terms included "built," "environment," "hospital design and construction," "interior design and furnishings," "patients' rooms," and "health care." Excluded from the review were articles published before 1999, non-English language articles, expert opinions, case reports, and letters. Three hundred abstracts were obtained. To be considered evidence in this review, the research had to involve nurses or patients in clinical settings, reported findings related to patient safety, and not be specific only to health information technology.

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Evidence Table

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Chaudhury 2006[57]	Single-occupancy rooms in acute care	Cross-sectional study	Survey of nurses about patient care, management, and infection control issues (Level 4).	77 administrative and staff nurses in 3 hospitals in Washington and 1 in Oregon	None	Nurses favor single-occupancy rooms because of their flexibility, being more appropriate for patient examination, quality of patient monitoring, improved patient comfort level, improved patient recovery rate, and scope of patient surveillance. 57 percent believed that health care acquired infections were low or very low in single-occupancy rooms. There was no difference in the number of patient falls, need for pain-reducing or sleep-inducing medications between the two types of rooms. Helpful characteristics of single-occupancy rooms were layout of the room; availability of space in the room; the arrangement of furniture; privacy; space for family members; storage for clean and dirty supplies; and the location of the sink, bathroom, door, and window; lighting; temperature control; and lower noise levels. Helpful characteristics of double-occupancy rooms were proximity to nursing station; visibility of patients for monitoring purposes; and the location of the sink, bathroom, door, and window.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Douglas 2005[60]	Built environment Patient-centered care	Cross-sectional study	Multiple methods, including 50 personal interviews, autophotographic study with 35 patients, novice-expert cohort of patients and clinicians, and a survey of past patients (Level 4).		None	Patients viewed the environment and internal areas of the hospital that made them feel comfortable and able to keep a sense of normalcy as having a positive effect on their feelings of well-being. Novices and experts considered the following important: good signage; controllable lighting and temperature; privacy; reduced noise levels; access to the natural environment; safety and security in internal and external areas; internal and external children's play areas; accommodations for visitors; shops and personal services; good 24-7 catering facilities; and good landscape designs with seating and garden areas. Patients reported the general atmosphere (e.g., feel of the environment, feeling safe and at home, having the TV close by, and being able to walk around) as important. Patients felt a loss of independence and control.
Douglas 2004[58]	Built environment	Cross-sectional study	Face-to-face interviews with hospital inpatients (Level 4).	21 patients in surgery, medicine, care of the elderly, and maternity in 1 hospital in the UK	None	Patients reported the general atmosphere (e.g., feel of the environment, feeling safe and at home, having the TV close by, and being able to walk around) as important. Patients interviewed felt a loss of independence and control Most important factors about the built environment were privacy, a homely environment, considerations for disabilities, being able to see outside, and to get outside.
Feeney 2007[61]	Built environment	Cross-sectional study	Assess the impact of a new, purpose-built acute unit on patients' behaviors and care needs (Level 4).	1 psychiatric unit in a hospital in Ireland	Implementation of a purpose-built acute psychiatric unit in a hospital in Ireland	After the new unit opened, there were fewer patients that left against medical advice, aggression levels in patients decreased, and levels of benzodiazepine dosing decreased.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fowler 1999[59]	Built environment	Cross-sectional study	Conducted 9 focus groups with patients (Level 4).	Patients in ambulatory, acute care, and long-term care settings	None	Patients and family members look for an environment that facilitates a connection to staff and caregivers, is conducive to a sense of well-being, and facilitates a connection to the outside world.
Gurses 2007[54]	Effects of physical environment	Cross-sectional study	Survey of nurses in intensive care units (ICUs) (Level 4).	272 nurses in 17 ICUs in 7 hospitals in Wisconsin	None	Reported performance obstacles included noisy work environment, distractions from families, hectic and crowded work environments, delay in getting medications from pharmacy, amount of time teaching families, equipment not being available, patient rooms not well stocked, insufficient workspace for completing paperwork, time spent seeking supplies or patient's charts, receiving many phone calls from families, delay in seeing new medical orders, and misplaced equipment.
Hendrich 2004[62]	Acuity-adaptable rooms	Pretest, post-test	Implementation of new acuity-adaptable rooms (Level 3).	A coronary critical care unit and its step-down medical unit at 1 hospital in Indiana	Evidence-based design of 56 new acuity-adaptable rooms for the combined coronary critical care and step-down unit.	After the move, there was a large reduction in clinician handoffs and transfers; a 70 percent reduction in medication errors; a reduction in patient falls; improvements in patient satisfaction; decrease in budgeted nursing hours per patient day; increased available nursing time for direct care without additional cost.
Rashid 2007[56]	Effects of physical environment	Cross-sectional study	Development of a survey instrument about underlying effects of environmental features on staff perception of patient comfort, patient safety, patient privacy, family integration, and working conditions (Level 4).	Nurse managers/directors in 7 adult ICUs built between 1993 and 2003	None	Respondents reported that private patient rooms enabled patient safety; ensured privacy of patients; access to patient status information and space for family was important; and flexible patient charting locations and adequate work surface/space were important.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Shepley 2002[63]	Built environment	Pretest, post-test design	A multi-method approach using behavioral mapping; interviews; questionnaires; and calibrated measures of walking, noise, and temperature (Level 3).	21 nurses were observed, 10 completed the questionnaire, and 8 nurses were interviewed in a neonatal ICU in 1 hospital.	Implementation of a new neonatal ICU, where the new design focused on the development of a more efficient floor plan, the provision of space for supportive family-centered care, and the use of natural light	On the new unit, nurses were found to spend most of their time in active baby care, followed by walking, conversations, passive baby care, and charting. More time was spent taking care of the babies on the new unit than on the old unit. Those responding to the questionnaires perceived the new unit as comforting and clean but less secure than the old unit. Family-centered care was perceived as supportive of babies and their families, though its ratings were lower for the supportiveness of nurses and physicians. The unit was rated as generally being efficient and the new lighting was thought to have a positive impact on the patients. Those who were interviewed felt that families were utilizing the majority of space designated to them. They felt the design was efficient, lighting was improved, and noise levels were lower.
Varni 2004[55]	Built environment	Cross-sectional study	Development of a measurement instrument about the built environment (Level 4).	Parents and staff in a children's convalescent hospital	None	Parent satisfaction with the structure and facility aesthetics was associated with higher satisfaction with care. Staff satisfaction with the facility aesthetics and work environment was associated with higher satisfaction and coworker relationships.

Chapter 29. Turbulence

Bonnie M. Jennings

Background

The health care environment was once regarded as safe and secure[1] for patients and staff. Turmoil and change have pervaded the U.S. health care system since the 1980s, contributing to a state of chaos and instability.[1] Today's health care work environment can therefore be characterized as turbulent—it is in a state of unrest, disturbance, agitation, or commotion.[2]

There are many sources of turbulence in 21st century health care. They can be grouped into five categories:

- Hectic conditions in hospitals;
- The rapid growth of large health care corporations, which has altered organizational structures and dynamics;
- Constantly changing health policies, such as those related to insurance—what is covered, what is paid for out-of-pocket, how Medicare Part D really works;
- World events that have placed new demands on health care workers, such as concerns related to bioterrorism; and
- An aging population that is seeking care for chronic conditions from a health care system designed for acute care.

Although turbulence from all of these categories works to create challenges for health care workers, it is turbulence on hospital units that has the most immediate effect on the nurses' work environment. Staff nurses are striving to meet complex patient needs that require rapid decisionmaking, despite there being fewer resources and more interruptions and distractions.

The focus of this review is predominantly on studies that explored turbulence at the level of the patient care unit. Although publications were located that addressed turbulence in health care, no systematic conceptualizations were found delineating or describing the features of turbulence. Moreover, there were indications of slippage between the terms *turbulence* and *uncertainty*. Nevertheless, *turbulence* seems to capture key components of the dynamic and complex work environment that add to the challenge of providing quality care and keeping patients safe.

Research Evidence

Perhaps because turbulence remains to be clarified conceptually, a number of studies relied on qualitative methods. Although these investigations do not meet the criteria for inclusion according to most evidence hierarchies, they provide a rich description of turbulence. The 11 qualitative studies that were identified through database searches examined the work environment from the perspective of various health care personnel—Registered Nurses (RNs),[3–11] physicians,[12] and physical therapists.[13]

Although these studies varied in the rigor of their analytic approaches, five themes appeared across them. In general, turbulence was viewed as a *loss of control*[6, 11, 13] due to simultaneous demands; new, difficult, or unfamiliar work; heavy patient loads; and excessive responsibility.[6] Staff experienced the loss of control as a sense of chaos that infiltrated both their professional

and personal lives.[13] As the environment became more turbulent, *noise* escalated.[3, 6] *Problems with equipment and supplies* (e.g., malfunctioning, missing, calling for cumbersome processes to acquire) were also addressed as elements of turbulence.[3, 5, 11] Aspects of *workload*, particularly variability associated with patient turnover—due to admissions, discharges, and transfers—were mentioned as well.[4, 7, 11, 13]

Turbulence and Communication: The Qualitative Evidence

The dominant discovery from qualitative investigations concerned how turbulence altered various aspects of *communication*, leading to breakdowns, distractions, interruptions, loss of information during handoffs,[3-6, 8-10] and impaired decisionmaking.[3, 4, 10, 12] Although these studies did not always explore patient outcomes, they offer initial evidence to suggest that turbulence may upset certain aspects of communication, thereby compromising patient safety.

Findings from three qualitative investigations can be used to illustrate how turbulence might contribute to heavy communication loads and interruptions. In the first study,[5] eight experienced acute care nurses were observed and interviewed. The investigators in this study coined the term "stacking" to characterize a care management strategy in which nurses kept track of patient care that remained to be done. Evidence of cognitive stacking was also found in the second study,[10] where both ethnography and human factors engineering techniques were used to analyze the work of seven RNs on medical and surgical units. Based on 43 hours of observation, the investigators found that, on average, nurses had a cognitive load of 11 activities; the maximum load averaged 16. These numbers become highly meaningful when viewed in relation to a classic paper from psychology that identified seven, plus or minus two, informational concepts as the limit for information processing.[14] The cognitive stacking experienced by these medical-surgical nurses often exceeded seven.

In the third study,[9] communication related to nurse call systems was studied in two hospitals. Data were gathered from 41 nurses through observations and focus groups. The call systems were viewed by RNs as a source of unnecessary interruptions: 70 percent of the patient calls in one hospital and 80 percent in the other were for issues that did not require the skills of an RN. Interruptions were also common in the previously mentioned study of medical-surgical RNs, comprising an average of 7 percent of their work time.[10] Forty-seven percent of the interruptions happened during patient-related interventions, with 22 percent of these occurring in the medication room during medication preparation.

Turbulence and Medication Errors

The likely connection between turbulence and medication errors was also found in interview data from eight novice RNs who recounted their experiences with near-miss (n = 2 cases) or adverse events (n = 6 cases).[4] All six adverse events and one of the near misses were related to medication administration. Factors in the environment that may have contributed to these errors included a sense of time pressure, inadequate handoffs, impaired decisionmaking, or awkward workflow patterns—all of which could pertain to turbulence.

The quantitative studies can be categorized according to three ideas: medication errors, patient turnover, and communication. Medication errors were explored in three studies that examined features of turbulence.[15-17] In one study,[15] the investigators discovered that the work environment was more likely to be hectic and staff were more likely to be distracted in the 30

minutes preceding medical errors, 91 percent of which related to medication administration. In another study,[16] two protocols were designed to reduce distractions during medication administration. Although there were fewer distractions with one protocol (64 distractions) than the other (180 distractions), both protocols were effective in minimizing disruptions as compared to the control group (484 distractions). The differences among the three groups were statistically significant ($P = .0001$). Interruptions were the most common source of distractions across all three groups. Finally, in an intervention study designed to reduce patient transfers between coronary care and step-down units,[17] the medication errors index was reduced by 70 percent. Transfers were characterized as a "hiccup" in care delivery that could allow error to be introduced. Moreover, transfers take time that could be better spent in caring for patients (see Table 1).

Patient Turnover

The second grouping of quantitative studies considered census and staffing variability or patient turnover related to admissions, discharges, and transfers, as well as observation patients.[17-23] The census variability from patient turnover demonstrates the need to replace midnight census as an indicator of patient volume; it also contributes to turbulence in the environment. The previously mentioned intervention study,[17] for example, reduced patient turnover from transfers by 90 percent through using acuity-adaptable rooms for coronary patients.

The importance of patient turnover is further illustrated in work by Houser,[24] who used structural equation modeling to assess features of the complex work environment on patient outcomes. Although workload, measured by length of stay and midnight census, demonstrated a negative relationship with patient outcomes, it was not a statistically significant predictor of outcomes. Adding patient turnover to the workload measure may have yielded different findings.

Patient turnover was used in combination with other variables in an additional two studies. The first[19] illustrates the slippage between turbulence and uncertainty. The investigators measured objective uncertainty—at times referred to as environmental turbulence—using patient turnover divided by midnight census. Although objective uncertainty was predictive of emotional exhaustion ($P < 0.01$) among staff nurses, the relationship was negative. The investigators suggest this unexpected finding may reflect that patient census variability possibly mediates the emotional effects of environmental turbulence because of the relief offered by occasional decreases in patient turnover.

In the second study,[21] path analysis was used to test a model to predict environmental and personal characteristics affecting nurse performance. Similar to objective uncertainty, the measure of turbulence included patient turnover. Although turbulence did not demonstrate direct effects on nursing performance, it did have a direct negative relationship with interpersonal relations and communication skills that was statistically significant ($p \leq 0.01$). These findings begin to illustrate that more turbulent environments may exert undesirable effects on communication with patients, families, and other staff.

Turbulence and Communication: The Quantitative Evidence

Turbulence and communication were explored in other studies as well. Communication mechanisms were examined at one academic health science center based on three types of unit level practice environments—complex, unpredictable and rapidly changing, or stable.[25] Patient

care communication mechanisms used by the RNs were similar regardless of the degree of stability in the practice environment. The investigators suggested that quality could be better sustained if nurses learned to adjust their communication according to demands in the practice setting.

Communication was quantified and described in two studies. In observing eight emergency department (ED) nurses and physicians for about 20 hours across all shifts, 831 distinct communication events were identified.[26] On average, each of the eight clinicians spent 89 percent of their time communicating; they experienced 42 communication events per hour. Interruptions characterized one-third of the communication events, with each clinician experiencing an average of 15 interruptions per hour.

In the second study,[27] communication patterns were evaluated between the operating room (OR) charge nurses and other OR staff members at four hospitals—two university and two community. The OR suites ranged in size from 4 to 18 rooms. Observations and a data collection tool were completed on 17 nonconsecutive days, for a total of 2,074 communication episodes observed over about 100 hours. Communication episodes per hour ranged from 32 to 74, with more communication episodes associated with the larger OR suites. Charge nurses most often communicated with OR nurses (39 percent). The most common purpose of communication related to equipment coordination. Most communication occurred face-to-face (69 percent), with only 7 percent of the exchanges occurring via intercom. The duration of the communication ranged from 10 seconds to 10 minutes, with a mean of 40 seconds and a median of 20 seconds. Despite the overall brevity of most communication, the investigators did not assess interruptions.

The findings from this collection of qualitative and quantitative investigations have strong implications for practice (see Table 1). Turbulence can be said to emanate from two major sources—workload and communication. Reducing workload and improving communication, with particular attention to minimizing interruptions, could have dramatic effects on stabilizing the practice setting.

Table 1: Summary of Research Evidence Related to Turbulence—Key Findings Center on Communication and Workload Issues

Communication	• Breakdowns • Distractions • Interruptions • Inadequate handoffs (e.g., loss of information) • Impaired decisionmaking • Overload of information (cognitive stacking) • Noise • Interpersonal relations
Workload	• Excessive responsibility • Heavy patient loads • Patient turnover (admissions, discharges, transfers) • Simultaneous demands • New, difficult, unfamiliar work • Time pressure • Equipment and supply issues

Evidence-Based Practice Implications

Common sense suggests that turbulence could interfere with care delivery in several ways. However, the practice implications related to turbulence are only beginning to surface. There is a paucity of studies examining turbulence, fewer still that include patient outcomes, and only three that met criteria for inclusion in the evidence table (see Evidence Table). Even these studies must be considered with caution. None of the studies, for example, was designed to allow causality to be inferred.[17]

However, messages that can be used in practice can be constructed by combining the findings from studies in the evidence table with those using qualitative methods and the quantitative investigations that did not focus on patient outcomes. First, it appears that mitigating turbulence has a positive return in regard to patient safety. In particular, efforts to reduce environmental turbulence may be a major remedy for reducing medication errors. Second, intriguing and potentially fruitful areas for future exploration include cognitive stacking and cognitive shifts, interruptions and other distractions such as noise, and the overall effect of turbulence on communication in general. Finally, features of workload, such as patient turnover and time pressure, are also important avenues for future investigations. Data indicate that each of these elements is connected to patient safety in important ways.

Needed: A Conceptual Framework

Turbulence is an emerging concept that appears to have important ramifications for patient safety. Empirical work is limited, however, by the absence of a model that specifies the components of turbulence. Developing and testing a theoretical model of turbulence would therefore make an important contribution to guiding future research. Exploring similarities and differences between turbulence and uncertainty would also advance conceptual and theoretical clarity. Additional qualitative work may be required to achieve this goal.

Although common sense suggests that chaos is not compatible with patient safety, the understanding based on research findings is limited. Findings from a few studies are beginning to indicate there is a connection between environmental turbulence and medication errors.[4, 10, 15-17] The relationship of turbulence to other clinical outcomes and patient safety indicators remains to be illuminated. More rigorous designs would facilitate a better understanding of the effects of turbulence on patient outcomes. Instrument development would also make a contribution, if a psychometrically sound measure of turbulence could be developed once there is greater conceptual clarity.

Concurrently, although some individuals may regard intervention studies as a bit premature, evidence is accumulating in support of the belief that features of workload and communication have undesirable effects on patient safety. A challenge to researchers, therefore, is to design easy-to-introduce ways to reduce environmental turbulence. Questions and avenues of pursuit might include establishing a metric of a safe patient load, developing an intervention to mitigate the undesirable effects of patient turnover, introducing ways to minimize interruptions, developing processes and procedures to improve handoffs, and determining how to reduce cognitive overload.

Additional possibilities include working with architects and engineers to construct patient care units for the future. These units would take into consideration the needs of both patients and

staff. The overall goal would be to reduce turbulence for the purpose of creating a safer, more secure environment for both patients and staff.

Lastly, there is currently a gap in examining turbulence in long-term care, outpatient settings, and the home. Along with advancing the understanding of turbulence in each of these care settings, it would be useful to explore turbulence across the care continuum as it applies to patient safety and quality care.

Conclusion

Turbulence is a concept that appropriately characterizes contemporary conditions surrounding nurses' work. Because this concept is more recent in its application to health care, the literature about it in relation to quality care and patient safety is sparser. Nevertheless, as indicated in Table 1, ideas related to turbulence cluster nicely within two themes—communication and workload. Focusing efforts on improving communication and managing workload could offer much needed help to the practicing nurse who is often found working in a highly turbulent environment.

Search Strategy

Literature for this review was identified with the help of a reference librarian. Both MEDLINE® and CINAHL® databases were searched from 1995 to 2005 with the goal of being as inclusive as possible. The search terms were slightly different for each database because of differences in MeSH® headings. The terms included: turbulence, work interruptions, attention/or distractions, uncertainty, variability, unpredictability, workload or work overload, loss of control, and work environment. Citations were limited to research reports published in the English language.

The MEDLINE search identified 158 possible citations and the CINAHL search identified 1,324 possible citations. The abstracts for each of the 1,482 studies were reviewed. Based upon information in the abstracts, all but 119 publications were eliminated from consideration. Reasons for excluding papers were that they were not related to nurses in particular, health care staff in general, quality, or patient safety. For example, some studies identified initially pertained to memory assessments, environmental factors related to racial disparities, statistical tests, and studies of particular patient populations. The remaining 119 articles were reviewed in their entirety, 94 of which were eliminated from further consideration because they were not pertinent to turbulence per se (i.e., they were related to other concepts such as stress or leadership), or because they were simply short reports lacking in details.

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Evidence Table

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Grayson 2005[15]	Work conditions	Case control	Patient outcomes (Level 4), medical errors (medication and procedural) (Level 1)	11 acute care hospitals, 112 of 300 nursing personnel (RNs, licensed practice nurses, nursing assistants, patient care technicians) involved in a recent medical error that resulted in minimal or no harm to the patient.	None per se: working conditions were described at 3 points in time and attributes of the work environment were explored to determine the prevalence of potential triggers for errors.	Preliminary results for the first 112 interviews indicate: 91% of the errors related to medication administration. Participants were more likely to report a hectic working environment in the 30 minutes prior to making an error compared to the rest of the shift (OR = 2.6; 95% CI = 1.3-5.4) and more likely to feel distracted (OR = 4.1; 95% CI—1.9-10).
Hendrich 2004[17]	Patient transfers	Pretest, post-test	Design: Level 3, Patient outcomes, sentinel events (medication errors and falls) (Level 1), patient satisfaction and financial outcomes	Two, 28 bed floors in an acute care hospital, Patient transfers.	Acuity-adaptable rooms to provide progressive and critical care in the same setting.	During the two years before the change, the coronary care and step-down units averaged more than 200 intra-unit transfers each month; after the acuity-adaptable rooms were introduced, transfers were reduced by 90%, the medication error index was reduced by 70%, the fall index was reduced from an annual rate of about 6 to 2, and patient dissatisfaction declined.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Pape 2003[16]	Distractions	Non-randomized trial	Design: Quasi-experimental. The dependent variable was the number of distractions experienced by the nurse	A medical-surgical unit with an average patient census of 30, in a 520-bed acute care hospital, Nurses (n = 24)—46% (n = 11) licensed practical nurses, 17% (n = 4) of the RNs had BSNs	Two protocols were tested. Both provided the nurses checklists to guide their medication procedures. In addition, for the focused protocol, staff members were asked not to interrupt the nurse during medication administration. For the Medsafe protocol, in addition to the checklist and staff instructions, the nurses wore a special vest when administering medications. The control group received their medications under usual conditions. Each group (control, focused, Medsafe) was tested for 8 cycles yielding 24 high-volume medication cycles (the unit of analysis started with the beginning of medication administration and ended when the administered medications were documented).	The control group experienced 484 distractions (M = 60.5, SD 12.9), there were 180 distractions with the focused protocol (M = 22.5; SD = 8.5), and 64 distractions with the Medsafe protocol (M = 8, SD = 4.5). Statistically significant differences were found between the control group and each of the protocols (p = 0.001) and between the two protocols (p = 0.014) indicating that fewer distractions occurred when protocols were used as compared to the control group although the fewest distractions occurred with the Medsafe protocol. Across all groups, the most common distraction was interruptions by personnel (n = 267, M = 11.13), followed by hearing conversations by others (n = 215, M = 8.96). Loud noise was a less frequent distraction (n = 34, M = 1.42).

Chapter 30. Nursing Workload and Patient Safety—A Human Factors Engineering Perspective

Pascale Carayon, Ayse P. Gurses

Background

The heavy workload of hospital nurses is a major problem for the American health care system. Nurses are experiencing higher workloads than ever before due to four main reasons: (1) increased demand for nurses, (2) inadequate supply of nurses, (3) reduced staffing and increased overtime, and (4) reduction in patient length of stay.

First, the demand for nurses is increasing as a result of population aging. Between 2000 and 2020, the United States population is expected to grow by 18 percent (31 million), but the over-65 population, with more health care needs, is expected to grow by 54 percent (19 million).[1, 2] Second, the supply of nurses is not adequate to meet the current demand, and the shortage is projected to grow more severe as future demand increases and nursing schools are not able to keep up with the increasing educational demand.[3, 4] When a nursing shortage occurs, the workload increases for those who remain on the job.[5] Third, in response to increasing health care costs since the 1990s, hospitals reduced their nursing staffs and implemented mandatory overtime policies to meet unexpectedly high demands, which significantly increased nursing workloads. Fourth, increasing cost pressure forced health care organizations to reduce patient length of stay. As a result, hospital nurses today take care of patients who are sicker than in the past; therefore, their work is more intensive.[6]

There are several important consequences of high nursing workload. Research shows that a heavy nursing workload adversely affects patient safety.[7] Furthermore, it negatively affects nursing job satisfaction and, as a result, contributes to high turnover and the nursing shortage.[8] In addition to the higher patient acuity, work system factors and expectations also contribute to the nurses' workload: nurses are expected to perform nonprofessional tasks such as delivering and retrieving food trays; housekeeping duties; transporting patients; and ordering, coordinating, or performing ancillary services.[9] A 1998–1999 survey of more than 43,000 nurses in five countries found that 17 percent to 39 percent of respondents planned to leave their job within a year because of job demands.[9] Heavy nursing workload increases burnout and job dissatisfaction, which in turn contributes to high nurse turnover.[10] This chapter focuses on the impact of nursing workload on patient safety. We first present different concepts and models of nursing workload, then discuss the impact of workload on patients and on nursing staff, presenting various mechanisms of the relationship between nursing workload and patient safety. Finally, we describe a human factors engineering approach on how work systems can be redesigned to reduce nursing workload or to minimize the negative impact of a heavy nursing workload.

Concepts and Models of Nursing Workload

Nursing workload measures can be categorized into four levels: (1) unit level, (2) job level, (3) patient level, and (4) situation level.[11] These measures can be organized into a hierarchy. The situation- and patient-level workloads are embedded in the job-level workload, and the job-level

workload is embedded in the unit-level workload. In a clinical unit, for example, numerous nursing tasks need to be performed by a group of nurses during a specific shift (unit-level workload). The type and amount of workload of nurses is partly determined by the type of unit and specialty (e.g., intensive care unit [ICU] nurse versus general floor nurse), which is the job-level workload. When performing their job, nurses encounter various situations and patients, which are determinants of the situation- and patient-level workloads.

Workload at the Unit Level

The most commonly used unit-level workload measure is the nurse-patient ratio. The nurse-patient ratio can be used to compare units and their patient outcomes in relation to nursing staffing. Previous research provides strong evidence that high nursing workloads at the unit level have a negative impact on patient outcomes.[7, 12, 13] These studies' suggestions regarding improving patient care are limited to increasing the number of nurses in a unit or decreasing the number of patients assigned to each nurse. However, it may not be possible to follow these suggestions due to costs and the nursing shortage. The major weakness of this type of research is that it conceptualizes nursing workload at a macro level, ignoring the contextual and organizational characteristics of a particular health care setting (e.g., physical layout, information technology available) that may significantly affect workload. Research should examine the impact on nursing workload of work factors in the health care microsystems.

Workload at the Job Level

According to this conceptualization, the level of workload depends on the type of nursing job or specialty (ICU nurse versus operating room nurse). For instance, Schaufeli and LeBlanc[14] used a job-level measure of workload to investigate the impact of workload on burnout and performance among ICU nurses. Previous research linked job-level workload (a working condition) to various nursing outcomes, such as stress[15, 16] and job dissatisfaction.[17] Workload measures at the job level are appropriate to use when comparing workload levels of nurses with different specialties or job titles (ICU nurses versus ward nurses).[18] However, workload is a complex, multidimensional construct, and there are several contextual factors in a nursing work environment (e.g., performance obstacles and facilitators) other than job title that may affect nursing workload.[19] In other words, two medical ICU nurses may experience different levels of workload due to the different contextual factors that exist in each ICU. The workload at the job-level conceptualization fails to explain the difference in the workloads of these two nurses.

Workload at the Patient Level

This conceptualization assumes that the main determinant of nursing workload is the clinical condition of the patient. Several patient-level workload measures have been developed based on the therapeutic variables related to the patient's condition (e.g., Therapeutic Intervention Scoring System)[15, 20, 21] and have been extensively discussed in the nursing literature. However, recent studies show that factors other than the patient's clinical condition (e.g., ineffective communication, supplies not well-stocked) may significantly affect nursing workload. As with the previous two workload measures, patient-level workload measures have not been designed to measure the impact of these contextual factors on nursing workload.

Situation-Level Workload

To remedy the shortcomings of the three levels of measures explained above and complement them, we have suggested using another way to conceptualize and measure nursing workload based on the existing literature on workload in human factors engineering: situation-level workload.[11] In addition to the number of patients assigned to a nurse and the patient's clinical condition, situation-level workload can explain the workload experienced by a nurse due to the design of the health care microsystem. In a previous study, we found that various characteristics of an ICU microsystem (performance obstacles and facilitators)—such as a poor physical work environment, supplies not well stocked, many family needs, and ineffective communication among multidisciplinary team members—significantly affect situation-level workload.[22] For example, sometimes several members of the same family may call a nurse separately and ask very similar questions regarding the same patient's condition. Answering all these different calls and repeating the same information about the patient's status to different members of the family is a performance obstacle that significantly increases the (situation-level) workload of nurse.

It is important to note that the impact of this performance obstacle on nursing workload would not be apparent if we used a unit-level or patient-level workload measure. Compared to workload at the job level, situation-level workload is temporally bound: it explains the impact of a specific performance obstacle or facilitator on nursing workload over a well-defined and relatively short period of time (e.g., 12-hour shift), rather than using the overall experience of the nurse in a given microsystem. Situation-level workload is multidimensional, that is, different types of performance obstacles and facilitators affect different types of workload. Whereas the distance between the patients' rooms assigned to a nurse affects physical workload, the condition of the work environment (noisy versus quiet, hectic versus calm) affects the overall effort spent by the nurse to perform her job.[23] No prior study investigated the impact of the microsystem characteristics on situation-level nursing workload.[19] In summary, by studying workload at the situation level, researchers can identify the characteristics of a microsystem that affects workload. This information is vital for reducing nursing workload by redesigning the microsystem. In the last section of this chapter, a human factors engineering approach based on the situation-level workload is described.

Research Evidence

Impact of Nursing Workload on Patients

A heavy nursing workload seems to be related to suboptimal patient care[10, 24] and may lead to reduced patient satisfaction.[25] A 2004 report by the Agency for Healthcare Research and Quality (AHRQ) describes several AHRQ-funded studies on the relationship between hospital nurse staffing and quality of care (e.g., urinary tract infection, hospital-acquired pneumonia) and patient safety outcomes (e.g., failure to rescue).[26]

Much of the research investigating the impact of nursing workload on patient safety focused on linking nursing staffing levels with patient outcomes. There is strong evidence in the literature that nurse staffing levels significantly affect several nursing-sensitive patient outcomes.[13, 26, 27]

Several studies found a significant relation between lower nurse staffing levels and higher rates of pneumonia.[28-30] For example, a multisite study in California found that an increase of 1 hour worked by registered nurses (RNs) per patient day correlated with an 8.9 percent decrease in the odds of pneumonia among surgical patients.[28] Another study found a significant relationship between full-time-equivalent RNs per adjusted inpatient day and rate of pneumonia: the rate of pneumonia was higher with fewer nurses.[31] However, other studies have not confirmed these findings;[31, 32] for example, the evidence regarding the impact of nurse staffing levels on pneumonia is conflicting. As workload is affected by more than just staffing levels, a deeper understanding of nursing workload is required to better assess the impact of workload on patient outcomes. Later, a human factors engineering approach to nursing workload that can provide this deeper understanding of nursing workload and its causes will be described, allowing for the development and implementation of solutions aimed at reducing or dealing with workload.

Nursing staffing levels have been shown to have a significant impact on nosocomial infections. For example, Needleman and colleagues[13] found that among medical patients, a higher number of hours of care per day provided by RNs was related to lower urinary tract infection rates. A retrospective cohort study in a neonatal ICU revealed that the incidence of *E cloacae* infection in the unit was significantly higher when there was understaffing of nurses.[33] A prospective study in a pediatric cardiac ICU found a significant relation between the monthly nosocomial infection rate in the unit and the nursing hours per patient day ratio: there were more nosocomial infections when the number of nursing hours per patient day was lower.[34]

Although not as strong, some evidence exists regarding the impact of nurse staffing levels on failure to rescue (death within 30 days among patients who had complications) and mortality. A study using administrative data from 799 hospitals in 11 States revealed that a higher number of hours of RN care per day was associated with lower failure to rescue rates.[13] In a study of 168 nonfederal adult general hospitals in Pennsylvania, Aiken and colleagues[10] found that each additional patient per nurse was associated with a 7 percent increase in the likelihood of mortality within 30 days of admission and in the likelihood of failure to rescue. An earlier study found that hospitals that had more RNs per admission had lower mortality rates.[35]

There were four studies that found a relationship between nurse staffing and patient outcomes. One study found that having a nurse-patient ratio of less than 1:2 during evening shifts was associated with a 20 percent increase in length of stay in patients who had abdominal aortic surgery in Maryland hospitals between 1994 and 1996.[36] Researchers conducted studies in 1992 and 1994 using hospital cost reports and discharge data in New York and California, finding that more nursing work hours were associated with reduced length of stay.[37] Additionally, a critical incident study of Australian ICUs revealed that insufficient nursing staff was linked to drug administration or documentation problems, inadequate patient supervision, incorrect ventilator or equipment setup, and self-extubation.[38]

A majority of the studies on nursing workload and patient safety used nurse-patient ratio as the measure of nursing workload. According to research on workload in human factors engineering (see section above), it is well known that workload is a complex construct, more complex than the measure of nurse-patient ratio.[11] It is unlikely that the multidimensional, multifaceted structure of workload can be captured by one unique, representative measure. Therefore, the belief is that researchers who use the nurse-patient ratio as a measure of workload offer a limited contribution to understanding the impact of nursing workload and designing solutions for reducing or mitigating nursing workload. One reason for the extensive use of the

nurse-patient ratio may be that this measure is easy to use and is readily available in existing databases. But tools used by human factors researchers can comprehensively assess workload, facilitate the identification of the sources of excessive workload, and provide direction for corrective interventions.[11]

How Does Nursing Workload Impact Patient Safety?

According to the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety,[39, 40] structural/organizational characteristics of health care work systems, such as nursing workload, can affect quality of care and patient safety. In this section, a description of how nursing workload can affect patient safety will be offered (see Table 1). The first five mechanisms describe the impact of a heavy workload experienced by one nurse on that particular nurse. The last mechanism describes the systemic and organizational impact of a heavy workload experienced by a nurse's coworkers and team members.

Table 1: Relationship Between Nursing Workload and Patient Safety

Mechanisms	Description	Examples
Time	Nurses who have a heavy workload may not have sufficient time to perform tasks safely, apply safe practices, or monitor patients, and may reduce their communication with physicians and other providers.	No or little time to double-check medications
Motivation	Nurses who have a heavy workload may be dissatisfied with their job, thus affecting their motivation for high-quality performance.	No or little motivation and commitment to high levels of performance High workload creating frustration and contributing to the development of negative attitude toward one's job.
Stress and burnout	Nurses who have a heavy workload may experience stress and burnout, which can have a negative impact on their performance.	Reduced physical and cognitive resources available for nurses to perform adequately
Errors in decisionmaking (attention)	High cognitive workload (one dimension of nursing workload) can contribute to errors, such as slips and lapses or mistakes.	Forgetting to administer medications
Violations or work-arounds	High workload conditions may make it more difficult for nurses to follow rules and guidelines, thus compromising the quality and safety of patient care.	Inadequate hand washing
Systemic/organizational impact	The heavy workload of a nurse, nurse manager, or another provider could affect the safety of care provided by another nurse.	A charge nurse may not be available to help other nurses with their patients when needed.

Nursing workload and lack of time. Nursing workload definitely affects the time that a nurse can allot to various tasks. Under a heavy workload, nurses may not have sufficient time to perform tasks that can have a direct effect on patient safety. A heavy nursing workload can influence the care provider's decision to perform various procedures.[41] A heavy workload may also reduce the time spent by nurses collaborating and communicating with physicians, therefore affecting the quality of nurse-physician collaboration.[42] A heavy workload can lead to poor nurse-patient communication.[43, 44]

Nursing workload and deteriorated motivation. Several studies have shown the relationship between nurses' working conditions, such as high workload, and job dissatisfaction.[10, 45, 46] Job dissatisfaction of nurses can lead to low morale, absenteeism, turnover, and poor job performance, and potentially threaten patient care quality and organizational effectiveness.[47] Researchers have found positive associations between job satisfaction and job performance,[48] and patient satisfaction and quality of care.[49]

Impact of workload on nursing stress and burnout. High workload is a key job stressor of nurses in a variety of care settings, such as ICUs.[15, 16, 50] A heavy nursing workload can lead to distress (e.g., cynicism, anger, and emotional exhaustion)[51] and burnout.[10] Nurses experiencing stress and burnout may not be able to perform efficiently and effectively because their physical and cognitive resources may be reduced; this suboptimal performance may affect patient care and its safety.

Nursing workload and errors. Workload can be a factor contributing to errors.[52, 53] Errors have been classified as (1) slips and lapses or execution errors, and (2) mistakes or knowledge errors.[52] High workload in the form of time pressure may reduce the attention devoted by a nurse to safety-critical tasks, thus creating conditions for errors and unsafe patient care.

Nursing workload and violations or work-arounds. Violations are defined as deliberate deviations from those practices (i.e., written rules, policies, instructions, or procedures) believed necessary to maintain safe or secure operations.[54] The literature on violations emphasizes the role of the social and organizational context, where behavior is governed by operating procedures, codes of practice, rules, and regulations.[54, 55] This approach emphasizes factors in the work system that can contribute to violations. The health care field has begun to explore caregivers' violations of protocols.[56] A survey describing medical practice was administered to 315 nurses, doctors, and midwives and 350 members of the general public in the United Kingdom. The study examined two factors manipulated within nine scenarios of surgery, anesthetics, and obstetrics. The first factor, behavior, was described as an improvisation (no rule available), a violation of clinical protocol, or compliance with a clinical protocol. The second factor, patient outcome, was described as good, bad, or poor. Samples of health care providers and the general public were asked to evaluate the nine scenarios with regard to the inappropriateness of the behavior, the likelihood that they would take further action (i.e., reporting by health care provider and complaining by the public), and responsibility for the outcome (e.g., the health care professional, the patient, the protocol itself, the hospital). Results showed that violations of protocols and bad outcomes were judged most harshly. Whether outcomes were good or bad, violations were evaluated more negatively. The authors of the study warned against overreliance on procedures (or protocols) as a form of organizational defense against accidents or claims. Procedures may stifle innovation and make people less able to function in novel situations.

Alper and colleagues[57] conducted a survey of 120 nurses (59 percent response rate) in three units of a pediatric hospitals to assess self-reports of violations in the medication administration process. Between 8 percent and 30 percent of the nurses reported violations in routine situations, and between 32 percent and 53 percent of the nurses reported violations in emergency situations. The most frequent violations or work-arounds occurred in matching the medication to the medication administration record and checking the patient's identification.

Further research is needed to understand the work system factors that lead to violations. Violations occur more frequently when nurses are under time pressure or high workload because of emergency situations. Under high workload, nurses may not have time to follow rules and

guidelines for safe care, especially if following the rules and guidelines necessitate additional time, such as hand washing.

Systemic, organizational impact of nursing workload. This final mechanism of the relationship between nursing workload and patient safety is based on the systemic, organizational impact of nursing workload: a heavy workload experienced by a nurse not only affects this nurse, but can also affect other nurses and health care providers in the nurse's work system. Understaffing may reduce time nurses have to help other nurses. This lack of time may also result in inadequate training or supervision of new nurses.

Practice and Research Implications

We propose a human factors engineering approach to nursing workload and patient safety, which is based on the SEIPS model of work system and patient safety.[58, 59] This approach is based on the key principle of human factors engineering, i.e., work system design.[60, 61] According to the work system model, several elements of the work system can affect nurses and their performance, safety, and well-being.[58] These work system elements are causes or factors contributing to nursing workload. The first step of the proposed approach is therefore to understand how the work system of nurses can contribute to their workload. Human factors engineers have developed and used various methods to assess each element of the work system model and the interaction between the elements,[62] such as observations of the work situation;[62, 63] direct measurement of the work environment and workstation; and interviews, focus groups, and survey of workers.[40, 64] Once the human factors engineers have identified the elements and characteristics of the nurses' work system that contribute to workload, they can redesign the work system to reduce the workload.

In a previous study,[23] the causes of situational workload experienced by nurses in 17 ICUs in Wisconsin were identified, demonstrating that there were differences in the factors that lead to a heavy nursing workload in different ICUs. For example, compared to their colleagues in other participating ICUs, a higher number of nurses of a 24-bed medical surgical ICU reported the following factors that led to high workload: difficulty finding a place to sit down and do paperwork, distance between patients' rooms, poor condition of the equipment, spending a lot of time searching for patients' charts, and a crowded and disorganized work environment. Since this ICU was larger than the other ICUs in the study and many specialties were involved in the care of patients in this ICU, it was not surprising to see such work system factors as a crowded and disorganized work environment, and spending a lot of time searching for patients' charts (e.g., different specialties searching for the chart during the day).

Once the work system factors contributing to nursing workload have been identified, interventions aimed at reducing or mitigating the workload can be designed. The work system redesign interventions should follow the two basic principles of the Balance Theory of Carayon and Smith: (1) eliminating the source of the excessive workload, or (2) compensating or balancing out the workload.[60, 61] According to the Balance Theory, redesigning the work system should aim at eliminating the negative aspects of work; however, this is not always feasible or practical. The Balance Theory, therefore, proposes an alternative approach aimed at compensating for or balancing out the negative aspects of work. For instance, "making available to nurses resources and social support to assist them in accomplishing their duties"[50, 51] can be conceptualized as a compensating mechanism: different types of support (e.g., informational

support, practical support, affective support) can be provided to help nurses deal with negative aspects of their work, such as workload.

Another key concept of the human factors engineering approach to nursing workload is the work *system*: any change in one element of the work system can affect other elements of the work system in negative and/or positive ways.[60, 61] For instance, work hour limits for physicians have affected nurse schedules. Nurses are often required to work increased overtime to compensate for reduced physician hours.[65] This is an example of how changing one element in the work system of physicians can negatively affect the work system of nurses. Table 2 summarizes the research implications of the proposed human factors engineering approach to nursing workload and patient safety.

Table 2: Research Implications on Nursing Workload and Patient Safety

Research Implications	Objectives
Measurement of situational workload	Test and evaluate various methods for measuring nursing workload at the situational level.
Identification of work system factors that contribute to situational workload	Identify the work system factors that contribute to nurses' situational workload under various conditions and in various care settings.
Evaluation of the impact of situational workload on outcomes	Evaluate the impact of situational workload on various outcomes, such as nurses' job satisfaction and stress, nurses' perceptions of quality and safety of care, and patient outcomes. Conduct this research in various care settings and organizational settings.
Development of strategies for reducing situational workload	Develop, implement, and evaluate interventions for reducing situational workload and its negative impact on nurses and patients.
Evaluation of barriers to improving nurses' work system and reducing situational workload	Identify the organizational and structural barriers to effective changes in nurses' work system and the challenges in reducing situational workload.

Conclusion

Nursing workload is affected by staffing levels and the patients' conditions, but also by the design of the nurses' work system. In this chapter, a description of different levels of workload, including situational workload, was offered, and a proposal for a human factors engineering approach aimed at reducing workload or at mitigating or balancing the impact of workload on nurses and patient care was suggested.

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Evidence Table. Nurse workload and patient safety

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Aiken 2002[10]	Hospital nurse staffing	Cross-sectional study	Risk-adjusted patient mortality, failure to rescue, job dissatisfaction, job-related burnout	Linked data from 10,184 nurses surveyed, 232,342 surgical patients discharged from the hospital between 04/01/1998 and 11/30/1999, and administrative data from 168 hospitals in Pennsylvania	In hospitals with high patient-to-nurse ratios, patients experience higher 30-day mortality and failure-to-rescue rates, and nurses are more likely to report burnout and job dissatisfaction.
Anderson & Maloney 1998[25]	Nurse workload and patient satisfaction	Cross-sectional study	Patient satisfaction	Survey data from 188 patients in a 250-bed Army medical treatment facility	Patient satisfaction was negatively correlated with average daily census, and positively correlated with the number of nursing care hours required and the number of registered nurses available.
Archibald 1997[34]	Nurse staffing levels and patient census in ICU	Cross-sectional study	Rate of nosocomial infections per 1000 patient days	One pediatric cardiac intensive care unit; 782 admissions during one year	Higher patient census was related to higher rates of nosocomial infections. There was an inverse correlation between the monthly nosocomial infection rates and the nurse/patient ratio.
Beckmann 1998[38]	Nursing staffing issues in incidents reported by ICU staff	Noncomparative study	Incidents associated with nursing staff shortage reported to the Australian Incident Monitoring Study-ICU (AIMS-ICU) project	89 nursing staff shortage incidents and 373 incidents involving nursing staff shortage contributing factors	Incidents involving nursing staff shortage contributed primarily to problems in unit management (65%) and patient management (48%).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Keijsers 1995[24]	Burnout (emotional exhaustion and depersonalization)	Cross-sectional study	Standardized mortality ratio for each of the 20 participating ICUs; perceived personal performance; perceived ICU performance	576 nurses from 20 ICUs	High burnout of ICU nurses is related to poor perceived unit performance and poor perceived personal performance. Nurses in well-performing ICUs (as measured by the standardized mortality ratio) reported higher burnout than nurses in poor-performing units.
Lichtig 1999[37]	Nurse staffing	Cross-sectional study	Adverse patient outcomes (pressure ulcers, pneumonia, UTIs, postoperative infections), length of stay	Hospital cost reports and patient discharge data from hospitals in the States of California and New York	Higher nurse staffing and higher proportion of RNs were related to lower length of stay. Lower rates of adverse outcomes were related to a higher proportion of RNs.
Manheim 1992[35]	Regional variation in hospital mortality	Cross-sectional study	Severity-adjusted Medicare hospital mortality rate	3,796 hospitals in nine US Census regions	The percentage of RNs per adjusted admission was a negative predictor of mortality rates.
Needleman 2002[13]	Hours of nursing care per patient	Cross-sectional study	Rates of urinary tract infections, rates of failure-to-rescue, in-hospital death, rate of adverse outcomes	Administrative data from 1997 for 799 hospitals in 11 States	A higher proportion of hours of nursing care was related to better quality of care outcomes, such as lower rates of urinary tract infections among surgical patients and lower rates of pneumonia, shock or cardiac arrest and “failure-to-rescue” among medical patients. There was no association between hours of nursing care per patient and the in-hospital death rate and the rate of adverse outcomes.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Pronovost 1999[36]	Organizational characteristics of ICUs	Observational study with patient data collected retrospectively and ICU data collected prospectively	In-hospital mortality and hospital and ICU length of stay	All Maryland hospitals that performed abdominal aortic surgery from 1994 to 1996	Having an ICU nurse:patient ratio of less than 1:2 was associated with increased resource use.

Chapter 31. Organizational Workflow and Its Impact on Work Quality

Carol Cain, Saira Haque

Background

What Is Workflow?

Workflow, loosely defined, is the set of tasks—grouped chronologically into processes—and the set of people or resources needed for those tasks, that are necessary to accomplish a given goal. An organization's workflow is comprised of the set of processes it needs to accomplish, the set of people or other resources available to perform those processes, and the interactions among them. Consider the following scenario:

> On a slow Friday afternoon in the emergency room, as one nurse prepares to go off shift, the clerk looks up from the desk and asks, "By the way, since you're passing by housekeeping on your way out, would you remind them that room 12 still needs to be cleaned?"
>
> "No problem," replies the nurse, and indeed, on a slow Friday afternoon, it is no problem. The informal methods and processes that the hospital has developed over the years to keep the enterprise humming work well, in general, and can work very well in optimal times. It's no trouble to remind housekeeping to come up; it's no trouble to run a special specimen down to the lab, and certainly no trouble to catch the attending physician during rounds to get a quick signature. Even if these small adjustments are forgotten, in due time the regular hospital schedule will bring the right people to clean the room, to pick up the lab specimen, to document the encounter.

These same methods that an organization uses to get work done, however, can begin to show stress under trying circumstances. When the ward is full and it takes 12 hours for a room to be readied for the next patient, that impact is felt throughout the organization. When the number of small interruptions outweighs the amount of planned work done in a given hour, that impact is felt in slower progress, lower job satisfaction, and potentially lower quality of care. In many situations, it is very clear to all what needs to get done. Where organizations differ is in how they do it. The examination of how an organization accomplishes its tasks often concerns the organizations' workflow.

In health care, as in other industries, some workflows are designed, while others arise organically and evolve. The systems and methods by which organizations accomplish specific goals differ dramatically. Some organizational workflows seem more straightforward than others. Most often, when workflow processes are looked at in isolation, the processes appear quite logical (and even efficient) in acting to accomplish the end goal. It is in the interaction among the processes that complexities arise. Some of these interactions hide conflicts in the priorities of different roles in an organization, for example, what the nursing team is accountable to versus the physician team and its schedule. Organizations also adapt workflows to suit the

evolving environment. Over time, reflecting on organizational workflows may show that some processes are no longer necessary, or can be updated and optimized.

Why Is It Important to Nurses?

Health care has often faced the pressure to design, or redesign, its workflows to be more efficient and effective. In many cases, the trigger for examining workflow is in response to changes in how things are done. Today, the need to think about workflow design is more pressing due to several factors, including:

- The introduction of new technologies and treatment methodologies into clinical care
- The challenge of coordinating care for the chronically ill
- The participation of a growing array of professionals in a patient's care team, and new definitions in their roles
- Cost and efficiency pressures to improve patient flow
- Initiatives to ensure patient safety
- Implementation of changes to make the care team more patient-focused

One important reason that workflow is of pressing concern for today's clinicians is the introduction of new health care information technology (health IT) into clinical practice. Health IT promises many benefits for improving quality and efficiency. However, the introduction of health IT can be very disruptive to existing workflows in an organization. Health IT systems often implicitly assume a workflow structure in the way their screens and steps are organized. Organizations that are thoughtful about workflow design are more likely to be successful in adapting to health IT.[1]

In contrast to industries such as manufacturing, health care is a service industry that relies heavily on good information. In closely following and taking care of patients, nurses are guardians of a rich source of information. This valuable information can be lost when poor workflows impede communication and coordination or increase interruptions.[2] Characteristics of a poorly functioning work process include unnecessary pauses and rework, delays, established workarounds, gaps where steps are often omitted, and a process that participants feel is illogical.

The design of good organizational workflow is not simply about improving efficiency. Workflow processes are maps that direct the care team how to accomplish a goal. A good workflow will help accomplish those goals in a timely manner, leading to care that is delivered more consistently, reliably, safely, and in compliance with standards of practice. An excellent workflow process can accommodate variations that inevitably arise in health care through interaction with other workflow processes, as well as environmental factors such as workload, staff schedules, and patient load.

Research Evidence

Health services researchers have explored workflow issues from several angles, including mapping processes from other industries into health care. Literature about workflow can be found in several different domains, such as quality improvement, technology implementation, and process improvements. One common thread throughout the literature is the importance of interdisciplinary involvement in all aspects of workflow analysis and implementation.

Reviewing the evidence to date, targeted studies of particular interventions and technologies amply show that good workflow design has significant (expected and unexpected) impacts on

care delivery.[3] The literature also demonstrates a relative lack of sophistication in studies of the field: whether researchers are initially concerned with the problem or whether it arises organically from the results; whether the researchers have a theoretical framework to interpret their findings; whether there is consistency in the outcomes of interest; whether the target(s) of study are structural, cultural, and/or functional; and whether the researchers are able to generalize from the findings in one setting to another. Many studies demonstrated significant benefit from careful consideration of workflow, but few studies provided easily adaptable tools and methods for immediate, consistent implementation.

Effect on Efficiency

Workflow analysis has often been used with the goal of improving efficiency. In response to financial pressure and incentives driving provider organizations, minimizing slack time has become important. Some of the studies discussed below demonstrated the power of analyzing and changing workflow to improve efficiency.

Workflow analysis can be used to redesign existing processes. A classic study of this type is Cendan and Good's[4] analysis of the routine tasks of the various members of the operating room (OR) team. They found that there was a wide variability in functions based on clinical and organizational factors. They designed a new workflow based on the analysis and conducted a pilot study. Part of their recommended solution involved defining functions in a more consistent fashion. They were able to improve turnover and improve the mean number of cases handled in a day. A significant factor in their success was their consideration of workflow from both the physician and the nursing perspectives.

Efficiency can also be improved by carrying out processes in parallel, rather than improving the efficiency of existing steps.[5] Friedman and colleagues[6] compared the impact of administering anesthesia in the induction room versus in the OR for hernia repair patients. They found that the OR time used by the surgeon decreased without significant impacts on patient satisfaction or outcomes.[6] Harders and colleagues[7] employed a combination of approaches. They used parallel processing and process redesign to improve workflow in a tertiary care center with multiple OR suites. This combination of approaches allowed for a reduction in nonoperative time. Similarly, in a study of trauma teams, Driscoll and Vincent[8] modified task allocation so that standard tasks performed during a trauma code were conducted in parallel rather than sequentially.

In each of these approaches, role definition played a critical role in the success of the efforts. Each study found that nursing routines often included nonclinical tasks, such as tracking down missing information or supplies.[9] By defining roles and essential processes, it was possible to use ancillary staff for these tasks. In order for the redesign to be successful, nursing involvement was important from the beginning. An interdisciplinary approach provided the basis for the workflow analysis and redesign; this was cited as a success factor in multiple studies.[4, 6, 7]

Common Issues

Workflow issues often arise in studies of technology. One well-studied domain area is barcode medication administration (BCMA).[10] BCMA is a technology that has been shown to improve care quality by reducing reliance on memory, increasing access to information, and increasing compliance with best practice. However, very simple inconveniences—such as the need to access a patients' wrist for the barcode strip—have led to workflow workarounds, such

as scanning barcodes off a key ring rather than the patient. In this case, the nurses' adaptation to make their work more efficient circumvents some of the intended benefits of the defined process.

More complex interactions have also been observed. Because many BCMA systems require that the physician enter an order before the nurse can have access to the medication, some nurses have, in critical situations, "borrowed" medication from one patient on the ward to give to another until the medication for the second patient appears in the system. As a result, the nurse cannot readily document the administration of the order until the order has been entered by the physician. In some situations, a shadow system of informal paper documentation supplements, duplicates, or confuses the documentation captured in an electronic system.

When technology does not adequately support the goals of the care team, it often causes workaround workflows. These alternate workflows are a cause for concern because these informal, evolutionary systems rely on the clinicians' memories, and bypass decision-support safeguards that the system may provide. Studies have documented other negative effects,[11] such as degraded coordination between nurses and physicians, nurses dropping activities during busy periods, and decreased ability to deviate from routine sequences.

Information Transfer

Health care organizations provide valuable services that rely on large amounts of high quality information. Information transfer is complicated because caring for one patient can involve many providers and information sources. Thus, many errors occur at handoff or transition points.[12] Dykes and colleagues[13] found that many hospitals in the United States have dual paper and electronic records, leading to redundancies and inefficiencies in information. Other information tools include proprietary paper forms, the phone, the electronic record system, the whiteboard, the pager, and schedules.[14] In addition, informal meetings and verbal orders frequently also serve as information transfer devices.[15]

One attempt to address this complexity is an electronic portal that provides access to systems through one interface.[16] Though this can mitigate the problem, it cannot fully address the communication needs of a care team.

A common class of problems with information transfer and handoffs includes degradation of information.[17] If methods of transfer are informal and not documented, patient information may not be passed on when staff members leave a unit. In addition, the lines of responsibility and expectations are not always clear.[17] Incorporating formalized information transfer tools and protocols into workflow processes may help. Another problem complicating information transfer is interruptions. These interruptions often cause a break in workflow, which can impact what information is documented and passed on.[18, 19]

Intra-Professional Information Transfer

Nursing work is often fragmented and rushed, due to external pressures and the dynamic environement.[20] However, nurses serve as critical integrators and coordinators of care. Health IT tools, which can help nurses better manage and transfer information and make the information more widely available have the potential to improve practice.[21] Intraprofessional handoffs may occur within or across departments. In either case, communication and coordination is improved by having a structured documentation format.[22]

Lamond[23] reviewed the content of nursing intershift reports and found that more information was documented in the patient notes than was given in the report. The report information tended to be more overall assessments of patient care, which was not necessarily documented. Thus, it is not clear if the detailed information was transferred in subsequent reports. Perrott[24] found that customizing data fields and having nurses involved from the beginning enhanced nursing handoffs in the intensive care unit (ICU).

By understanding nursing workflow, barriers and facilitators for information transfer can be discussed and improved upon.[25] If handoff mechanisms are informal, then they might not be documented in a workflow analysis.[26] Health IT systems should not replace these handoffs, but could be used to augment the process.[27] However, when the processes are not well understood, the technology may not be used and may even be a burden.

Inter-Professional Information Transfer

Inconsistent or incomplete information during patient care transfers is a commonly cited communication difficulty.[28] This problem is exacerbated by systems and processes with duplicate or outdated information. There is a great deal of information available, but it is not always available in a streamlined or organized fashion.[29]

Clinical providers trained in different disciplines are socialized and trained differently, so they do not necessarily know what the others need.[29] Thus, when designing and implementing information technology across departments, it is important to have an interdisciplinary team involved throughout the process.[22] Physicians and nurses do not generally have the same employer and often have varying loyalties and end goals.[4] Thus, it is important to consider many perspectives when designing handoff and communication practices.

One way to look at interprofessional collaboration is to look at information needs. Reddy and colleagues[30] reviewed information needs of various providers in the ICU. They found that some roles, including nurses, served as information sources for other providers. Thus, it is important to consider the workflow implications of changing information sources. When a face-to-face communication with a nurse is replaced by an electronic report, what is lost and gained? Electronic access provides the benefits of ready access to large quantities of source data, potentially supplemented with decision support. What may be lost are functions of information synthesis, summarization, and coordination. In a survey of chief nursing officers, Dykes and colleagues[13] emphasized the role of nurses as coordinators and communicators.

Riley and Manias[31] looked at physician–nurse communication in an OR setting. They found that nurses often had informal knowledge of physicians and their habits, which they used to control practices. This knowledge was not necessarily codified formally, so new nurses would have difficulty in estimating workflow. Health care organizations have engaged in efforts to standardize inter-professional communication, for example through requiring the use of SBAR for situational briefing.[32]

It is not always necessary to have a separate process for interprofessional communication. Indeed, other efforts can be repurposed for interprofessional communication. For example, Cunliffe[33] described a nursing discharge summary process which was repurposed to provide a nurse–general practitioner communication device. A nursing discharge summary provided detailed information about nursing and social care for the patient after they left the hospital. In addition, sending this to the general practitioner (GP) provided a mechanism for communication so that the GP would be well-informed about the patient's care. Similarly, a resident sign-out

system could also be accessed by other professionals.[34] However, communication lines tend to be separate and dependent on professionals, so it is not clear how much intraprofessional access occurs. Patterson and colleagues[35] studied handoff strategies in other industries and outlined some common strategies for effective handoffs. Often, documentation was a supplement to the handoff, rather than the sole mechanism for information transfer.

Health Information Technology

Health IT, used well, can improve efficiency and organizational workflow. In health care, redundant information is often created and stored. As a result, care providers spend a great deal of time reconciling information from various sources. Integrating health IT with the workflow of various departments can help to reduce this redundancy.[22] However, if workflow is not considered and the technology is not thoughtfully implemented, the benefits cannot truly be achieved. To use technology most effectively, its potential impact to transform care delivery must be realized.[36]

While it is important to consider workflow when implementing health IT, it does not mean that health IT should leave processes intact. Health IT can bring about positive process change and better workflow. Because IT can consolidate and display information, it can be used as an opportunity to improve upon teamwork and communications.[37] Understanding existing clinical workflow prior to implementation provides a baseline to redesign systems and develop better processes.[38] Scharmhorst, Johnson, and Li[39] emphasized the importance of understanding the system prior to implementing technology, to ensure that technology streamlines nursing workflow, rather than making it more complicated. In a study of mobile cabinets with barcode scanning for medications, Braswell and Duggar[40] found that, by analyzing workflow ahead of time, both pharmacy and nursing staff reported improvements to existing work processes after implementation. Workflow concerns can lead to failure to adopt new technologies. A study of electronic prescribing systems standards finds that many of the electronic standards are adequate but provider adoption is low because the systems do not fit into workflow.[41] The evaluators recommend that the standards and systems be revised to accommodate the large role of nurses in electronic prescribing in the office setting.

Focus on Computerized Provider Order Entry

Computerized Provider Order Entry (CPOE) is an easily measurable, frequently implemented, and often intrusive instance of health IT, and has been studied often in the literature. CPOE is commonly associated with its impact on physician practice. However, there are workflow implications in CPOE implementation for the entire care team, including physicians and nurses.[42] For example, if physicians refuse to use the CPOE system, it creates adverse impacts on nursing workflow.[3, 28] Sometimes, nurses become the de facto order entry personnel, in addition to their nursing duties. These workarounds also have effects downstream. Delays in order entry can hold up medication delivery. The introduction of CPOE technology may surface informal practices that may not be in compliance with prescribing scopes of practice. Thus, nurses are a key success factor in CPOE implementation.[43] Because nurses often are primarily responsible for communication and coordination of care, understanding nursing workflows with respect to order entry is critical.[44]

Payne[45] found that implementing CPOE had a profound impact on work patterns, communication methods and roles. In analyzing workflow around electronic prescribing, the range of tasks completed by the nonprescribers was outlined.[46] After outlining the work processes and information flows, they were able to adapt the system to accommodate the necessary tasks. Similarly, Wright and colleagues[47] found that physician-nurse communications were impacted by the CPOE implementation. Paper-based order entry often relies on visual cues, such as a folded piece of paper. If the loss of context and visual cues is not accounted for in the CPOE implementation, then the nursing workflow is adversely impacted because of the uncertainty around orders.

Piasecki and colleagues[48] conducted a workflow analysis to look at the benefits of implementing CPOE in an emergency department setting. These researchers developed a return-on-investment tool to measure the outcomes of the implementation and found that many of the savings did not make a direct impact on the bottom line of the organization. This was, in part, because the changes in workflow were not fully understood until after implementation.

Though guidelines for analyzing workflow are few, the common factor was consideration of all affected roles in the organization, not only those involved with entering data into the IT system. Breslin and colleagues[49] found that having an interdisciplinary team was important in the success of a Vocera implementation. This team included clinical and nonclinical staff. By being inclusive, they learned about workflow from a variety of perspectives and were able to implement their tool in a fashion that would improve upon existing practices.

Ongoing Work in Nursing Workflow Research

Research into the workflows of nurses has long roots in studies of how nurses spend their time and how nursing teams should be staffed.[50-52] Nurse researchers embarking on observational research of nursing work can take advantage of previously developed tools for work task analysis and time motion study.[53-55]

With the introduction of new technologies, the research frontier includes studies of how nursing work is affected, with the aim of ensuring quality time at the bedside. An ongoing large multi-site time-motion study of nurse workflow[56] includes the involvement of frontline nurses in the design and improvement of their work spaces and technologies. It represents one way that lessons learned from past research can be brought to bear on future workflow design, with the intent of mitigating the pain of learning workflow and technology weaknesses through implemented experience.

Practice Implications

The research findings for these studies of operational workflows have practice implications for nurses and researchers. Throughout the literature, the importance of bringing multiple parties to the table was emphasized. Because organizational workflows often cross the lines of professional disciplines, workflow design from any single perspective runs the risk of sub-optimizing against other constraints, priorities, and schedules.

Conscious workflow design has been shown to improve the efficiency of existing work processes or enable parallelization of work. In designing such systems, researchers emphasize the importance of clearly defining roles and responsibilities, preferably with multi-disciplinary input. Designing workflow is of critical importance to all roles in a health care organization,

because the effects of decisions by an expert in one role may have downstream effects on others. A workflow optimized to serve one role, such as the nurse, can be onerous or seem irrational to another. Because each professional role deals with fairly complex, role-specific work processes, it is often difficult for experts in one role to understand and envision how proposals will affect other roles, even with the best intentions. Research on information transfer in organizational settings demonstrates that adaptations to poor workflows can lead to increased interruptions, workarounds, and informal or ill-defined communication. To improve the reliability of workflows accomplishing their desired goals, and to reduce the risk to patient safety, researchers recommend structured communications and clear agreements about roles and responsibilities in a hand-off.

Health IT systems surface many of the long-standing issues around workflow. The implementation of health IT systems can, at first glance, seem like a superficial intrusion into the way things are done. For some, it feels like the addition of another documentation step in the process of regular clinical care. This step can be disruptive and a burden, but it does not dramatically change the way work is done. Yet there are many downstream effects on communication and coordination within an organization. Analyzing workflow beforehand can help prevent some of these unintended consequences. Technology does not necessarily improve institutional efficiencies, but can bring opportunities for improvement to light.[42] Sittig and colleagues[38] found that while considering that technology was important, it was also important to consider organizational and workflow factors prior to implementation, or the benefits may not be realized. In order to realize good outcomes, interdisciplinary consideration of process and technology factors was important.[57]

In many organizations, the adoption of health IT is motivated by the desire to accomplish goals that are difficult without a structured electronic system. These goals include reducing medication errors through barcoding; improving clinical decisionmaking through decision support, such as alerts and reminders; measuring clinical quality performance; proactively reaching out to patients for population health management; or simply the ability to analyze clinical information, for example, by charting a patients' blood pressure based on nursing notes. These additional expectations of a health IT system mean that the organization can expect dramatic changes in workflow—the health IT implementation is a vehicle to trigger larger improvement activities.

It is important to realize that health IT systems have a built-in sense of how things are done, in fact, have an inherent workflow that may or may not map to the organizations' workflow. Consider the case of CPOE. Let's describe the workflow process as a series of tasks, linked chronologically, that require organizational resources. The logical model within a health IT system usually goes something like this:

1. The provider enters an order.
2. The pharmacist verifies the order.
3. The order is delivered to the point of care.
4. The nurse administers the order.

There are two things to note about this perfectly reasonable assumption about how things are done. The first is that the workflow is very linear. It will be very important to understand what happens if that linearity is disrupted somehow. For example, if the pharmacist fails to verify the order, will the system prevent the order from being "released" until this step is accomplished? Flexibility within a linear workflow is very important to the smooth operation of a complex service organization like a health care institution. Practitioners have a responsibility to check that

a health IT system reacts gracefully to a change in workflow, lest patient care be compromised. The second thing to note is that the workflow within the system only reflects one of the ways health care is delivered in an organization. In many critical care settings, for example, medications must be administered quickly, before any interaction with a CPOE system. Practitioners should also ask whether the health IT systems they are implementing reflect all of the main workflow processes within their organization.

When a new health IT system or a new technology fails to accommodate the real workflows of an organization, interacting with the technology becomes a greater burden on the organization than is required. In essence, there is "the way the world works" and then "the way the computer thinks the world works," and it is the constant responsibility of system users to reconcile the two world views. In fact, implementing health IT systems within organizations poses such a challenge that the Office of the National Coordinator for Health IT has estimated that as many as 30 percent of all implementations fail.[58] Thoughtfully constructing the workflow inherent to the technology can smooth technology acceptance.[59, 60]

Before implementing information technology in a health care environment, it is important to have an understanding of processes and information flows. In addition, it is important to consider various roles in the different departments, and to consider ideas from multiple sources.[22] Each department and role may have a different perspective of the encounter and its necessary elements.[36, 61] In addition, many organizations have a variety of tacit assumptions and information exchanges which might not be documented in a traditional analysis. Thus, it is important to consider multiple sources of data in order to develop a more complete understanding of workflow and processes.[36]

In the United States, hospitals are generally organized by functions. Because of that, workflow is also organized around these functions. Information systems were developed around these functions and were designed to meet the needs of a particular department. However, patient care takes place through a broader perspective. Thus, these functions need to be integrated.[20] In conducting a workflow assessment, it is important to consider how workflow currently functions and how it might change to improve patient care and reduce errors throughout the system.[20, 62] In addition, this kind of analysis can help find flaws in the process for which information technology can be leveraged.[20]

The truth is that many care teams do well even when workflow processes are designed poorly. Health care practitioners understand the clinical needs of patients. Health care workers often go to heroic lengths to make sure that the right thing gets done. When a problem arises, most clinicians would not hesitate to pick up the phone, run the errand, or do what is necessary to insure good care. Yet clinician resources are not unlimited. When nurses, like all people, get tired, they may become forgetful When they are rushed, they may not remember to do everything necessary.[63] These issues may be exacerbated by a health IT system that seems not to understand what the clinicians want to do—sometimes because the workflows in the health IT system do not match those in the real organization. In the seminal work on clinical error, the health care community acknowledged that most errors are the result of systematic deficiencies.[64] Good workflow processes are an aid to practitioners to insure that the system behaves to support high quality care. Nurse informaticists can work with their counterparts to apply some of the principles found in the literature to practice.

Research Implications

Workflow design is a difficult endeavor because of the complexity of most health care organizations and the division of labor into expert roles. Health care organizations are service organizations that are very flexible and interdependent in response to dynamic patient needs. For many work processes, the established workflow evolved over time in response to the kind of tasks and resources available, and were not explicitly considered or designed. Changes to organizational workflow are an opportunity to think through how the care team can provide good patient care reliably under a variety of circumstances.

Research on workflow issues can be very rewarding because of its closeness to real-world operational challenges. Study participants often experience a high level of frustration with their current situation, and are eager to have assistance in thinking through complex organizational effects. The research often starts with a theoretical model that helps define the problem space, such as conceptualizing the structure, process, and outcomes[65] or the tasks, actors, and information.[66] The model can be made operational through computer modeling, and used to represent particular problems.

In support of workflow design activities, computer simulation tools have been developed to help decisionmakers map their organizational roles and understand the impact of different workflow choices.[67-69] Models of workflow processes show the trajectories of the care providers, patients, and information. By representing workflow in a manner which is easily accessible to others, managers and researchers can identify where issues are likely to arise and develop tools to prevent them. Modeling workflow also usefully defines roles and delineates how the care team understands its job functions and work processes

For health IT, workflow design is especially difficult because many of the assumptions about workflow are implicit. The designers of IT systems benefit from conversations with their users to understand how clinical care is provided in the organization. Without the input of users, it is tempting to apply the same workflows to different organizations. Many issues can be easily resolved through small changes in user interface or clinical decision support rules—changes that are very difficult to predict in advance. Although some issues can be resolved through customizing the health IT system, others are more intractable. The health IT system may simply reveal latent problems with the old workflow. As more organizations embark on large-scale health IT implementations, a scalable method for incorporating workflow considerations is urgently needed, so that new health IT systems do not cause harm.[70] When issues have been surfaced, through conversations, observation, modeling, and other methods, researchers have the opportunity to bring to bear established quality improvement methods to workflow design. Studies to date have relied on ad-hoc methods to effect improvement after studying workflow, and there are opportunities to apply structured methods to assist an organization in responding to workflow discoveries.

Many of the research articles reviewed involved a descriptive case study. Some studies utilized a grounded theory approach. Few articles utilized a conceptual framework to frame the results. While research on service organizations has been applied to health care organizations, much work remains to be done in delineating how health care work differs from other industries, in particular to understand whether results from inquiries in other fields, such as manufacturing, can be generalized to health care. In addition, there is a need for research to demonstrate a link between performance indicators and workflow.[71] Nurse researchers have an opportunity to take the research that has been done to date and apply it on a broader scale. Much of the work that has

been done outlines specific implementation efforts or describes a single department. By taking a systems approach to organizational workflow, coordination of patient care throughout the trajectory of their stay can be improved.

Search Strategy

The search for workflow issues in delivering high quality nursing care is complicated because workflow, by its nature, touches on many organizational issues and roles. Literature that identifies specific problems in patient safety may allude to their greater systemic workflow causes or effects. Even literature that specifically considers workflow may limit the analysis to one organizational role. Thus, our literature search did not attempt to be a comprehensive search of literature published on workflow, but rather a scan of areas in the medical and nursing literature where relevant publications are likely to appear. There is also a longer history of research literature in other fields, notably industrial engineering and management.

We looked at MEDLINE® and CINAHL® articles published in English. Because workflow is not a standardized term in either database, we searched it as a keyword in its various permutations. We did the same with handoffs, as we knew that this was a common study topic where workflow issues surface. In addition, we did searches using combinations of related terms in each database. The terms we used were in categories dealing with continuity of care, care teams, information needs, information systems, and patient safety. We found that the keyword search yielded more consistent information than the standardized terms, in part because the terms were developed with specific purposes in mind. Studies of workflow are still fairly new, and it is hoped that as the field matures, it will be easier to identify a unique body of work.

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Evidence Table

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Adams 2000[72]	IT; workflow	Changing practice project and Published Guidelines	Case studies	Case management	Teaching hospitals	IT brings about new workflows and information recording; can be helpful for the case manager; case managers may need to transform their workflows
Ammenwerth 2003[73]	User acceptance	Pretest and post-test	Questionnaire: 3 months before system implementation, 3 months after, 9 months after	Nurses on four wards of a hospital in Germany	Questionnaire	Previous acceptance of the nursing process and the previous amount of self confidence are two important factors influencing acceptance of a new computer based documentation system; consider fit between nursing workflow and functionality of system; some wards adapted system to their needs and others did not; some felt that it shows what they do all day
Bahlman 2005[60]	Workflow; OR; Information transfer; Implementation	Pretest and Post-test	Reviewed workflow processes for redesign	OR	Changed workflow processes	Needed to review workflow processes first; figured out ideal systems and tried to have technology match them
Banet 2006[44]	Workflow; ED; Information transfer; implementation	Pretest and Post-test	Looked at implementation of CPOE in ER and nurse perceptions	ER staff	CPOE implementation	Nurse perception of effective use of design is needed for successful implementation of information system changes; introducing CPOE into workflow is complicated; documentation time might not change
Bigelow 2006[75]	Workflow; Standards	Pretest and Post-test	Case study	Hospital system	Placed standards in an accessible document repository	New format allows for changes in workflow because standards can be looked up from multiple locations. reducing time spent searching for information

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Bowcutt 2003[29]	Interprofessional communication; Information transfer	Unpublished research	Roundtable discussion	NA	NA	Systems can enhance workflows, but they need to meet user needs; there's more information to sort through; data is not streamlined enough; if physicians don't want to do CPOE, the nurse suffers; clinical staff need to know that their documentation impacts others' workflow
Braswell 2006[40]	Implementation	Pretest and Post-test	Reviewed workflow and time spent before and after implementation	Nursing unit	Added mobile cabinets with barscanning for medications	Better teamwork with pharmacy; improvement on workflow; better documentation because of bar scanning
Breslin 2004[49]	Implementation	Case–control study, Pretest and post-test study	Observation; Documented communication workflows; Looked at phone calls; Survey	Staff within units in a hospital in Baltimore	Implemented Vocera and compared units with and without it	Having the technology saved time; less overhead paging, more efficient workflow; time savings
Bricon-Souf 1999[68]	Workflow; Modeling	Noncomparative study	Modeled flow of actors and information	ICU	NA	Development of a workflow model needs to include actors and information; flexibility and adaptability of model are important because processes are complex
Brixey 2005[18]	Workflow; Interruptions	Noncomparative study	Observation; Ethnography	RNs at a level 1 trauma center	NA	Understanding context around interruptions is good for understanding workflow; good to know causes and implications of interruptions
Brixey 2006[19]	Workflow; Interruptions	Noncomparative study	Observation; Ethnography	RNs and MDs at a level 1 trauma center	NA	Categorized activities and interruptions for doctors and nurses; layout can cause break in workflow; unavailable supplies or information can cause interruptions; technologies can contribute to more interruptions

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Browne 2004[76]	Workflow; Process redesign	Noncomparative study	Description	Hospital	Integrated fall alert so that other areas can see it; feedback was positive	Redesigned fall prevention process and included it in clinical information system; developed evidence based tool; tailored interventions to specific patient risks; integrated fall risk information into system
Burke 2005[12]	Medication administration; Information transfer	Unpublished research	Discussion of medication administration	NA	NA	Many medication errors occur at patient care transition points; nurses are very important at these points
Campbell 2006[3]	Safety	Unpublished research	Discussion of unintended consequences	NA	NA	Think about broader issues of safety; many medical errors aren't reported
Campbell 2006[77]	Safety	Quality improvement	Observation, interviews, conference.	5 medical centers with different CPOE products	Identify, describe and categorize unintended consequences of CPOE implementation	More/new work for clinicians; unfavorable workflow issues; demands for systems changes; people continued to use paper systems; communication patterns and practices changed
Cendan 2006[4]	Change; Workflow; OR	Pretest and Post-test	Analyzed and improved workflow	OR staff of a tertiary care center	Workflow diagrams were redrawn; critical moments were identified	Turnover improved and the mean number of cases improved; looked at interdisciplinary patterns
Chan 2006[78]	Workflow; Efficiency	Pretest and Post-test	Interviews	Nursing staff	Changed nursing delivery model	Some nursing work is formulated in a task-oriented assembly-line approach; allocate work assignments based on skills; some routine activities are not formalized
Christakis 2003[79]	Continuity; Information transfer	Cross-sectional study	Survey	Parents of patients at a pediatric clinic who received care at multiple sites	Cross-sectional survey of patients' families compared to organizational measures	Importance of continuity of care to promote coordination; greater objective measure of coordination was associated with improved perceptions of care coordination; consistent provider contact is associated with improved care coordination

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Clegg 2006[80]	Workflow, Efficiency; information transfer; Interprofessional communication	Pretest and Post-test	Implementation of a single assessment process for elderly patients	Elderly population in the UK	Implemented the new process and changed workflow to enhance information transfer	Improved documentation helped with sharing information; changed workflow helped to make this information available to those who needed it, reducing redundant questioning of patient
Cronin 2004[81]	Workflow, Efficiency	Noncomparative study	Description	Hospital	NA	Described challenges of incorporating IT into workflow
Cunliffe 2003[33]	Discharge; Communication; Coordination	Noncomparative study	Description of rationale and processes for developing a nursing discharge summary	Hospital in UK	Developed a standardized, structured formal discharge summary	Communication and coordination help with discharge planning; could be applied to other aspects of care; information tools can be used for multiple purposes
Driscoll 1992[8]	Coordination; Team structure	Pretest and Post-test	Observation, Survey	Trauma teams in Hospitals	Organizational changes were made during resuscitations - task allocation and horizontal team organization	When the structure of trauma team changed, complexity and distribution of individual tasks came to light; hard to get team members to work simultaneously; old habits occasionally recurred
Dykes 2006[13]	Information technology; Interprofessional communication	Pretest and Post-test	Survey, Interviews	Health care professionals in acute settings	Survey by HIMSS nursing informatics task force	95% of respondents had dual paper and electronic systems; nurses communicate and coordinate about care both formally and informally; IT does not reduce clinical thinking
Egan 2006[16]	Information transfer	Noncomparative study	Reviewed a dashboard of relevant patient information	ICU and OR staff	Determined who looks at what information and at what stage of the process	A dashboard with the data nurses need could help synthesize information, across hospitals and within departments; information availability can transform workflow; real-time data flowing from disparate devices into a single interactive display

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Elder 1998[82]	Nurse role	Unpublished research	Discussion	NA	NA	Need to clarify role of nurse, which has moved from task oriented process to outcome oriented - the focus isn't just on following orders but on the entire illness and being a manager of care
Friedman 2006[6]	Change; Workflow; OR	Case–control study	Reviewed time and workflow of group with standard versus parallel processing	Patients undergoing hernia repairs under local anesthesia	Case group has anesthesia in the OR at the start of surgery; control group had local anesthesia in the induction room during turnover time	Time decreased in case group; patient satisfaction similar; outcomes didn't change; OR time used by the surgeon decreased by 1/3; roles were redefined and team cohesiveness improved
Ghosh 2006[43]	CPOE; Implementation; Interprofessional communication	Noncomparative study	Interviews, focus groups	Chief Nursing Officers	How nurses impact and are impacted by CPOE	Nurses are a primary success factor in CPOE implementation; they have a critical role in communication, coordination and knowledge sharing; understanding communication processes is key to CPOE implementation
Guite 2006[22]	Change; Workflow; Implementation	Pretest and Post-test	Ethnography, interviews, process modeling	Level 1 trauma center	Documented each step of the current process with detailed flow diagrams; looked for opportunities for improvement and implemented a new process	Use IT to help redesign process; found considerable duplicate documentation; people have to spend time reconciling info; Consider a standardized language for shared data elements; need to integrate with workflow of various departments
Gurses 2006[14]	Information transfer; Coordination	Noncomparative study	Ethnography	Case managers at a level 1 trauma center	Information tools and processes	Information tools: bed management bundle, phone, EMR, whiteboard, text pager, schedule

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Gulliford 2006[83]	Continuity; Information transfer	Unpublished research	Discussion	NA	NA	Integration, coordination and sharing of information across providers is important; need to think about patient and provider perspective; continuity has a relational, management and informational component over time
Harders 2006[7]	Change; Workflow; OR	Pretest and Post-test	Analyzed current and new workflow	OR in tertiary care	Redesigned workflow	Reduction in nonoperative time; roles were redesigned; need to think about entire process with all team members
Johnson 2006[46]	Prescribing	Noncomparative study	Modeled development of electronic prescribing	ED	Implementation of an electronic prescribing model	Activity diagrams employ flowcharting techniques to model workflows, information exchange and business processes; Large range of tasks completed by non-prescribers, so they need to be considered in implementation
Joint Commission 2005[84]	Handoffs	Unpublished research	Discussion of JCAHO expectations of handoffs			Handoffs aren't just between departments, can also be within a given department; need to discuss barriers and facilitators for communication and obtain team involvement
King 2004[85]	IT; Workflow	Unpublished research	Discussion	NA	NA	Challenge to develop systems to satisfy multiple caregivers; think through information needs and activities across departments
Kinney 2007[62]	IT; Workflow	Unpublished research	Discussion	NA	NA	Need to understand workflow of current system before implementing IT or technology created new problems and unearths existing ones
Kirkley 2003[59]	Workflow	Noncomparative study	Description	Nursing	NA	IT can help streamline processes; implement IT as part of a larger effort to reorganize workflow and processes; Understanding goals; system should think like a nurse thinks

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Lamond 2000[23]	Information transfer; Shift change	Changing practice	Content analysis of medical notes, nursing documentation and shift reports	Medical and surgical units in hospitals	Looked at types and amount of information, order of information in shift report	More information was in patient notes than what was given in shift report; some information more often communicated in shift report than in patient notes; Evaluations and judgments are part of the report; Global information about how people are doing are more often found in the shift report than in other documentation
LaPenotiere 2004[61]	Workflow; Process redesign	Changing practice	Triage process design	Triage; ED	ED expansion built to fit desired processes.	Workflow changes described
Lium 2006[86]	Workflow	Cross-sectional study	Survey	Hospital	Frequency of EMR use	Nurses reported more EMR use when they changed their routine; clinicians need to figure out how to include the system in everyday work
Lykowski 2004[57]	CPOE; Workflow	Noncomparative study	Description of CPOE implementation process	Hospital		Multidisciplinary team involvement and incorporating process and technology led to good outcomes
Malhotra 2007[69]	Workflow; Modeling; ICU	Noncomparative study	Interviews and observations to document process and information flows in ICU	ICU in U.S.	Completed models at various levels	Communication, coordination, information needed; developed a model of workflows in an ICU
Manias 2001[87]	Rounds; Roles	Noncomparative study	Ethnographic study of 6 RNs; Participant observation, journals, interviews, focus groups	Critical care unit of a hospital in Australia	Description of process	Doctors use nurses to supplement information and provide extra details about patients; nurses discussed nursing knowledge during shift change

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
McKnight 2002[28]	Information transfer; Interprofessional communication	Cross-sectional study	Surveys, focus groups	Hospital	Semi-structured survey about perceptions of information needs and communication difficulties; focus groups with physician and nurses	Information needs and communications difficulties are common and can lead to errors; problems cited were difficulty in finding information, finding inaccurate or outdated information, limited time, not knowing the system; difficulty in identifying and contacting other health care providers; limited time to lookup information; nurses mentioned patient education materials; physicians talked about paging, inconsistent communication at transfer of patient care; need feedback on order status, face to face communication where mistrust or disagreement on care plans; lack of communication leads to errors or near-misses; people want to improve their own efficiency without thinking of system efficiency
Meadows 2002[88]	Workflow; Efficiency; Staffing	Unpublished research	Discussion			Think about how to be more efficient by using technology to help redesign workflow and communications
Meadows 2003[89]	Information transfer, Interprofessional communication	Unpublished research	Discussion			Use of technology to improve teamwork and communication; Don't mimic current workflows with IT but use it to transform workflow across disciplines
Mekhjian 2002[42]	CPOE; Workflow; Implementation	Case–control study	Rapid system evaluation; time and motion study; comparison of data between areas with differential implementation of systems	Inpatient units; academic medical center;	Implemented CPOE on some units	Process breakdowns such as patient safety issues, workflow interruptions and inefficiencies; Technology may not necessarily improve institutional efficiency; incorporate safeguards for errors and interruptions; cultural change needs to be considered

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Patterson 2004[35]	Handoffs	Unpublished research	Discussion	Various industries	NA	Can learn lessons about handoffs from other industries (NASA, power plants, railroad and ambulance dispatch centers); many strategies are informal, as in health care
Pape 2003[90]	Workflow; Evidence based practice; Information transfer	Noncomparative study	Reviewed nursing practices	Nursing unit	Description of practices and implementation of evidence-based practices	IT can change in how people make decisions; discussion of how to incorporate evidence based practice and counter "cookbook medicine" arguments; how to find practices, and identify them, and implement
Patterson 2005[26]	Interprofessional communication; Information transfer	Noncomparative study	Observed handoffs; Interviews across different industries	Various industries	Description of handoff practices	Found 21 strategies for effective handoffs; provide supporting documentation in addition to the handoff; Systems highlighted can potentially be used to facilitate these strategies
Payne 1999[45]	CPOE; Implementation; Interprofessional communication	Noncomparative study	Description of first three months post implementation	Hospital	CPOE implementation	Implementing CPOE changed work patterns, communication, roles
Perrott 2004[24]	Workflow; Medication	Noncomparative study	Ethnography, Document review, Interviews	ICU nurses	Nursing handovers in an ICU	Customization of data sets; nursing education; nurse involvement in installation (from vendor and organization) were all success factors
Philpin 2006[15]	Information transfer; ICU; Interprofessional communication	Unpublished research	Discussion of nursing role	NA	NA	Nurses work with a number of other occupation groups; constant flow of other people moving in and out; discovered separate charts for observations and recording of nursing work; different providers have different documentation requirements, which may differ from organizational requirements

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Piasecki 2005[48]	CPOE	Changing practice	Review workflow to determine time and FTE savings before and after CPOE implementation	Emergency Department	CPOE implementation	Worked with business school to develop a ROI tool to measure outcomes of technology implementation; analyzed workflow before and after implementation and found savings in time and money
Plsek 1999[36]	Change; Workflow	Unpublished research	Focus groups	Clinical and support staff of a multispeciality clinic	NA	Use a high-level flow chart to show a typical visit, but need to consider different perspectives; need to mentally escape from traditional rules of workflow; can use technology to help with workflow and change how things are done
Powell 2006[17]	Information transfer; Handoffs; Interprofessional communication	Unpublished research	Discussion about improving handoffs			Problems identified: accountability of transition, transfer of information, responsibility when communicating to receiving provider - need to set expectations with sending and receiving groups; use advanced practice nurses as coordinators across sites
Price 2000[91]	Workflow; Safety	Literature review	Discussion	NA	NA	Problem based learning is done in the classroom, but should be done on the floor as part of workflow; need to think about issues of patient safety and competing demands on time

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Reddy 2002[30]	Information needs; Information transfer	Noncomparative study	Ethnography to understand information needs of physicians, nurses, students, pharmacists etc	SICU	Observed rounds; looked to see who asked questions, the kind of questions asked, resource used to answer question	Nurses and pharmacists served as information sources rather than information seekers; human sources were used more than electronic or paper sources as the first source of information; orders but not rationale is documented; need to understand clinical workflows and organizational workflows (keeping the place running); build systems to support work activities
Riley 2006[31]	Interprofessional communication; Information transfer	Noncomparative study	Observational fieldwork; Individual and group interviews using 11 nurse informants; Journaling	OR nurses	Evaluated how they dealt with each other and physicians with respect to time and identified practices	Practices found: questioning judgment and timing, controlling speed, estimating surgeons' use of time, coping with different perceptions of time; knowledge of individual surgeons was a source of power for nurses
Sandberg 2005[5]	Process redesign; OR	Cross-sectional study	Analyzed current workflow; changed and evaluated new workflow	OR Staff	Redesigned OR	Changed the process to include parallel activities and reorganized the space; improved throughput in the redesigned OR
Sandberg 2006[92]	Change; Workflow, OR	Pretest and Post-test	Looked at recovery room flow sheets, time, and nursing effort required	Ambulatory laparascopic chole-cystectomy patients	Implementation of a pathway	PACU nurses indicated that their workload increased, but the data did not support that conclusion; data looked at interventions such as pain meds and iv fluids - but is not necessarily an accurate capture of nursing workload
Scharnhorst 2003[39]	Implementation; Workflow	Noncomparative study	Workflow analysis and usability testing	Nursing staff	Implementation of handhelds	Collecting nursing data can help to define and articulate the role of nurses in health care; handhelds can help with reduction of redundancies

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Shefter 2006[93]	Workflow; Implementation	Unpublished research	Discussion	Case management	Introduction of workflow tools	Workflow technology tools can help or hinder case management; integrate patient level and organizational level data to help with workflow; information tools (databases, records) and workflow tools can help with linkages; need to consider not just training but ongoing support
Sittig 2006[38]	CPOE; Medication; Implementation	Noncomparative study	Discussion of CPOE implementation	NA	NA	Need to consider related organizational and workflow factors (not just technology); CPOE and IT efforts can alter workflow processes; we could share experiences in an M&M format; use opportunity to develop better systems
Spear 2005[20]	Change; Workflow	Noncomparative study	Multiple case studies to demonstrate best practices	Hospitals	NA	Hospital care is organized around functions, but there is not a reliable way to integrate these functions; can achieve excellence by having an environment where work is designed to reveal problems soon, are addressed quickly, solutions are quickly disseminated and people are taught to experiment at all levels of the organization; nurses spend a lot of time tracking down materials, services and information versus providing care
Stahl 2006[94]	Change; Workflow, OR	Noncomparative study	Redesigned systems before making a new OR	OR Suite	Redesigned processes emphasizing parallel processing; added staff	Increased patient throughput; added an additional nurse; considered multiple disciplines and roles
Strople 2006[27]	Information transfer	Noncomparative study	Reviewed shift report content, format and media	Nursing staff at hospitals	Analyzed content	Use of electronic systems as an adjunct to the shift report can contribute to patient care

Source	Issue Related to Practice	Design Type	Study Design and Outcome Measures	Study Setting and Population	Study Intervention	Key Findings
Van Eaton 2004[34]	Information transfer	Changing practice	Evaluation, analysis and prioritization of existing system content; Planned for a new system using a model, focus groups, modifying and implementing system	Resident run inpatient and consult services at two teaching hospitals (31 residents)	Developed and implemented system	Most residents used paper patient list to manage work so they had to recopy it; combined data from hospital information systems with resident entered details; popular and widely used; combined data needed for processes such as rounding and sign-out at the end of the day
Waring 2006[9]	Workflow; OR; Information transfer; Interprofessional communications	Noncomparative study	Ethnography, Interviews	OR in the UK; Teaching hospital	Analyzed routines and patterns of work; did some interviews; looked at different roles	Nursing staff often spent time coordinating supplies, missing items, figuring out where the patient goes next; each department seemed to be its own hub with spokes going out to other departments; each department is dependent on the work of others, yet they don't each necessarily understand the big picture; inter-departmental breakdowns; delays with schedule between surgery and floors; nurses often did transfer work themselves, which led to more delays; nurses "pitch in" and do work that other roles do not
Wright 2006[95]	CPOE	Noncomparative study	Reviewed processes and communications	Hospitals	CPOE implementation	CPOE impacts MD-nurse communications; found in implementation that significant workflow changes would be required; loss of visual cues or physical presence to give contextual information about orders; paper reports are not accurate; people know about order processes in their own departments but not how it works elsewhere or downstream impacts

* IT = information technology; EHR = electronic health record; EMR = electronic medical record; OR = operating room; ED = emergency department; CPOE = computerized provider order entry; ICU = intensive care unit; RN = registered nurse; MD = physician; HIMSS = Health Information and Management Systems Society.

Chapter 32. Professional Communication

Jean Ann Seago

Background

Instructing nurses on communication is a bit like instructing birds on flying. All nurses have been taught communication skills as a basic part of a prelicensure nursing program and then retaught communication skills in postlicensure programs, continuing education programs, workshops, and meetings. Some nurses would be insulted that anyone would even raise the issue of communication since raising the issue implies that they are deficient in one of the most basic aspects of nursing care. However, the problem with good communication is that it is, ironically, easy to talk about but hard to put into practice. In the literature, there are numerous articles that provide opinion, both expert and otherwise, about communication,[1–7] but there is very little evidence about communication practices that have demonstrated an impact upon patient outcomes. The purposes of this chapter are to discuss evidence of professional communication practices or strategies that have been tested empirically and have a relationship with patient outcomes or patient safety, and to provide communication tools that might help practicing nurses maintain and improve patient outcomes and patient safety.

This chapter will focus on communication strategies in hospitals and those related to communication between nurses and physicians. Studies related to communication between physicians and patients or nurses and patients were included if they were determined to be sufficiently methodologically rigorous and had a direct relationship with patient outcomes or patient safety. There is a large body of research on communication in other health care settings and among other professionals, which was not included in this chapter.

Historical Context

The history of communication between doctors and nurses is well documented. A series of publications begun in 1967 describing the “doctor-nurse game” provides insight into the way nurses have historically made treatment recommendations to doctors without appearing to do so, the way doctors have historically asked nurses for recommendations without appearing to do so, and how both participants strive to avoid open disagreement.[8–27] Although some nurses have argued that much has changed—and improved—in the relationships between doctors and nurses since that initial 1967 article, there is little evidence, although much wishful thinking, to support that view.[28–31] Additionally, over the years, the literature has contained descriptions of verbal abuse of nurses by physicians,[32–35] disruptive physician behavior,[36, 37] and advice on how nurses can better “handle” physicians.[38–41] So, in spite of much discussion, communication between doctors and nurses often remains contentious and obscure.

Theoretical Foundations

Many professional groups study communication among humans, and a wide range of theories guides the work. For the purpose of this review, a sample of theories used to describe or study

nurse-physician communication will be presented in brief. Habermas' critical theory has been used to identify successful nurse-physician collaborative strategies, including a willingness to move beyond basic information exchange and to challenge distortions and assumptions in the relationships.[42] Theories of Foucault and other poststructuralists that have guided concept analysis of collaboration and explored the notion that the relationship between power and knowledge (knowledge and power are not fixed, meaning not stable, and the idea that there is a hidden or "real" discourse) help explain the relationships between nurses and doctors.[43, 44] Various perspectives from the field of organizational behavior, including the structural (behavior is rational) perspective, the human resource (human needs and motivation) perspective, the political (competition for resources) perspective, and the cultural (organizational culture and climate) perspective, have been used to guide activities to improve nurse-physician communication.[45]

Feminists and scientists have used oppressed-group behavior theory to explain much of nurses' work and its structure in hospitals, including nurse-physician relationships.[34, 46–54] Many scientists and writers have evoked the issue of gender as it relates to the work of nurses and the relationship between nurses and doctors. Early literature related to gender tends to emphasize nurse image, and later work focuses more on nurse job satisfaction; job retention; and differences in decisionmaking, attitudes, perceptions, and ethical or moral dilemmas.[55–73] Mark and colleagues argue for theory development related to nurse staffing and patient outcomes, maintaining that one of the important and unexplored areas is the "why" of the nurse-physician relationships and the hypothesis that "enhanced" nurse-physician communication would "result in early recognition and intervention of potentially hazardous patient situations"[74] (p. 13).

With the recent emphasis on patient safety, hospital error, and adverse events, some hospital executives have embraced human factors science and training ideas taken from the aviation industry (Crew Resource Management)[75] to try to address the issue of patient safety and the lack of collaboration or teamwork in hospital settings. One of the most intriguing recent ideas is the use of the leader-member exchange theory[76–88] to describe the interactions between nurses and doctors in hospitals. Hughes and colleagues[89, 90] used leader-member exchange theory to create a nurse-physician exchange relationship scale and discussed the relationship between nurses and doctors in terms of a supervisor-employee relationship. The physician can be thought of as being the leader or supervisor of patient care, and the nurse can be thought of as being one of the members or employees providing care. This conceptualization will undoubtedly be challenged by nurses and nurse leaders who advocate for nurse autonomy or nurse independence, but Hughes and colleagues make a compelling argument for viewing the hospital nurse-physician relationship through this theoretical lens. There exists a long and varied history between nurses and doctors, making it difficult to use only one theory to explain all the subtleties of the relationships or to hold the key to improving those relationships.

Significance—Why Do We Care About Nurse-Physician Communication?

Over the years, there have been repeated cries and admonitions for improving nurse-physician communication and questioning why it is so difficult to achieve.[1, 63, 91, 92] Some research has shown that the lack of interpersonal and communication skills of physicians and nurses is associated with errors, inefficiencies in the delivery of care, and frustration.[93] There is evidence, though conflicting, that links better collaboration with better patient outcomes,

specifically reduced medication errors,[45, 94] reduced risk of inpatient mortality,[95–98] improved patient satisfaction,[99] and some support for efficiency measures such as shorter hospital length of stay.[100–103] However, several major reviews and studies found no relationship between nurse-physician collaboration and patient outcomes such as mortality or self-reported health status.[100, 102, 103] Physician satisfaction is generally not related to perceived increased collaboration; most frequently the evidence links perceived increased collaboration with nurse satisfaction.[4, 36, 104, 105] Additionally, nurses and physicians view the level of collaboration very differently, with nurses typically perceiving less collaboration and poorer communication than physicians.[70, 106–108] So, even though the descriptive evidence for improved patient outcomes and improved hospital efficiency is conflicting, it does not clearly negate the premise that better communication and collaboration could have an impact on patient outcomes.

In the nursing literature, nurse-physician communication is discussed or studied using terms such as empowerment, autonomy, collaboration, coordination, teamwork, transitioning, organizational culture, climate, and relationships. Assessment of the descriptive studies listed in the evidence table and references from other studies provide results, information, and opinion about nurse-physician communication, but they are not interventional studies. Some of the more compelling descriptive studies are included in the evidence table but do not meet the rigor required of randomized controlled trials. The setting of much of the descriptive or interventional work is intensive care units, emergency departments, or operating rooms and is often focused on nurse change-of-shift report;[109–112] physician/resident handoff/sign-off;[113–115] nurse-physician interaction, both routine and emergent;[91, 116–118] foreign language use by physicians and nurses;[119–124] and communication with patients.[125–131]

One of the recurring themes in the literature is the difference in perceptions between nurse and physician.[36, 69, 70, 106–108, 132–134] Nurses are typically less satisfied than physicians with the communication or interaction patterns and express the need for their opinions to be heard by physicians.[133] Areas of particular difference involve those of ethical decisionmaking and the moral dilemmas confronted by nurses related to these decisions.[135–137] There is also a body of literature on the differences between patient and provider (both nurses and physicians) in perceptions of care, quality, or comfort.[138–143] Although these papers provide important descriptions and information about nurse, physician, and patient communication, they are only briefly mentioned to provide context for this chapter. The focus of the chapter is on communication between physicians and nurses and whether there is a relationship with patient safety or other patient outcomes.

Research Evidence

There is no shortage of manuscripts in the literature that advocate, based only on opinion, for one or another method of building teamwork, collaboration, or communication, including recognizing corporate culture,[144] quality improvement,[145] continuous assessment and regular communication,[146] and reducing conflict.[147] Other publications detail the experience of one institution or unit in improving communication or teamwork using strategies such as the Comprehensive Unit-Based Safety Program developed at Hopkins,[148] Surgical Morning Meetings[149] using daily goals in an intensive care unit,[150] or interdisciplinary rounds.[151] These individual experience descriptions typically report varying outcomes or lack measured outcomes.

Evidence for Interventions That Improve Positive Communication—What Works?

This review found no randomized controlled trials (RCTs) that investigated communication interventions between nurses and physicians that had a patient outcome as a measure of interest. The RCTs included in the evidence table tested whether various communication training sessions for physicians improved communication with patients.[152–157] The evidence indicates that communication training is effective in improving physician attitudes, beliefs, and communication ability. There is also evidence that an intervention called peer leader education[155] can result in fewer symptom days, lower oral steroid rates, and reduced cost for children with asthma. In general, longer training programs (2–3 days) had greater positive effects, and the effects were longer lasting. Two RCTs tested the effect of training patients about care using information or technology and found slight improvement in patient perceptions of care.[158, 159]

Four systematic literature reviews were found that evaluated aspects of communication. One review of 14 studies measured the effect of communication training on physicians, using self-rating of the training effects, but provided no evidence of a relationship between the training and patient compliance or health status, and ambiguous effects on patient psychosocial health.[160] The second review of 26 studies concluded that various interventions had no effect on patient expectations, had conflicting lung-function outcomes, improved systolic blood pressure with any interaction, and decreased pain with improved patient-practitioner interaction.[161] The third review of 89 studies found no patient outcome changes (health status, disease incidence, cure rates, mortality rates, complication rates) with implementation of interprofessional education versus single-discipline education.[162] The fourth review, covering two studies, concluded that after communication training, team development meetings, or weekly rounds, there was no difference in patient mortality rates; but staff satisfaction increased, and there were conflicting results on length of stay.[100]

The literature search provided three nonrandomized controlled trials (NRCTs) with control groups related to interventions aimed at improving effective communication.[163–165] One study described a communication training intervention, a second added personnel (nurse practitioners and hospitalists) and multidisciplinary rounds to the environment, and the third used weekly meetings to discuss role relationships. The first study improved hospital employee work satisfaction and perception of opportunities and decreased information overload.[163] The second study improved physician perception of collaboration between nurses and doctors, but produced no change in nurse perception of collaboration.[164] The third study decreased consumers' belief in shared responsibility for care versus a physician-dominated responsibility for care, and increased consumers' belief that powerful individuals influence a consumer's health status.[165]

Included in the evidence tables are seven quality improvement projects without a control or comparison group. These projects are included as examples of the numerous studies in the literature that essentially describe the experience of one or two institutions in implementing an organizational change to improve doctor-nurse collaboration or communication. Dechairo-Marino and colleagues[166] report on a teamwork training program that produced no differences in self-reported collaboration or satisfaction; McFerran and colleagues[167] describe implementation of a structured communication technique known as Situation-Background-Assessment-Recommendation (SBAR), changing policies, debriefing, and multidisciplinary reports in four Kaiser Permanente sites. No long-term measures are reported, and only the short-term expectations for the "communication initiative" were met. Leonard and colleagues[168] report on

another Kaiser study of various groups in the organization trained in SBAR, assertion checklists, and briefings. Reported outcomes associated with the intervention include reduced wrong-site surgery, decreased nurse turnover, and improved employee satisfaction; however, no specifics on the measurement of these outcomes are provided. Lassen and colleagues[169] describe development and education of a collaborative practice (primarily physician specialists) decisionmaking protocol that was associated with a decrease in rule out sepsis diagnosis, use of antibiotics, patient days, costs, and readmissions in one neonatal intensive care unit (NICU).

Dutton and colleagues[170] reported that daily discharge multidisciplinary rounds were related to decreased length of stay in the emergency department and emergency department closures in one trauma center. Copnell and colleagues[134] reported no difference in perception of doctor-nurse collaboration after introduction of a nurse practitioner in two NICUs. Boyle[4] reported an increase in perceived doctor-nurse communication skills, nurse leadership skills, and problem-solving, and a decrease in nurse stress after a six-module training session called Collaborative Communication Intervention. The designs of these quality projects were too weak to allow any sort of conclusions to be drawn.

Practice Implications

There is insufficient empirical evidence to recommend any specific communication strategy or technology device to improve doctor-nurse communication. However, there is mixed or weak evidence to support using some of the techniques described in the cited literature. It is likely that focusing an organization on any strategy and persisting in that focus will be associated with, at least temporarily, a change in doctor-nurse communication patterns (e.g., Hawthorne effect). Given the paucity of available evidence, the following suggestions are offered for possible consideration in efforts to improve professional communication:

- Carefully evaluate various strategies for doctor-nurse communication using measurable outcomes that are important to your organization; plan to use a strategy that meets the needs and culture of your organization.
- Select a strategy, focus training, and provide organizational support and sufficient resources toward improving doctor-nurse communication.
- Slowly implement the change using sufficient resources and sufficient time.
- Do not implement multiple changes simultaneously.
- Persist in that strategy for an extended period of time (years, not weeks or months).
- Critically and rigorously evaluate the strategy using patient outcomes and worker satisfaction.
- After allowing sufficient thought and time for implementation and evaluation, be willing to publicly eliminate the strategy if it does not improve the outcomes.

Hospitals have used many communication tools such as written and verbal orders, reports, rounds, and team meetings. As the United States shifted to the "business model" for hospitals, organizations have tried to change culture or climate, create transformational leaders and knowledge workers, implement continuous quality improvement or total quality management, form quality circles, and train the one-minute manager. Some hospitals have used and are currently using technology ranging from pencil and paper, medication rooms and carts, orange vests for the medication nurse so she will have fewer interruptions, Pyxis or other automatic medication dispensers, landline telephones, fax machines, beepers, e-mail, personal digital

assistants (PDAs), cellular telephones, wireless devices, direct information transfer, and Web access.

Other recent technology includes mobile communication systems such as Vocera, electronic medical records, computerized physician order entry, and bar-coding for medication administration. A number of organizations are also trying SBAR, organizational support structures such as Rapid Response Teams or techniques such as customer relationship management from business or crew resource management from aviation. Other organizations are trying systems such as Situation-Trajectory-Intent-Concern-Calibrate (STICC) using the Hands-on Automated Nursing Data System Method from the University of Illinois at Chicago and funded by AHRQ, or Gerontology Interdisciplinary Team Training from the Hartford Foundation and the American Geriatrics Society. Few, if any, of these methods or devices have been empirically tested. Without careful consideration and evaluation, efforts to improve communication problems that exist in present-day hospitals may lead to implementation of strategies that will be ineffective.

Research Implications

Based on the literature review, future research is needed to assess the following:

- What should be the communication competencies of physicians and nurses; and should these competencies be assessed periodically?
- How can health information technologies be used to ensure effective communication between physicians and nurses, across settings and among the various care delivery models?
- What is the impact of effective communication strategies on hospitalized patient outcomes and medical errors?
- What is the impact of effective communication strategies on nurse and physician job satisfaction, and how does provider satisfaction relate to patient outcomes?
- How can communication skills training for practicing physicians and nurses have a career-long impact on their communication skills?

Conclusion

Within health care, there have been and will continue to be many approaches to professional communication. Unfortunately, the body of evidence is very limited, and the research findings to support professional communication and the relationship with patient safety and quality are not available at this time. There were limited studies that tested specific interventions aimed at changing nurse-physician communication, and there is some evidence that focusing on a doctor-nurse communication may have a positive effect. Health care organizations and providers will be challenged as they seek to improve the effectiveness of professional communication, given all the subtleties of the nurse-physician relationships.

Search Strategy

Search strategies employed included the use of the electronic databases PubMed®, CINAHL®, the Cochrane Collection, and relevant AHRQ reports. Keywords included physician, nurse, relationships, communication, coordination, collaboration, autonomy, teamwork, MD,

RN, patient, outcome, safety, and adverse event. Reference lists of select publications were investigated for potential manuscripts, and literature related to relevant measurement instruments was sought.

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Evidence Table

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Randomized Controlled Trials						
Ellison 2004[159]	Patients	Design Type 2 (RCT) (Level 2) questionnaire	Patient satisfaction (Level 3)	1 hospital 85 patients	Standard care plus1 day telerounding; standard care substituting 1 day with robotic telerounding	Improvement in telerounding patients of examination thoroughness, quality of discussion, postoperative care coordination, availability of MD; in robotic telerounding improvement in availability of MD.
Fallowfield 2003[153]	MD/patient	Design Type2 (RCT)— pre/postvideotape (Level 2)	At 12 months, same as 3 months (Level 3)	Oncology MDs, UK	3 day residential communication skills training course	Same effect with use of leading questions, open-ended questions, and response to patient cues; improvement in fewer interruptions, increased summarizing; decline in expressions of empathy.
Jenkins 2002[152]	MD/pt	Design Type 2 (RCT)—P-P videotape (Level 2)	At 3 months attitudes, empathy, responses (Level 3)	Oncology MDs, UK	3 day residential communication skills training course	Improved attitudes and beliefs toward psychosocial issues compared to controls; increased expressions of empathy; open questions; appropriate responses to patient cues and psychosocial probing; self-reported changes in communication styles.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Joos 1996[157]	MD/pt	Design Type 2 (RCT)—P-P questionnaire (Level 2)	Communication skills (Level 3), and compliance and utilization (Level 2)	42 MDs and 348 patients with chronic conditions	4.5 hours of training	Increased number of times MDs elicited patient and RN concerns, increased patient perception of amount of information received, no change in patient compliance with medications or appointments; no change in patient utilization.
Levinson 1993[156]	MD/pt	Design Type2 (RCT)—P-P audiotape (Level 2)	Communication skills (Level 3)	53 community-based MDs and 473 patients	A short CME program (4.5 hours) and a long CME program (2.5 days)	Short program: no effect. Long program: more open-ended questions, asked patient opinions, gave more biomedical information, patients disclosed more information, decrease in negative affect for both, patients had fewer signs of outward distress during visit.
Lozano 2004[154]	MD/children (3–17) with asthma	Design Type2 (RCT)—cluster P-P interview and questionnaire (Level 2)	Asthma symptom days, asthma-specific functional status, frequency of oral steroid courses (Level 1)	42 primary care practices in 3 locations	Peer leader education (PLE) and peer leader + nurse-mediated organizational change (PACI)	Peer leader: fewer symptom days per year & lower oral steroid rates. Peer leader + nurse: fewer symptom days per year & greater adherence to treatment by parent report.
Sullivan 2005[155]	MD/children (3–17) with asthma	Design Type 2 (RCT)—cluster P-P interview and questionnaire (Level 2)	Symptom-free days (SFDs); asthma-related health care costs (Level 1)	42 primary care practices in 3 locations	Peer leader education (PLE) and peer leader + nurse-mediated organizational change (PACI)	SFD: 6.5 with PLE vs. usual, 13.5 with PACI vs. usual; compared with usual incremental cost effectiveness ratio was $18/SFD gained for PLE and $68/SFD gained for PACI.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Tran 2002[158]	ED patients	Design Type 2 (RCT) (Level 2) questionnaire	Patient length of stay (LOS), wait time, perception of LOS, ratings of nurse skills and MD skills (Levels 3 & 4)	1 hospital ED 619 patients	Providing patients with information q 15 minutes during stay	No difference in LOS, wait time, nurse skills. Decrease in perceived LOS and wait time and increase in perception of MD skills.
Nonrandomized Controlled Trials and Quality Improvement (QI) Projects						
Boyle 2004[4]	MDs/RNs	Design Type 6 P-P 2 units no control (Level 5)	Communication skills, increased staff satisfaction, lower stress, increased problem-solving using videotape vignettes, questionnaire	1 ICU from 2 hospitals	Collaborative Communication Intervention over 8 months: 23.5 hours for 6 modules	Increased perceived RN and MD communication skills, improved nurse leadership and problem-solving, decreased staff nurse personal stress.
Copnell 2004[134]	MDs/RNs	Design Type 6 P-P 2 units no control (Level 5)	Perception of collaboration	2 NICUs	Added NP	No difference before and after NP; MDs and RNs disagreed about collaboration with MDs scoring higher.
Dechairo-Marino 2001[166]	RNs	Design Type 6 action research—P-P 1 group-no control (Level 5)	RN reports of collaboration with MDs and RN Satisfaction with decisionmaking process- (Level 3)	1 university teaching hospital; RNs in 3 med-surg units and 2 ICUs	Activities to promote interdisciplinary teamwork between MDs/RNs, including developing principles, discussion in meetings, 1 4-hour class on decisionmaking	No differences
Dutton 2002[170]	MDs, nurses, patients discharge planners	Design Type 8-no control group (Level 5)	Patient volume, LOS, ED closure (Level 3, 4)	1 hospital trauma service	Daily discharge multidisciplinary rounds	Increase in patient volume, decrease in LOS, decrease in ED closure.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lassen 1997[169]	Well-newborn nurses, pediatricians, neonatologists	Design Type 13-QI project with a control time (Level 5)	# of admissions with R/O sepsis, LOS, # of doses of antibiotics, costs, # of readmissions, reduction in practice variation (Levels 1, 2, 3)	1 tertiary hospital	Collaborative practice decisionmaking protocol development; education	Decrease in # of R/O sepsis diagnosis, decease in % of patients treated with antibiotics, decrease in patient days, decrease in costs, decrease in readmissions.
Leonard 2004[168]	Various groups in Kaiser Permanente	Design Type 14-QI project-no control (Level 5)	Improve communication and teamwork by standardized communication (Level 3)	different groups of MDs and RNs	Introduce standardized communication methods such as SBAR, assertion, checklists, critical event training, and briefings	Standardized briefings related to reduced wrong-site surgery, decreased nurse turnover, improved employee satisfaction, improved teamwork climate, communication, and taking responsibility for errors—but few specifics provided.
McFerran 2005[167]	Perinatal RNs, certified registered nurse anesthesists and MDs	Design Type 13 QI project-no control (Level 5)	Long-term measures: birth event data, medical-legal data, patient satisfaction data (Levels 1 & 2); short-term measures: implementation of 2-3 interventions using human factors technique during 1 year (Level 3)	4 Kaiser Permanente medical centers perinatal staff	4-hour human factors education program, SBAR communication technique, revising escalation policy, identifying safe communications, debriefs after adverse events, multidisciplinary reports, assertion, just culture statement (Level 3)	No long-term measures reported; 4 sites met short-term expectations for only communication initiatives.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Roberts 1976[163]	Hospital employees (non-MD and nonsupervisors)	Design Type 3—NRCT-P-P 2 groups with 1 being control (Level 3)	Employee perception of organizational communication, job satisfaction, and opportunities for innovative job behavior (Level 3)	1 urban hospital; ED staff members	2.5-3 hour training sessions weekly for 4 consecutive weeks	Increase satisfaction with work, pay, coworkers, job; increase perception of opportunities for innovation; increase desire for interaction with peers; and decrease in information overload.
Weiss 1985[165]	MD/RN/consumer	Design Type 3—NRCT with 3 groups, with 2 being matched control groups (Level 3)	Belief regarding value of shared versus physician-dominated responsibility for health care and beliefs that powerful individuals influence consumer health status (Level 4)	Recruited in large urban area	Discussion of role relationships, and problems for 2.5 hours 1 evening/month for 20 months	Decline in belief in shared versus physician-dominated responsibility for health care and increase in belief that powerful individuals influence the consumer's health status.
Vazirani 2005[164]	Unit organization; RN, MD, residents, hospitalist, NP	Design Type 3—NCRT 2 groups with 1 being control (Level 3)	Collaboration, communication (Level 3)	1 hospital; 1 control unit and 1 intervention unit	Added NP, hospitalist, daily multidisciplinary rounds	Perception by MDs of greater collaboration between physicians and nurses with largest effect with residents, between physicians and NPs, better communication between MDs; no difference in nurse perception of communication or collaboration between nurses and MDs, nurses perceived better communication with NPs than MDs.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Systematic Literature Reviews						
Di Blasi 1996 (Cochrane Collaboration-Centre for Reviews and Dissemination)[161]	Patients with various health problems	Design Type 11 structured review (Level 1) RCTs with and without placebo	Health outcome, symptom resolution, functional status (Level 1); health service use, medication adherence, anxiety, satisfaction (Level 3)	26 studies with 3,811 participants: poor quality studies with small sample sizes	Various treatments or disease management, including labeling, changing patient expectations, combining treatment information with emotional support	Labeling: no effect; changing patient expectations: conflicting results—improved lung function with suggestion of drug effects but improved systolic blood pressure following any interaction; combined information with support: improved outcomes, mixed result—6 studies found decrease in pain with improved patient-practitioner interaction, style of interaction can influence physical health but with small effects.
Hulsman 1999 (Cochrane Collaboration-Centre for Reviews and Dissemination)[160]	Graduate or postgraduate MDs	Design Type 11 structured review (Level 1); evaluation studies RCT and NRCT P-P video, discussion, role play, audio, written, self-rating	Receptive behaviors, information behavior, interpersonal and affective behavior, psychosocial problems and emotions (Level 3); compliance, health status, psychosocial status (Level 2)	14 studies, 408 participants, 135 controls	Training, education using lecture, modeling, discussion, role play—4-96 hours over 2 days to 6 months	10 studies report some training effect with best designed reporting fewest effects; improved self-rating of communication and recognition of psychosocial patient problems, no conclusive patient compliance effect, no effect on health status, ambiguous effect of psychosocial health. The other 4 studies report no effects.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Zwarenstein 2000 (The Cochrane Collaboration)[100]	Chiropodists/podiatrists, dentists, dietitians, MDs, hygienists, psychologists, nurses, pharmacists, occupational therapists, and others	Design Type 11 structured review (Level 1); RCT, controlled before and after, and interrupted time series	Self-reported health status, disease incidence, cure rates, mortality, complication rates (Level 1); adherence, satisfaction, continuity of care, costs (Level 3)	89 studies; none met the inclusion criteria	Interprofessional education (IPE) versus single-discipline education	No conclusive evidence of the effectiveness of IPE in relation to professional practice or health outcomes.
Zwarenstein 2000 (The Cochrane Collaboration)[100]	MDs/RNs	Design Type 11 structured review (Level 1); RCT, controlled before and after, and interrupted time series	MD/RN collaboration/joint decisionmaking (Level 3), costs(Level 4); LOS, mortality (Level 1)	2 studies with 1,102 admissions in one and 417 admissions in the other	Training, workshops, ward reorganization, team development, meetings, patient-centered care, 4 times weekly rounds, weekly case conference	1st study: shorter LOS, reduced costs, no difference in mortality rate, increased staff satisfaction. 2nd study: no difference in LOS and no difference in mortality rates.
Descriptive						
Aiken 1994[171]	MDs/RNs	Design Type 4 cross-sectional (Level 5)	Medicare mortality rates (Level 1)	39 Magnet hospitals, 139 controls	None	Magnet hospitals (higher autonomy, control, MD relationships, RN hours, skill mix) had lower Medicare mortality rates.
Aiken 1999[99]	MDs/RNs	Design Type 4 cross-sectional (Level 5)	30-day mortality, patient satisfaction, nurse-patient ratios, control by bedside nurses; specialty physicians (Levels 1, 3)	40 units in 20 hospitals; 1,205 patients and 820 nurses	None	Better nurse-patient ratios, lower mortality; higher nurse control, higher patient satisfaction.
Alt-White 1983[105]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Nurse-physician collaboration (Level 3)	46 units, 446 nurses	None	Primary nurse, critical care units, unit communication, coordination, nurse satisfaction associated with better collaboration.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Baggs 1997[107]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Nurse/physician collaboration and satisfaction with decisionmaking, nurse retention (Level 3)	3 ICUs in 3 hospital	None	Collaboration was associated with satisfaction for all but more strongly for nurses; nurse satisfaction with decisionmaking was not associated with retention.
Baggs 1999[95]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Mortality, ICU readmission (Level 1)	3 ICUs in 3 hospitals	None	In the medical ICU, there was an association between nurse perception of collaboration and lower risk of patient death or ICU readmission; MD reports of collaboration were not associated with patient outcomes.
Estabrooks 2005[98]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5	30-day mortality	49 hospitals	None	Greater nurse-physician relationships, more temporary positions, higher nurse education level, and richer skill mix associated with better 30-day mortality.
Kaissi 2003[106]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Nurse-physician interpersonal interaction/teamwork (Level 3)	2 hospitals	None	78% of nurses rated experience with MDs as very low/low or adequate.
King 1994[108]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Nurse-physician collaboration (Level 3)	90 nurses, 40 physicians, 4 hospitals, and 2 hospital ships	None	MDs & RNs disagreed with MDs perceiving higher collaboration than RNs.
Knaus 1986[97]	MDs/RNs	Design Type 4, 8 cross-sectional with no comparison group (Level 5)	Actual and predicted mortality, coordination of care (Levels 1, 3)	13 hospitals	None	Hospitals with less actual mortality than predicted had better coordination of care and communication between RNs/MDs and among MDs.

Source	Communication Targets	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rosenstein 2002[36]	RNs/MDs/executives	Design Type 4, 8 cross-sectional with no comparison group (Level 5)	Nurse-physician relationship (Level 3)	Network of hospitals; 1,200 responses from RNs, MDs, executives	None	MDs and RNs were significantly different; more RNs have witnessed disruptive MD behavior, more RNs say the disruptive behavior is important in nurse morale; nurses perceive less support for conflict; nurses perceive MDs as unaware of relationship.
Zimmerman 1993[103]	MDs/RNs	Design Type 4, 8 cross-sectional with no comparison group (Level 5)	Strong medical and nursing leadership, collaboration, coordination, communication, mortality, LOS (Levels 1, 3)	9 ICUs in 9 hospitals; 316 RNs and 202 MDs	None	No difference in risk-adjusted mortality or LOS between high-performing and low-performing ICUs.
Shortell 1994[101]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	LOS, nurse turnover, technical quality of care, meeting family needs (Levels 3, 4)	42 ICUs	None	Higher scores on leadership, coordination, communication, conflict management, associated with shorter LOS, higher technical quality of care, greater ability to meet family needs.
Thomas 2003[70]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	Collaboration, communication (Level 3)	8 ICUs in 2 hospitals; 90 MDs, 230 RNs	None	Most MDs rated collaboration and communication as high or very high; most RNs rated it as low or very low.
Zimmerman 1991[102]	MDs/RNs	Design Type 4, 8 cross-sectional no comparison group (Level 5)	ICU LOS, predicted hospital mortality (Levels 1, 3)	40 hospitals	None	Lower mortality associated with better technological adequacy and work environment; shorter LOS associated with better communication, culture, coordination, conflict management.

Appendix

Measurement Instruments

Source	Measurement Instrument	Concepts	Number of Items & Response Style
Shortell 1991[172]	ICU Nurse-Physician Questionnaire; 48 items selected from the Organizational Culture Inventory (OCI)	Organizational culture, leadership, communication, coordination, problem-solving	48 items; 1–5 point Likert scale
Roberts 1974[173]	Organizational Communication	Communication	35 items; 7–10 point Likert scale
Choi 2004[174]	Perceived Nursing Work Environment (PNWE)	Nursing management, nursing process, RN/MD collaboration, nursing competence, scheduling climate	42 items; 4 point Likert scale
Weiss 1985[175]	Collaborative Practice Scales	RN/MD interaction and influence on patient care	9 items RN & 10 items MD; 6 point Likert scale
Aiken 2000[176]	Nursing Work Index-Revised (NWI-R)	Autonomy, RN/MD relationships, control of practice	57 items; 4 point Likert scale
Temkin-Greener 2004[177]	PACE team performance questionnaire	Interdisciplinary team performance	59 items; 5 point Likert scale
Baggs 1994[178]	Collaboration and Satisfaction About Care Decisions (CSACD)	RN/MD collaboration	14 items; 7 point Likert scale
Dougherty 2005[179]	A review of instruments measuring RN/MD collaboration	RN/MD collaboration	Collaborative Practice Scale, Collaboration and Satisfaction About Care Decisions, ICU Nurse-Physician Questionnaire, Nurses Opinion Questionnaire, and the Jefferson Scale of Attitudes Toward Physician-Nurse Collaboration

Chapter 33. Professional Communication and Team Collaboration

Michelle O'Daniel, Alan H. Rosenstein

Background

In today's health care system, delivery processes involve numerous interfaces and patient handoffs among multiple health care practitioners with varying levels of educational and occupational training. During the course of a 4-day hospital stay, a patient may interact with 50 different employees, including physicians, nurses, technicians, and others. Effective clinical practice thus involves many instances where critical information must be accurately communicated. Team collaboration is essential. When health care professionals are not communicating effectively, patient safety is at risk for several reasons: lack of critical information, misinterpretation of information, unclear orders over the telephone, and overlooked changes in status.[1]

Lack of communication creates situations where medical errors can occur. These errors have the potential to cause severe injury or unexpected patient death. Medical errors, especially those caused by a failure to communicate, are a pervasive problem in today's health care organizations. According to the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCHAO), if medical errors appeared on the National Center for Health Statistic's list of the top 10 causes of death in the United States, they would rank number 5—ahead of accidents, diabetes, and Alzheimer's disease, as well as AIDS, breast cancer, and gunshot wounds.[1] The 1999 Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, revealed that between 44,000 and 98,000 people die every year in U.S. hospitals because of medical errors.[2] Even more disturbing, communication failures are the leading root cause of the sentinel events reported to the Joint Commission from 1995 to 2004. More specifically, the Joint Commission cites communication failures as the leading root cause for medication errors, delays in treatment, and wrong-site surgeries, as well as the second most frequently cited root cause for operative and postoperative events and fatal falls.[1]

Traditional medical education emphasizes the importance of error-free practice, utilizing intense peer pressure to achieve perfection during both diagnosis and treatment. Errors are therefore perceived normatively as an expression of failure. This atmosphere creates an environment that precludes the fair, open discussion of mistakes required if organizational learning is to take place. In the early 1990s, Donald Berwick wrote about patients needing an open communication system instead of experiencing adverse events stemming from communication failures.[3] More than a decade later, this concept still has profound implications on our method of health care delivery. As such, this chapter will review the literature on the important role of communication and team collaboration in helping to reduce medical errors and increase patient safety.

Research Evidence

What Are Communication and Team Collaboration?

Webster's Dictionary defines communication as "the imparting or interchange of thoughts, opinions, or information by speech, writing, or signs." It is important to consider that communication is not just verbal in form. One study states that 93 percent of communication is more affected by body language, attitude, and tone, leaving only 7 percent of the meaning and intent based on the actual words said.[4] Whereas the spoken words contain the crucial content, their meaning can be influenced by the style of delivery, which includes the way speakers stand, speak, and look at a person.[1] However, critical information is often transmitted via handwritten notes, e-mails, or text messages, which can lead to serious consequences if there is miscommunication.

Collaboration in health care is defined as health care professionals assuming complementary roles and cooperatively working together, sharing responsibility for problem-solving and making decisions to formulate and carry out plans for patient care.[5, 6] Collaboration between physicians, nurses, and other health care professionals increases team members' awareness of each others' type of knowledge and skills, leading to continued improvement in decisionmaking.[7]

Effective teams are characterized by trust, respect, and collaboration. Deming[8] is one of the greatest proponents of teamwork. Teamwork, he believes, is endemic to a system in which all employees are working for the good of a goal, who have a common aim, and who work together to achieve that aim. When considering a teamwork model in health care, an interdisciplinary approach should be applied. Unlike a multidisciplinary approach, in which each team member is responsible only for the activities related to his or her own discipline and formulates separate goals for the patient, an interdisciplinary approach coalesces a joint effort on behalf of the patient with a common goal from all disciplines involved in the care plan. The pooling of specialized services leads to integrated interventions. The plan of care takes into account the multiple assessments and treatment regimens, and it packages these services to create an individualized care program that best addresses the needs of the patient. The patient finds that communication is easier with the cohesive team, rather than with numerous professionals who do not know what others are doing to mange the patient.[9] Table 1 is a compilation of some of the components found in the literature of a successful teamwork model.[10–14]

It is important to point out that fostering a team collaboration environment may have hurdles to overcome: additional time; perceived loss of autonomy; lack of confidence or trust in decisions of others; clashing perceptions; territorialism; and lack of awareness of one provider of the education, knowledge, and skills held by colleagues from other disciplines and professions.[15] However, most of these hurdles can be overcome with an open attitude and feelings of mutual respect and trust. A study determined that improved teamwork and communication are described by health care workers as among the most important factors in improving clinical effectiveness and job satisfaction.[16]

Table 1. Components of Successful Teamwork

- Open communication
- Nonpunitive environment
- Clear direction
- Clear and known roles and tasks for team members

- Respectful atmosphere
- Shared responsibility for team success
- Appropriate balance of member participation for the task at hand
- Acknowledgment and processing of conflict
- Clear specifications regarding authority and accountability
- Clear and known decisionmaking procedures
- Regular and routine communication and information sharing
- Enabling environment, including access to needed resources
- Mechanism to evaluate outcomes and adjust accordingly

Extensive review of the literature shows that communication, collaboration, and teamwork do not always occur in clinical settings. For example, a study by Sutcliff, Lewton, and Rosenthal[17] reveals that social, relational, and organizational structures contribute to communication failures that have been implicated as a large contributor to adverse clinical events and outcomes. Another study shows that the priorities of patient care differed between members of the health care team, and that verbal communication between team members was inconsistent.[16] Other evidence shows that more than one-fifth of patients hospitalized in the United States reported hospital system problems, including staff providing conflicting information and staff not knowing which physician is in charge of their care.[18] Over the past several years, we have been conducting original research on the impact of physician and nurse disruptive behaviors (defined as any inappropriate behavior, confrontation, or conflict, ranging from verbal abuse to physical or sexual harassment) and its effect on staff relationships, staff satisfaction and turnover, and patient outcomes of care, including adverse events, medical errors, compromises in patient safety, poor quality care, and links to preventable patient mortality. Many of these unwanted effects can be traced back to poor communication and collaboration, and ineffective teamwork.[19–22]

Unfortunately, many health care workers are used to poor communication and teamwork, as a result of a culture of low expectations that has developed in many health care settings. This culture, in which health care workers have come to expect faulty and incomplete exchange of information, leads to errors because even conscientious professionals tend to ignore potential red flags and clinical discrepancies. They view these warning signals as indicators of routine repetitions of poor communication rather than unusual, worrisome indicators.[23]

Although poor communication can lead to tragic consequences, a review of the literature also shows that effective communication can lead to the following positive outcomes: improved information flow, more effective interventions, improved safety, enhanced employee morale, increased patient and family satisfaction, and decreased lengths of stay.[1, 24–26] Fuss and colleagues[27] and Gittell and others[28] show that implementing systems to facilitate team communication can substantially improve quality.

Effective communication among staff encourages effective teamwork and promotes continuity and clarity within the patient care team. At its best, good communication encourages collaboration, fosters teamwork, and helps prevent errors.

Barriers to Effective Communication

Health professionals tend to work autonomously, even though they may speak of being part of a team.[29] Efforts to improve health care safety and quality are often jeopardized by the communication and collaboration barriers that exist between clinical staff. Although every organization is unique, the barriers to effective communication that organizations face have

some common themes. Table 2 indicates some common barriers to interprofessional collaboration that we have learned from our research and focus groups with hospitals across the country.

Table 2. Common Barriers to Interprofessional Communication and Collaboration

- Personal values and expectations
- Personality differences
- Hierarchy
- Disruptive behavior
- Culture and ethnicity
- Generational differences
- Gender
- Historical interprofessional and intraprofessional rivalries
- Differences in language and jargon
- Differences in schedules and professional routines
- Varying levels of preparation, qualifications, and status
- Differences in requirements, regulations, and norms of professional education
- Fears of diluted professional identity
- Differences in accountability, payment, and rewards
- Concerns regarding clinical responsibility
- Complexity of care
- Emphasis on rapid decisionmaking

The barriers indicated in Table 2 can occur within disciplines, most notably between physicians and residents, surgeons and anesthesiologists, and nurses and nurse managers.[30, 31] However, most often the barriers manifest between nurses and physicians. Even though doctors and nurses interact numerous times a day, they often have different perceptions of their roles and responsibilities as to patient needs, and thus different goals for patient care. One barrier compounding this issue is that because the United States is one of the most ethnically and culturally diverse countries in the world, many clinicians come from a variety of cultural backgrounds. In all interactions, cultural differences can exacerbate communication problems.[1] For example, in some cultures, individuals refrain from being assertive or challenging opinions openly. As a result, it is very difficult for nurses from such cultures to speak up if they see something wrong. In cultures such as these, nurses may communicate their concern in very indirect ways. Culture barriers can also hinder nonverbal communication. For example, some cultures ascribe specific meaning to eye contact, certain facial expressions, touch, tone of voice, and nods of the head.

Issues around gender differences in communication styles, values, and expectations are common in all workplace situations. In the health care industry, where most physicians are male and most nurses are female, communication problems are further accentuated by gender differences.[32]

A review of the organizational communication literature shows that a common barrier to effective communication and collaboration is hierarchies.[33–37] Sutcliff and colleagues' research[17] concurs that communication failures in the medical setting arise from vertical hierarchical differences, concerns with upward influence, role conflict, and ambiguity and struggles with interpersonal power and conflict. Communication is likely to be distorted or withheld in situations where there are hierarchical differences between two communicators, particularly

when one person is concerned about appearing incompetent, does not want to offend the other, or perceives that the other is not open to communication.

In health care environments characterized by a hierarchical culture, physicians are at the top of that hierarchy. Consequently, they may feel that the environment is collaborative and that communication is open while nurses and other direct care staff perceive communication problems. Hierarchy differences can come into play and diminish the collaborative interactions necessary to ensure that the proper treatments are delivered appropriately. When hierarchy differences exist, people on the lower end of the hierarchy tend to be uncomfortable speaking up about problems or concerns. Intimidating behavior by individuals at the top of a hierarchy can hinder communication and give the impression that the individual is unapproachable.[1, 38]

Staff who witness poor performance in their peers may be hesitant to speak up because of fear of retaliation or the impression that speaking up will not do any good. Relationships between the individuals providing patient care can have a powerful influence on how and even if important information is communicated. Research has shown that delays in patient care and recurring problems from unresolved disputes are often the by-product of physician-nurse disagreement.[39] Our research has identified a common trend in which nurses are either reluctant or refuse to call physicians, even in the face of a deteriorating status in patient care. Reasons for this include intimidation, fear of getting into a confrontational or antagonistic discussion, lack of confidentiality, fear of retaliation, and the fact that nothing ever seems to change. Many of these issues have to deal more with personality and communication style.[40] The major concern about disruptive behaviors is how frequently they occur and the potential negative impact they can have on patient care. Our research has shown that 17 percent of respondents to our survey research in 2004-2006 knew of a specific adverse event that occurred as a result of disruptive behavior. A quote from one of the respondents illustrates this point: “Poor communication post-op because of disruptive reputation of physician resulted in delayed treatment, aspiration, and eventual demise.”[19]

Leaders in both medicine and nursing have issued ongoing initiatives for the development of a cooperative rather than a competitive agenda to benefit patient care.[5, 39, 41, 42] A powerful incentive for greater teamwork among professionals is created by directing attention to the areas where changes are likely to result in measurable improvements for the patients they serve together, rather than concentrating on what, on the surface, seem to be irreconcilable professional differences. The fact that most health professionals have at least one characteristic in common, a personal desire to learn, and that they have at least one shared value, to meet the needs of their patients or clients, is a good place to start.

Practice Implications

Known Benefits of Communication and Team Collaboration

A large body of literature shows that because of the complexity of medical care, coupled with the inherent limitations of human performance, it is critically important that clinicians have standardized communication tools and create an environment in which individuals can speak up and express concerns. This literature concurs that when a team needs to communicate complex information in a short period of time, it is helpful to use structured communication techniques to ensure accuracy. Structured communication techniques can serve the same purpose that clinical practice guidelines do in assisting practitioners to make decisions and

take action. Research from aviation and wilderness firefighting is useful in health care because they all involve settings where there is a huge variability in circumstances, the need to adapt processes quickly, a quickly changing knowledge base, and highly trained professionals who must use expert judgment in dynamic settings. Research shows that in these disciplines, the adoption of standardized tools and behaviors is a very effective strategy in enhancing teamwork and reducing risks.[1, 17, 43–54, 60, 61]

Crew Resource Management (Aviation). Experts in aviation have developed safety training focused on effective team management, known as Crew Resource Management (CRM). Improvements in the safety record of commercial aviation may be due, in part, to this training. Realizing that 70 percent of commercial flight accidents stemmed from communication failures among crew members, CRM sought to standardize communication and teamwork. The concept originated in 1979, in response to a NASA workshop that examined the role that human error plays in air crashes. CRM emphasizes the role of human factors in high-stress, high-risk environments. John K. Lauber, a psychologist member of the National Transportation Safety Board, deemed CRM as "using all available sources—information, equipment, and people—to achieve safe and efficient flight operations."[44, 45] CRM encompasses team training as well as simulation, interactive group debriefings, and measurement and improvement of aircrew performance. This represents a major change in training, which had previously dealt with only the technical aspects of flying. It considers human performance limiters (such as fatigue and stress) and the nature of human error, and it defines behaviors that are countermeasures to error, such as leadership, briefings, monitoring and cross-checking, decisionmaking, and review and modification of plans. From a practical standpoint, CRM programs typically include educating crews about the limitations of human performance. Trainees develop an understanding of cognitive errors and how stressors (such as fatigue, emergencies, and work overload) contribute to the occurrence of errors. Operational concepts stressed include inquiry, seeking relevant operational information, advocacy, communicating proposed actions, conflict resolution, and decisionmaking. CRM is now required for flight crews worldwide.

The development and implementation of CRM in aviation over the last 25 years offers valuable lessons for medical care. Sexton and colleagues[51] compared flight crews with operating room personnel on several measures, including attitudes toward teamwork. This landmark study included more than 30,000 cockpit crew members (captains, first officers, and second officers) and 1,033 operating room personnel (attending surgeons, attending anesthesiologists, surgical residents, anesthesia residents, surgical nurses, and anesthesia nurses). Questionnaires were sent to crew members of major airlines around the world (over a 15-year period). The operating room participants were mailed an analogous questionnaire, administered over a period of 3 years at 12 teaching and nonteaching hospitals in the United States, Italy, Germany, Switzerland, and Israel.

The Sexton study and other analyses suggest that safety-related behaviors that have been applied and studied extensively in the aviation industry may also be relevant in health care. Study results show successful CRM applications in several dynamic decisionmaking health care environments: the operating room, labor and delivery, and the emergency room.[26, 31, 55, 56] As with aviation, the medical application of CRM has required tailoring of training approaches to mirror the areas in which human factors contribute to mishaps. In anesthesiology, 65–70 percent of safety problems (accidents or incidents) have been attributed at least in part to human error. In response, several anesthesiologists from the Veterans Affairs Palo Alto Health Care System and Stanford University developed Anesthesia Crisis Resource Management (ACRM), modeled on CRM.[55] Kaiser Permanente, a nonprofit American health care system providing care for 8.3

million patients, has also adopted CRM with successful results.[54] In response to the occurrence of a sentinel event—a medical error with serious consequences—Eglin U.S. Air Force (USAF) Regional Hospital developed and implemented a patient safety program called Medical Team Management (MTM) that was modeled on the aviation industry's CRM program and focused on communication, teamwork, and reporting to determine the impact of a patient safety program on patterns of medical error reporting.[57] This study was a retrospective review of 1,102 incident reports filed at Eglin USAF Regional Hospital in Florida between 1997 and 2001. Collected data from the comparison periods (1998 and 2001) were statistically analyzed using the chi-square test. This study indicates that, since the implementation of MTM, there has been a statistically significant increase in the number of reports filed at Eglin USAF Regional Hospital and a decline in the severity of incidents. These findings suggest that since the implementation of MTM, there have been changes in the patterns of error reporting, and with training, staff are able to prevent more serious incidents. Table 3 highlights the application of a CRM model to medicine.

Table 3. Application of a CRM Model to Medicine

- Design of systems to absorb errors through redundancy, standardization, and checklists
- Movement from placing blame to designing safe processes and procedures, i.e., applying a systems approach
- Assurance of full immunity while implementing a nonpunitive approach
- Debriefing of all events, including near misses, that have learning potential. Focus on the severity of the potential risk rather than on the severity of the event's final outcome is more conducive to establishing effective prevention programs.
- Institutionalization of a permanent program for risk identification, analysis, and dissemination of the lessons learned throughout the professional community

SBAR. Doctors and nurses often have different communication styles in part due to training. Nurses are taught to be more descriptive of clinical situations, whereas physicians learn to be very concise. Standardized communication tools are very effective in bridging this difference in communication styles.

Michael Leonard, physician coordinator of clinical informatics at Kaiser Permanente, along with colleagues, developed a technique called SBAR (Situation-Background-Assessment-Recommendation). This technique has been implemented widely at health systems such as Kaiser Permanente.[1, 17, 58] Many other hospitals have embraced the SBAR communication tool or a similar tool created by the Studer Group (see Table 4).[59] For example, the Queen's Medical Center in Honolulu has incorporated the SBAR tool as a key component of its patient safety program. The SBAR technique provides a framework for communication between members of the health care team about a patient's condition. SBAR is an easy-to-remember tool used to create mechanisms useful for framing any conversation, especially critical ones, requiring a clinician's immediate attention and action. It allows for an easy and focused way to set expectations between members of the team for what will be communicated and how, which is essential for information transfer and cohesive teamwork. Not only is there familiarity in how people communicate, but the SBAR structure helps develop desired critical-thinking skills. The person initiating the communication knows that before they pick up the telephone, they need to provide an assessment of the problem and what they think an appropriate solution is. Their conclusion may not ultimately be the answer, but there is clearly value in defining the situation. Table 5, Guidelines for Communicating with Physicians Using the SBAR Process explains how

to carry out the SBAR technique in detail. The guidelines use the physician team member as the example; however, they can be adapted for use with all other health professionals.

Table 4. Studer Group Communication Guidelines for Nurses

- Have I seen and assessed this patient myself before I call?
- Are there standing orders?
- Do I have at hand
    - The chart?
    - List of current meds, IV fluids, and labs?
    - Most recent vital signs?
    - If reporting lab work, date and time this test was done and results of previous tests for comparisons?
    - Code status?
- Have I read the most recent MD progress notes and notes from the nurse who worked the shift ahead of me?
- Have I discussed this call with my charge nurse?
- When ready to call,
  Remember to identify self, unit, patient, room number.
    - Know the admitting diagnosis and date of admission.
    - Briefly state the problem, what it is, when it happened or started, and how severe it is.
- What do I expect to happen as a result of this call?
- Document whom you spoke to, time of call, and summary of conversation.
- Engage and treat physician with respect.

[Source: Studer Group. Patient Safety Toolkit – Practical tactics that improve both patient safety and patient perceptions of care. Gulf Breeze, FL: Studer Group., 2007.]

Table 5. SBAR (Situation, Background, Assessment, Recommendation)

- SBAR – a technique for communicating critical information that requires immediate attention and action concerning a patient's condition
- Situation – What is going on with the patient?
  "I am calling about Mrs. Joseph in room 251. Chief complaint is shortness of breath of new onset."
- Background – What is the clinical background or context?
  "Patient is a 62-year-old female post-op day one from abdominal surgery. No prior history of cardiac or lung disease."
- Assessment – What do I think the problem is?
  "Breath sounds are decreased on the right side with acknowledgment of pain. Would like to rule out pneumothorax."
- Recommendation – What would I do to correct it?
  "I feel strongly the patient should be assessed now. Are you available to come in?"

[Note: Kaiser Permanente, SBAR (Situation, Background, Assessment, Recommendation) tool, 2002. Source for version in this table: Institute for Healthcare Improvement. Guidelines for communicating with physicians using the SBAR process. http://www.ihi.org/IHI/Topics/PatientSafety /SafetyGeneral/ Tools/SBARTechniq ueforCommunicationASituationalBriefing Model.htm. Accessed Nov. 18, 2004.]

STICC (Situation Task Intent Concern Calibrate) is another type of structured briefing protocol used by the U.S. Forest Service to give direction to firefighters.[1, 17, 60, 61] The following five steps are involved:

- Situation: Here's what I think we face.
- Task: Here's what I think we should do.
- Intent: Here's why.

- Concern: Here's what we should keep our eye on.
- Calibrate: Talk to me. Tell me if you don't understand, can't do it, or see something I do not.

Establishing Culture To Support Communication and Team Collaboration

The literature reviewed shows that effective teams are characterized by common purpose and intent, trust, respect, and collaboration. Team members value familiarity over formality and watch out for each other to make sure mistakes are not made. Health care teams that do not trust, respect, and collaborate with one another are more likely to make a mistake that could negatively impact the safety of patients.

One of the first crucial steps is organizational commitment and willingness to address the situation. Commitment needs to come from the top down and bottom up, making a statement about the way the organization does business. The rallying point should be around behavioral standards and their relationship to patient safety. It's ironic that ever since the publication of the original IOM report, *To Err Is Human,* organizations have spent the bulk of their time and efforts in improving patient systems rather than addressing the human factor issues highlighted in the original report.[2] Several recent reports have suggested that while we have made progress in the patient safety movement, we have a long way to go in meeting the IOM recommendations.[62] Addressing defects in communication that affect collaboration, information exchange, appreciation of roles and responsibilities, and direct accountability for patient care are key components of any patient safety program. Clinical and administrative leaders must set the tone by establishing and adhering to behavioral standards that support agreed-upon code of conduct practices backed by a nonpunitive culture and zero-tolerance policy.

The next step in the process is recognition and self-awareness. Organizations must be able to assess the prevalence, context, and impact of behaviors to identify potential opportunities for improvement. Doing an internal assessment will help pinpoint the seriousness of the situation and provide clues to areas that need to be addressed. Assessment information can be gained from formal methods such as incident reports, survey tools, focus groups, department meetings, task forces or committees, direct observation, suggestion boxes, and hot lines. Informal methods such as casual meetings and gossip can also provide valuable surface information and should be evaluated more deeply as to the source, relevance, and significance of the events to determine next steps. In many organizations there are still remnants of reluctance to address the issue head on for fear of antagonizing a prominent surgeon or staff member. With growing concerns about workforce shortages, staff satisfaction and retention, hospital reputation, liability and patient safety, and the need for compliance to the latest Joint Commission proposed standards addressing disruptive behaviors, organizations can no longer afford to take a passive approach to the situation.[63–66]

Creating opportunities for different groups to just get together is a highly effective strategy for enhancing collaboration and communication. These group interactions can be either formal or informal. Encouraging open dialogue, collaborative rounds, implementing preop and postop team briefings, and creating interdisciplinary committees or task forces that discuss problem areas frequently provides an upfront solution that reduces the likelihood of disruptive events. When a disruptive event does occur, some organizations have implemented a time-out, code

white, or red light policy that addresses the issue in real time to prevent any further serious consequences.[59]

Developing and implementing a standard set of behavior policies and procedures is vital. These policies need to be consistent and universally applied. There should not be a separate policy for any one particular discipline or service. For the medical staff, the policies should become part of the medical staff bylaws with signed agreements to abide by these policies at the time of appointment and recredentialing. Included in the policies should be a standardized protocol outlining expected standards and the process for addressing disruptive behavior issues, recommendations, followup plans, and actions to be taken in the face of individual resistance or refusal to comply. Prior to implementation, make sure all employees are familiar with the existence, purpose, and intent of the policies and procedures.

For the process to unfold, the organization needs to encourage its employees to report disruptive behaviors. The organization needs to address issues related to confidentiality, fear of retaliation, and the common feelings that there is a double standard and that nothing ever gets done. Reporting mechanisms should be made easy and must be supported by the presence of a nonpunitive environment. The ideal vehicle for reporting is to address the situation in real time, but concerns about position, appropriateness, receptiveness, fear, hostility, and retaliation are significant impediments.[67] Appropriate vehicles for reporting may include reporting of the incident to a superior, filing an incident report, using a complaint or suggestion box, or reporting directly to a task force or interdisciplinary committee with assigned responsibilities for addressing these issues.[59] Besides maintaining confidentiality and reducing risks of retaliation, one of the most crucial aspects of the reporting system is to give recognition and assurance that the complaints will be addressed and actions will be taken. Responses should be timely, appropriate, consistent, and provide necessary feedback and followup.

Taking action though appropriate intervention strategies is next. On one level, generic educational programs can do a lot to spread the message and teach basic skills necessary to promote effective communication. Appropriate topics should include sessions on team dynamics, communication skills, phone etiquette, assertiveness training, diversity training, conflict management, stress management, and any other courses necessary to foster more effective team functioning and communication flow. Courses should be offered to all staff and employees at the organization: physicians, physicians in training, nurses, nursing students, and all other staff who have patient contact or play a role in the delivery of patient care. For individuals who have consistently exhibited disruptive behavior, education may need to be supported by more focused sessions and specific counseling. Another important strategy is to promote and assure competency training at all levels of the health care team. This is a key factor affecting trust and respect, which have such a strong influence on team collaboration.

Focused team training programs have been of particular value. One of the newer approaches to improving team collaboration and patient safety is through the principles learned from the aviation industry. Fostering an environment of trust and respect, accountability, situational awareness, open communication, assertiveness, shared decisionmaking, feedback, and education, interdisciplinary CRM training has brought significant improvements to communication flow in the perioperative setting.[52, 53]

Having a clinical champion or early adopter who actively promotes the importance of appropriate behavior, communication, and team collaboration can be an extremely valuable asset. Champions can come from the executive ranks or through the voluntary interest and enthusiasm of other staff members. Co-champions may be even more effective. Some

organizations have reported that having a nurse and physician (or other health care professional) go through a joint training program will help foster mutual cooperation and collaboration between the different disciplines.[59] Followup and feedback bring closure to the process. It is important to let people know that their input is welcomed, followup actions will be taken, and appropriate feedback will be provided.

Research Implications

The existing literature adequately outlines structured communication techniques that will help minimize medical errors. However, more research is needed on how to effectively deal with miscommunication and barriers to communication in real-time crisis situations. Also, the existing literature lacks concrete research confirming a cause-and-effect relationship between human factors and clinical outcomes of care.

Conclusions

Effective clinical practice must not focus only on technological system issues, but also on the human factor. As shown in this chapter, good communication encourages collaboration and helps prevent errors. It is important for health care organizations to assess possible setups for poor communication and be diligent about offering programs and outlets to help foster team collaboration. By addressing this issue, health care organizations have an opportunity to greatly enhance their clinical outcomes.

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Chapter 34. Handoffs: Implications for Nurses

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Background

The transfer of essential information and the responsibility for care of the patient from one health care provider to another is an integral component of communication in health care. This critical transfer point is known as a handoff.[1–3] An effective handoff supports the transition of critical information and continuity of care and treatment. However, the literature continues to highlight the effects of ineffective handoffs: adverse events and patient safety risks.[4–11] The Institute of Medicine (IOM) reported that "it is in inadequate handoffs that safety often fails first"[12] (p. 45). This chapter presents an overview of handoffs, a summary of selected literature, gaps in the knowledge, and suggestions for quality improvement initiatives and recommendations for future research.

What Is a Handoff?

First one needs to recognize the term "handoff" and synonymous terms that are used in a wide variety of contexts and clinical settings. There are a number of terms used to describe the handoff process, such as handover,[1, 13, 14] sign-out,[15, 16] signover,[17] cross-coverage,[18, 19] and shift report.[20–22] For the purpose of this discussion, the term "handoff" will be used and defined as, "The transfer of information (along with authority and responsibility) during transitions in care across the continuum; to include an opportunity to ask questions, clarify and confirm"[23] (p. 31). The concept of a handoff is complex and "includes communication between the change of shift, communication between care providers about patient care, handoff, records, and information tools to assist in communication between care providers about patient care"[1] (p. 1). The handoff is also "a mechanism for transferring information, primary responsibility, and authority from one or a set of caregivers, to oncoming staff"[17] (p. 1). So, conceptually, the handoff must provide critical information about the patient, include communication methods between sender and receiver, transfer responsibility for care, and be performed within complex organizational systems and cultures that impact patient safety. The complexity and nuance of the type of information, communication methods, and various caregivers for each of these factors impact the effectiveness and efficiency of the handoff as well as patient safety.

Why Is There a Problem With Handoffs Today?

As health care has evolved and become more specialized, with greater numbers of clinicians involved in patient care, patients are likely to encounter more handoffs than in the simpler and less complex health care delivery system of a few generations ago.[11] Ineffective handoffs can contribute to gaps in patient care and breaches (i.e., failures) in patient safety, including medication errors,[19, 24] wrong-site surgery,[9] and patient deaths.[4, 7] Clinical environments are dynamic and complex, presenting many challenges for effective communication among health care providers, patients, and families.[25–27] Some nursing units may "transfer or discharge 40 percent to 70 percent of their patients every day"[28] (p. 36), thereby illustrating the frequency of handoffs encountered daily and the number of possible breaches at each transition point.

Our expanding knowledge base and technological advances in health care spawn additional categories of health care providers and specialized units designed for specific diseases, procedures, and phases of illness and/or rehabilitation. This dynamic, ever-increasing specialization, while undertaken to improve patient outcomes and enhance health care delivery, can contribute to serious risks in health care delivery and promote fragmentation of care and problems with handoffs.[3, 10, 29] It is ironic that as health care has become more sophisticated due to advances in medical technology focused on saving lives and enhancing the quality of life, the risks associated with the handoffs have garnered attention in the popular press[30] and reports from health care organizations and providers.[3, 4, 6, 10, 31–35] The hazard that "fumbled handoffs"[7, 10] pose to patient safety and the delivery of quality health care cannot be ignored. Ineffective handoffs can lead to a host of patient safety problems; research[1] and development of strategies to reduce these problems are required.[33, 34]

What contributes to fumbled handoffs? An examination of how communication breakdown occurs among other disciplines may have implications for nurses. A study of incidents reported by surgeons found communication breakdowns were a contributing factor in 43 percent of incidents, and two-thirds of these communication issues were related to handoff issues.[36] The use of sign-out sheets for communication between physicians is a common practice, yet one study found errors in 67 percent of the sheets.[15] The errors included missing allergy and weight, and incorrect medication information.[15] In another study, focused on near misses and adverse events involving novice nurses, the nurses identified handoffs as a concern, particularly related to incomplete or missing information.[37]

Acute care hospitals have become organizationally complex; this contributes to difficulty communicating with the appropriate health care provider. Due to the proliferation of specialties and clinicians providing care to a single patient, nurses and doctors have reported difficulty in even contacting the correct health care provider.[38] One study found that only 23 percent of physicians could correctly identify the primary nurse responsible for their patient, and only 42 percent of nurses could identify the physician responsible for the patient in their care.[39] This study highlights the potential gaps in communication among health care providers transferring information about care and treatment.

A handoff is largely dependent on the interpersonal communication skills of the caregiver[33] as well as the knowledge and experience level of the caregiver. There is reported variability in quality,[40] lack of structure in how handoffs usually occur,[33] and variances in shift handoffs.[22, 41–43] Concern has been raised that the transition of care between providers during handoffs will continue to be problematic as research indicates that "only 8 percent of medical schools teach how to hand off patients in formal didactic session"[3] (p. 1097), creating a large educational gap in new professionals and persistence of traditional models. Physicians and nurses communicate differently. Nurses are focused on the "big picture" with "broad and narrative"[44] (p. i86) descriptions of the situation, whereas physicians are focused on bullets of critical information.[44] A technique that seeks to bridge the gap between the different communication styles of nurses and physician is the situation, background, assessment, recommendation (SBAR) briefing model[44] that is being used successfully to enhance handoff communication.[45]

The issue of handoffs has become so prominent that the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCAHO) introduced a national patient safety goal on handoffs that became effective in January 2006.[45] The national safety goals, developed by the Joint Commission with input from the Sentinel Event Advisory Group, identify new actions with the potential to protect patient safety.[46] The patient safety goal requires

health care organizations to "implement a standardized approach to "handoff" communications, including an opportunity to ask and respond to questions."[47] While the goal is simply stated, it is challenging to develop and implement effective strategies for handoffs across various health care settings, given the complexity of health care delivery. The Joint Commission's guidelines for implementation of the safety goal are presented in Table 1,[48] and suggested strategies for effective handoffs are listed in Table 2.

Table 1. Joint Commission 2008 Hospital Patient Safety Goals Implementation Expectations for Handoffs

1.	Interactive communications allowing for the opportunity for questioning between the giver and receiver of patient information.
2.	Up-to-date information regarding the patient's care, treatment and services, condition, and any recent or anticipated changes.
3.	A process for verification of the received information, including repeat-back or read-back, as appropriate.
4.	An opportunity for the receiver of the handoff information to review relevant patient historical data, which may include previous care, treatment, and services.
5.	Interruptions during handoffs are limited to minimize the possibility that information would fail to be conveyed or would be forgotten.

Source: Adapted from Joint Commission, National Patient Safety Goals Hospital Program.[48]

Following are examples of each of these handoff expectations:

1. Nurse Brown on unit A is receiving report from Nurse Green who is transferring the patient from unit B to unit A. The patient medication administration record (MAR) does not indicate the patient has received any pain medication in the past shift. When Nurse Brown asks about this, Nurse Green realizes she gave morphine sulfate but did not document it on the MAR. Due to Nurse Brown's question, Nurse Green realizes the omission and communicates the information and documents it in the medical record, preventing an accidental overdose of a medication.
2. A patient who had undergone a surgical procedure has not been out of bed since being transferred to the nursing unit. The offgoing nurse alerts the oncoming nurses that the patient will need help getting out of bed, possibly preventing a patient fall.
3. Handoffs require a process for verification of the received information, including read back, as appropriate. For example, the receiver of the telephone message regarding a laboratory value is asked to write it down and read the message back, including the name of the patient, the test, and the test result/interpretation.[49, 50] Information to be recorded should also include the name and credentials of sender and receiver and the date and time.[50]

   Laboratory Technician: I am calling with the lab results on Mr. Green.
   Nurse: Let me get a notepad. You are calling the lab results for Mrs. Marie White?
   Laboratory Technician: No, I am calling results for Mr. Tom Green ID #12345678. Mr. Green's potassium level is 5.1, which was drawn at 0700 today.
   Nurse: You reported that Mr. Tom Green's potassium level is 5.1. This is Nancy Jones, RN.
   Laboratory Technician: Thank you, Nancy. That is correct; Mr. Tom Green's potassium level is 5.1 This is Bill Smith, lab tech.
4. The receiver of the handoff information has an opportunity to review relevant patient/client/resident historical data, which may include previous care, treatment, and services. A patient has been transferred, and the nurse notes several omissions from

previous medication orders, including insulin. The nurse notifies the physician and obtains correct and complete medication orders, thereby avoiding a potentially serious medication error.

5. A nursing unit schedules staffing coverage to accommodate the shift change and minimize the occurrence of interruptions during change-of-shift report. Ancillary staff does not leave the nursing unit until report is completed to assure phones are answered and timely responses to call lights are made so nurses can provide report effectively and efficiently.

Table 2. Strategies to Improve Handoff Communication

	Strategy	Example
1.	Use clear language and avoid use of abbreviations or terms that can be misinterpreted.	During the reconciliation process, the nurse noted a medication that is usually administered once daily being given every other day. The handwritten order for daily was written QD but read as QOD. QD and QOD are on the Joint Commission official "Do Not Use" list.[51] According to the list, "daily" should be written instead of QD and QOD should be written as "every other day."[51]
2.	Use effective communication techniques. Limit interruptions. Implement and utilize read-backs or check-back techniques.	In the middle of a shift handoff, the unit clerk interrupts the nurse to inform her that a patient needs assistance to go to the bathroom. The nurse must leave report to assist the patient or find a nurse's aide to help the patient. During this interruption, the offgoing nurse is in a rush to leave and get her son from child care. Due to the need to leave quickly, the offgoing nurse forgets to document and report to the oncoming nurse that a patient fell right before the shift change. Efforts need to be made to ensure adequate staffing during shift report to minimize interruptions.
3.	Standardize reporting shift-to-shift and unit-to-unit.	The surgical unit standardized shift-to-shift handoff report with a one-page tool that is used for each patient, thereby providing a comprehensive, structured approach to providing the critical information on new and recovering postoperative patients.
4.	Assure smooth handoffs between settings.	One of the busiest units in the hospital is the emergency department (ED). Patients must be discharged or moved quickly out of the ED to an inpatient unit. To ensure rapid patient flow, a new handoff process is established that includes a phone call to the receiving unit, the assignment of an admission nurse so that there are no delays on the receiving unit, telephone report so the receiving unit can prepare any special equipment, and then a final verbal handoff between the two nurses while viewing the patient to verify the condition of the patient and ensure no changes from one setting to another.
5.	Use technology to enhance communication. Electronic records can support the timely and efficient transmission of patient information.	The hospital has an electronic record and utilizes portable computers. Walking rounds are made by the offgoing and oncoming nurse using the portable computer and visiting each patient for introductions and quick visual assessment. The use of this technology allows the nurse to view the patient's plan of care, medications, and IVs at a glance to prepare for care during the next shift.

Source: Adapted, in part, from Joint Commission International Center for Patient Safety. *Strategies To Improve Hand -Off Communication: Implementing a Process to Resolve Questions*. 2005.[34]

Table 3. Nurse-to-Nurse Change-of-Shift Handoff Report

Type of report	Strengths cited in literature	Weakness cited in literature	Practice implications (strategies for reducing errors and improving safety)
Verbal report on nursing unit	• Allows face-to-face interaction.[41] • Allows staff to debrief and discuss situations.[41] • Allows for clarification of information.[41] • Can present educational opportunity for staff.[41]	• Verbal only—poor retention of information by receiver.[55] • There may discrepancies between reported status and actual patient status.[22] • May be difficult to access all relevant information[41] for concise report. • Time consuming.[41] • Sensory Overload.[22, 75]	• Augment verbal report with preprinted, patient-specific forms containing data that can be transferred to the oncoming shift to decrease loss of information.[55] • Use electronic support to provide easily accessible data that is accurate and up to date.[34, 58] • Include bedside rounds to check patient status and congruence between report and patient condition.[22] • Use standardized process to assure transmission of essential information.[34, 45, 47, 55]
Verbal report at the patient's bedside	• Allows face-to-face interaction.[41] • Allows for clarification.[41] • Nurses can assess patient together.[41] • Allow the remedy of errors.[41] • Involve patient.[41, 52, 56]	• Confidentiality issues need to be addressed.[13, 41, 56] • Not all patients wish to participate in bedside report.[52] • Terms (jargon) used by nurses in report may pose a concern to patients if not explained.[52] • Nurses may be interrupted.[41]	• Monitor to assure confidentiality is protected, report in private setting.[56, 57] • Introduce self to patient.[57] • Encourage patient to participate, but not all patients will want or be able to participate and this needs to be respected.[52] • Develop protocol to guide the bedside handover process.[57] • Use standardized process to promote transmission of essential information.[34, 47]

Type of report	Strengths cited in literature	Weakness cited in literature	Practice implications (strategies for reducing errors and improving safety)
Audiotaped report	• Can be a more efficient process, concise[53] and "less time consuming"[41] • Tape may be repeated.[53] • Nurses who taped report can provide patient care while oncoming shift is listening to report.[53]	• May be difficult to hear or understand.[41] • Need access to equipment[2] • Question and answer interaction must be built into the process.[47] • Sensory Overload.[22] • There may discrepancies between reported status and actual patient status.[22] • Lack of educational opportunity.[41] • May not be current; timeliness of information dependent on when report was taped.[41]	• Need to assure there is an opportunity to ask questions about the report and interact between offgoing and oncoming shifts.[34, 47] • Include bedside rounds to check patient status and congruence between report and patient condition.[22] • Ensure sound quality of technology.[53] • Use standardized process to assure transmission of essential information.[34, 47] NOTE: Joint Commission National Patient Safety Standards require there to be an opportunity for exchange of information and ability to ask and answer questions.[47]
Written report	• Improvement in documentation.[54] • Effective management.[54] • Allows oncoming shift to review data.[54]	• Question and answer interaction must be built into the process.[47] • May be missing essential information if not documented.[54] • Quality of documentation may vary.[54]	• Need to assure there is an opportunity to ask questions about the report and interact between off going and oncoming shifts.[47] • Information also provided verbally with written report.[54] • Use standardized process to assure transmission of essential information.[34, 47] NOTE: Joint Commission National Patient Safety Standards require there to be an opportunity for exchange of information and ability to ask and answer questions.

Source: Adapted from O'Connell (2001), Challenging the handover ritual: recommendations for research and practice.

It is important to understand the context in which care is provided and be cognizant of the impact of the environmental processes on health care providers. The physical work environment may not be conducive to effective handoffs as it may be noisy[58, 59] and prone to interruptions, (i.e., pagers, phone calls),[60–63] and the handoff may be conducted under physical and emotional pressures.[11] A study examining communication patterns among physicians and nurses found thirty one percent of communication exchanges involved interruption, translating into roughly 11 interruptions an hour for physicians and nurses.[60] Spencer and colleagues[62] found 15 interruptions per hour. Barriers to transmission of accurate information in a patient transfer include incomplete medical record, lack of complete information provided by nurses, and the omission of essential information.[64] Handoffs are compromised if critical pieces of information are omitted because of difficulties with data access[4, 29] or if documentation is illegible[31, 33] or not transferred.[55] Despite efforts to promote the use of electronic patient records, according to a 2002 survey, less than 10 percent of hospitals have complete access to electronic systems such as computerized physician order entry (CPOE).[65]

The ever-increasing abundance of data requires that health care providers synthesize and make decisions using large amounts of complex information. Unfortunately, data quickly degrades; for example, critically ill patients have many clinical parameters that are being monitored frequently.[66] Decisions need to be based on trends in the data and current information, which is essential to making informed decisions.[66] Tremendous amounts of information are constantly being generated, such as monitored clinical parameters, diagnostic tests, and multidisciplinary assessments. When this large amount of information is combined with the numerous individuals—clinical and nonclinical—who come in contact with a patient during a treatment episode and data transmission, not all members of the health care team may be aware of all the information pertinent to each patient.[66]

In an effort to compress information and make it manageable among health care providers, handoffs may result in a "progressive loss of information known as *funneling*, as certain information is missed, forgotten or otherwise not conveyed" [66] (p. 211). The omission of information or lack of easy accessibility to vital information by health care providers can have devastating consequences.[4, 11] Such gaps in health care communication can cause discontinuity in the provision of safe care[67] and impede the therapeutic trajectory for a patient. These gaps present major patient safety threats and can impact the quality of care delivered.

Where Do Handoffs Occur?

Handoffs occur across the entire health care continuum in all types of settings. There are different types of handoffs from one health care provider to another, such as in the transfer of a patient from one location to another within the hospital[64] or the transition of information and responsibility during the handoff between shifts on the same unit.[1, 41, 43] Interdisciplinary handoffs occur between nurses and physicians, and nurses and diagnostic personnel, while intradisciplinary handoffs occur between physicians[3, 15, 31] or between nurses.[13, 14, 41, 42,43] Interfacility handoffs occur between hospitals and among multiple organizations,[68] including home health agencies,[69, 70] hospices,[71] and extended-care facilities.[72, 73]

Handoffs may involve use of specialized technology (e.g., audio recorders, pagers, hand-held devices, and computerized records),[2] fax,[73, 74] written documents,[54] and oral communication.[41, 75, 77] Each type and location of handoff presents similar as well as unique challenges. Given the variety of handoffs, the following discussion will focus on:

- Shift-to-shift handoff
- Nursing unit-to-nursing unit handoff
- Nursing unit to diagnostic area.
- Special settings (operating room, emergency department).
- Discharge and interfacility transfer handoff
- Handoffs and medications
- Physician-to-physician handoffs

Shift-to-Shift Handoff

There are paradoxes in communication and handoffs, especially at shift changes.[20] Many human factors play a role. Human factors (ergonomics) focus on behavior and interaction between human beings and their environment. Human factors engineering focuses on "how humans interact with the world around them and the application of that knowledge to the design of systems that are safe, efficient, and comfortable"[76] (p. 3). The handoff poses numerous human factors engineering implications. From the perspective of patient safety, the primary purpose of the shift report or shift handoff is to convey essential patient care information,[14, 43, 55, 78, 79] promote continuity of care[13, 41, 77, 78, 80] to meet therapeutic goals, and assure the safe transfer of care of the patient to a qualified and competent nurse. However, other reported purposes of shift report include education,[41, 78, 81] debriefing,[14, 41] socialization,[78, 82] planning and organization,[78] enhancement of teamwork,[81] and supportive functions.[83]

The intershift handoff is influenced by various factors, including the organizational culture. An organization that promotes open communication and allows all levels of personnel to ask questions and express concerns in a nonhierarchical fashion is congruent with an environment that promotes a culture of safety.[58] Interestingly, one study reported novice nurses seeking information approached those seen as "less authoritarian."[84] The importance of facilitating communication is critical in promoting patient safety. The shift-to-shift handoff is a multifaceted activity.[78, 85, 86] A poor shift report may contribute to an adverse outcome for a patient.[55]

Handoff intricacies. A phenomenon well known to nurses is the use of nurse-developed notations, "cheat sheets" or "scraps" of information, while receiving or giving intershift reports. A study of such note taking found scraps are used for a variety of purposes, including creating to-do lists and recording specific information and perceptions about the patient and family.[87] This approach presents some challenges, as no one else has easy access to the information; therefore, continuity of care may be compromised during a meal break, for example, or if the scrap or cheat sheet is misplaced.

Method of shift-to-shift handoff. Handoffs are given using various methods:[13, 41, 88, 89] verbally,[75, 77] with handwritten notes,[80, 87] at the bedside,[41, 52, 56, 57, 90, 92] by telephone,[91] by audiotape,[41, 53] nonverbally,[54] using electronic reports,[92] computers printouts,[14] and memory.[14] The strength of the bedside report method is its effort to focus on and include the patient in the report. There have been concerns regarding patient confidentiality,[41, 52, 56, 90] which could be compromised if not carefully addressed. A qualitative study focused on describing the perceptions of patients who were present during a bedside report found some patients are in favor of bedside handoff, while others are not.[52] Patients also expressed concern regarding the jargon used by nurses.[52] One patient noted that including the patient in the handoff added another level of safety as erroneous data could be addressed and corrected.[52] Case studies indicate the bedside handoff may be implemented for a number of reasons, including addressing specific

issues and improving care delivery.[57, 92] A summary of the strengths and weaknesses of verbal, bedside, written, and taped shift-to-shift reports is included in Table 3.

The challenge during handoffs across settings and times is to identify methods and implement strategies that protect against information decay and funneling,[66] contributing to the loss of important clinical information. It is a challenge to develop a handoff process that is efficient and comprehensive, as case studies illustrate.[57, 88, 92, 93] Observation of shift handoffs reveals that 84.6 percent of information presented in handoffs could be documented in the medical record.[42] A concern that emerged in this study was some handoff reports actually "promote confusion," and therefore the authors advocated improving the handoff process.[42]

Another concern with handoffs is the degree to which the report is actually congruent with the patient's condition. One study found 70 percent congruence between the shift report and the patient's actual condition, with an omission rate of 12 percent.[22] A synthesized case example of a psychiatric patient presents the adverse consequences for the patient if essential information is not communicated.[94] The importance of communicating objective descriptions of the patient condition is highlighted.

A study focusing on assessing the effects of manipulating information in a shift handoff on the receiving nurse's care planning found in the different types of taped reports that the information recalled ranged from 20 percent to 34 percent.[95] Another study, by Pothier and colleagues,[55] examined different methods for transferring information during 5 consecutive simulated handoffs of 12 fictional patients. Three methods of handoffs were analyzed; the method demonstrating the greatest amount of information retention involved utilization of a preprinted sheet containing patient information with verbal report, followed by note taking and verbal report method, and lastly, only verbal report. The retained total data points for each style of handoff varied considerably during the five handoffs. Over 96 percent to 100 percent of information was retained using the preprinted sheet containing patient information and verbal report. Only 31 percent to 58 percent of the data were retained using the note taking style and verbal report.[55] The verbal-only style demonstrated the greatest amount of information loss, with retention ranging from 0 percent to 26 percent.[55] None of the data was retained using the verbal-only method for two handoff cycles. The insertion of incorrect information was observed in the verbal-only method. The generation of incorrect data did not occur at all during the handoff with the written or preprinted form style of report. This study[55] supports the use of a consistent preprinted form with relevant patient information during shift report, with less reliance on verbal-only reports, in order to optimize communication.

Nursing Unit-to-Nursing Unit Handoff

Patients may be transferred frequently during their hospital stays.[28] Yet, the patient transfer is fraught with potential problems and can have an adverse impact on patients.[96, 97] Issues have been identified in the transfer handoff process, including incomplete medical records and omission of essential information during the handoff report.[64] A number of factors that contribute to inefficiency during patient transfers from one nursing unit to another have been identified,[97] including delay or wasted time caused by communication breakdowns, waiting for responses from other nurses or physicians or a response from patient placement management or bed control.[97] Bed control involves personnel who manage the bed assignments of new and transferring patients. Decreasing the number of transfers is a possible strategy to decrease risks associated with handoffs.[58]

Nursing Unit to Diagnostic Area

Patients are frequently sent from a nursing unit to diagnostic areas during the normal course of a hospitalization. Transfers have been cited as a contributor to medication errors between nursing units and diagnostic areas (e.g., radiology, cardiac catheterization, nuclear medicine).[19] It is important when patients change nursing units, particularly to a different level of care, or go to a procedure in another department that there is clear, consistent communication and that the receiving area staff have the information they need to safely care for the patient.[34] Complexity of the patient's condition may require that the nurse caring for the patient actually accompanies the patient to the new setting.

Special Settings

Operating room and postanesthesia. Several special handoff situations occur in certain hospital settings. The operating room (OR) is considered "one of the most complex work environments in health care"[98] (p. 159), with a reported mean of 4.8 handoffs per case. Nursing staff average 2.8 handoffs per case, with a range of one to seven handoffs.[98]

There have been at least 615 wrong-site surgeries reported to the Joint Commission between 1995 and 2007.[99] To help prevent wrong-site surgery, the Joint Commission developed the Universal Protocol for Preventing Wrong Site Surgery, Wrong Procedure, Wrong Person Surgery™.[100, 101] It is based on the consensus of experts and endorsed by more than 50 professional organizations.[100] Effective interdisciplinary communication is critical. For example, a health care organization using a perioperative briefing process reported that no wrong-site surgeries have occurred since the adoption of the interdisciplinary briefings.[44]

Dierks suggests five categories for handoffs in the OR: (1) baseline metrics/benchmarks, (2) most recent phase of care, (3) current status, (4) expectations for the next phase of care, and (5) other issues such as "who is to be contacted for specific issues"[102] (p. 10). The use of a team checklist in the OR was pilot tested in another study and found to show "promise as a method for improving the quality and safety of patient care in the OR"[103] (p. 345).

A study focused on OR communication processes identified a number of patterns and found the most common reason for communication in 2,074 episodes was coordination of equipment, followed by "preparedness" for surgery.[104] The authors recommend increasing the use of automated processes to enhance process flow, especially related to "equipment management," thereby helping with transmission of information in a more efficient manner.[104]

Communication in handoffs is critical in all phases of care. However, a survey of 276 handoffs conducted in a postanesthesia care unit (PACU) revealed 20 percent of postoperative instructions were either not documented or written illegibly.[105] The nurses rated the handoffs from anesthesia staff as "good" in 48 percent of cases, "satisfactory" in 28 percent, and "bad" in 24 percent.[105] A number of suggestions for improving the quality of the postanesthesia care unit handoff protocol were presented including the need to communicate information verbally to the nurse.[105]

Emergency department. A study of five emergency departments (EDs) revealed that there were differences in the characteristics of handoffs among the EDs studied, but "nearly universal" attributes of handoffs were also noted.[106] The researchers developed a conceptual framework for addressing handoffs in the emergency setting. The handoffs were not one way communication processes as both the offgoing and oncoming providers were engaged in interactive handoffs. [106]

According to Behara and colleagues,[106] 8 of 21 handoff strategies used in other industries[2] were observed "consistently" in the ED setting, while four were used less often and nine were not or rarely used. The handoff in the ED setting is viewed as a "rich source for adverse events"[17] (p. 1). There are inherent risks in handoffs, but it was also noted that the handoff can provide the opportunity for two health care providers to assess the same situation and identify a "previously unrecognized problem"[17] (p. 2).

Studies focused on emergency nursing handoffs highlight unique aspects of this process.[107, 108] Currie reported in a survey of 28 ED nurses that the top three concerns nurses had with handoffs were missing information, distractions, and lack of confidentiality.[108] Recommendations included the development of guidelines to improve the handoff process in the ED.

Discharge and Interfacility Transfer Handoff

Handoffs from one facility to another occur frequently between many different settings.[68–70, 71, 72, 73, 109–111] Handoffs take place between hospitals when patients require a different level of care. The usual interfacility handoffs are between hospitals and long-term care facilities, rehabilitation centers, home health agencies, and hospice organizations. The factor that tends to make these handoffs challenging is gaps and barriers to communication among these agencies.[68, 111, 112] Handoffs between facilities are also impacted by the cultural differences between the types of facility.[73] Agencies are often geographically separate, requiring physical relocation of the patient, belongings, and paper records. Once the transfer has taken place, seeking additional information becomes a challenge.[73]

The continuity of patient care requires communication among various health care organizations.[68, 71, 73, 110, 113–115] One problem noted is nurses in different settings have different perceptions about what is important to be conveyed, such as different perceptions between the hospital and home health care.[70, 116] Another area of concern noted in transfers from hospitals to other health care organizations is incomplete documentation. More information was transmitted when a standard form to communicate information was utilized between a hospital and home health agency (HHA).[69] The usage of referral forms varies among health care institutions.[109] Rates of transmission of information differ from hospitals to HHAs[69, 109, 113] and to extended-care facilities.[72] It was found that HHAs affiliated with hospitals received more referral data than free-standing HHAs.[113]

Discharge planning forms address "the anticipation of a certain type of gap and also of an effort to create a bridge to permit care to flow smoothly over the gap"[67] (p. 793). One example of the development of such a form using "a consensus process" resulted in the implementation of a Patient Transition Information Checklist to help improve communication between hospitals and nursing homes.[114] Another type of form for communication of patient information among health care organizations was developed in Germany; however, followup revealed use of the form was not as widespread as anticipated because process barriers emerged, precluding users from easily completing and transmitting the forms.[111] Development of any type of "patient accompanying form"[111] requires numerous considerations and a balance between being comprehensive and not being cumbersome to use.[111] There also needs to be adequate resources to allow health care providers to retrieve necessary data and transmit patient information between agencies.[111]

Inadequate discharge planning has been implicated in adverse outcomes of patients.[117, 118, 119] A study of 400 patients found 76 patients incurred an adverse outcome after discharge from the hospital. The researchers reported "ineffective communication contributed to many of the

preventable and ameliorable adverse events"[119] (p. 166). The most frequent type of adverse event was related to medications. The implications of this study indicate the need to enhance communication in the handoff between the hospital and posthospital care. Suggested potential strategies to improve the handoff include discharge planning and education of patients related to medications prior to discharge.[119]

A number of contributors to a failed handoff in the discharge planning process have been identified, including, lack of knowledge about the discharge process,[117] lack of time,[117] lack of effective communication,[119, 120] patient and family issues,[117, 120] system issues,[120] and staffing issues.[117, 120] Communication issues have emerged as a potential contributor to readmissions.[121] An ineffective nursing handoff has been identified as a contributor to miscommunication within the discharge process.[122] The improvement of discharge planning requires that emphasis be placed on collaboration and interdisciplinary communication.[112] Well-orchestrated discharge planning is recommended to help improve patient safety[123] by controlling the risk of gaps occurring in the discharge process and its inherent handoffs.

Handoffs and Medications

Medication errors are considered preventable events.[124] Handoff issues (e.g., transfer, shift change, cross-coverage) have been identified by the United States Pharmacopeia (USP) through its MEDMARX® reporting program as a contributing factor to medication errors within health care organizations.[19, 24]

Incomplete transfer of medication information is recognized as a possible contributor to patient safety problems as patients are discharged from the hospital.[119, 125] Reasons for medication handoff failures include incomplete patient education and the "inability of ambulatory care providers (including nursing homes) to receive discharge medication information"[126] (p. 93). Medication changes during the transition (handoff) from hospital to skilled nursing facilities were identified as a cause of adverse drug events in a New York study.[127] One study reported patients who received medication information and counseling demonstrated more compliance with their medication regimen than patients who did not receive such information.[128]

There are multiple case examples of medication errors related to handoffs across the continuum of care.[129, 130] In fact, USP has reported that 66 percent of medication reconciliation errors occur during the transfer or transition of a patient to another care level.[130] A number of recommendations have been developed to improve the medication reconciliation process and reduce risks for patients.[130, 131] In addition, medication reconciliation is a Joint Commission patient safety goal,[47] with specific requirements for the process.[47, 132]

Physician-to-Physician Handoffs

Studies conducted to better understand physician-to-physician handoffs[31, 33] may have implications for nurses. Poor handoffs included omissions of essential information such as medications, code status, and anticipated problems.[31] Other issues contributing to failed communication processes included lack of face-to-face interaction and illegible documentation.[31] The weaknesses identified in another handoff study included incomplete and or illegible information, difficulty accessing clinical information quickly, communication failures, and difficulty contacting other doctors.[33] Strategies to address handoff problems include providing

legible, accurate, relevant, comprehensive information and the use of a face-to-face report.[31] Suggestions for improvement include development of a process to enhance transmission of information, for example, the adoption of templates; use of technology; use of communication processes such as SBAR, education, and evaluation of handoffs;[31] and a standardized handoff process.[33]

Evidence-Based Practice Implications—Handoffs for Today's Health Care Environment

The Australian Council for Safety and Quality in Health Care evaluated 777 papers for possible inclusion in a literature review on handoffs.[1] A total of 27 papers met the inclusion criteria, but it was reported that "no best practice" (p. 2) existed related to systems emerged in the search—although a number of recommendations were provided for systems, organizational, and individual factors.[1] Handoffs are an extremely complex phenomenon to study as they occur in a variety of settings; stages along the continuum of care; and among various personnel with different skill sets, priorities, and educational levels.

Contributors to handoff problems included failed communication,[4, 5, 6, 7, 10, 31] omissions,[31, 64, 108] distractions,[108] lack of or illegible documentation,[31, 33, 73] lack of utilization of transfer forms,[69] incomplete medical records,[64] lack of medication reconciliation,[129, 130] and lack of easy accessibility to information.[6, 33, 73] A variety of environmental issues emerged—including designs[28, 58]—that served to increase, rather than decrease, the number of handoffs. Interfacility handoffs posed a number of challenges, including cultural differences[73] and lack of integrated systems, thereby increasing the likelihood of transmission difficulties between organizations. Organizational and system failures or lack of systems to support the handoff process emerged as contributors to adverse events.[4, 6, 7, 10] A lack of knowledge was found regarding effective handoff processes,[117] and education on effective handoff strategies was also lacking.[3, 117] Handoff processes need to include consideration of the person involved in the handoff and their level of education, expertise, and comprehension (e.g., the novice nurse's informational needs may be different from the expert nurse).[41] Novices also differ from expert nurses in their use of information.[84]

There must be an organizational commitment to the development and implementation of systems that support effective handoffs as well as a just culture.[133, 134] This includes cultures of safety and learning.[134] A safety culture supports identifications of problems and errors to be addressed to prevent the recurrence.[134–136] A culture of learning promotes learning from the experiences of the past to prevent a recurrence of tragic fumbled handoffs. Environments and processes need to be designed to promote desired outcomes[76] and enhance patient safety.[137]

Electronic Support of Handoffs

A number of reports and studies have called for systems that allow ease of access to accurate information to improve handoffs.[6, 10, 15, 29, 89, 138] Electronic technology requires that design issues be considered and adequate resources be allocated for successful implementation and acceptance.[139] Research of computerized support for physician handoffs suggests this is a strategy that merits further consideration and evaluation.[16] A study at two hospitals reported the implementation of a computerized system for resident handoff enhanced delivery of care and decreased the number of patients missed on rounds.[138] There have been limited studies on

computerized clinical documentation systems (CDS) in the nursing shift handoff. One study reported nurses perceived shift-to-shift handoffs more positively after the implementation of the CDS.[140] Access to a physician computerized sign-out was rated positively by nurses and was reported to improve communication.[141]

Decrease Transfers of Patients

Decreasing the number of patient transfers may reduce the risks that occur during handoffs.[58] It has been suggested that "many patient transfers could be prevented by altering facility designs and nursing care models found in acute care hospitals"[97] (p. 163), thereby decreasing the need for handoffs. The implementation of "acuity-adaptable rooms" demonstrated a 90-percent decrease in patient transports; the same study also reported a decrease in medication errors of 70 percent.[28] More research of this strategy is recommended.[58]

Effective Handoff Process

A recurrent theme observed in the handoff literature is the need to convey essential information to the oncoming shift or provider. A standardized process to guide the transfer of critical information has been recommended.[33, 34, 45, 48, 108] The use of protocols that include the use of phonetic and numeric clarifications are important in helping convey information accurately.[11, 136] The Sentara health care organization adopted behavior-based expectations to improve the handoff process and used tools including the five Ps (patient/project, plan, purpose, problems, and precautions).[136] It reported a 21-percent increase in effective handoffs.[142] A medical center using SBAR in the handoff process reported less missing information in handoffs after implementation of SBAR.[45] The use of protocols such as safe practice recommendations related to reconciling medications[131, 132] and communicating critical test results[49, 50] should be used in designing strategies for more effective handoffs. Some hospitals have reported developing strategies to improve the communication between the hospital and other providers.[44, 71, 73, 74, 114] A summary of problems and barriers with handoffs observed in this review of literature are presented in Tables 4, 5, and 6. Strategies that have been reported in the literature are also included in the tables; however, more research is needed to identify evidence-based guidelines. The Evidence Table at the end of this chapter presents a summary of selected sources addressing handoffs.

Human Factors

The study of human factors engineering is currently being used to improve patient safety,[76] and there are an increasing number of strategies and tools that can be used to design systems in a manner to decrease adverse outcomes. Designs to promote patient safety should include integration with "forcing" functions to prevent errors. However, there needs to be testing of proposed solutions to assure validity of these tools in the health care environment.[76] Lessons learned from other industries are fostering the adoption of human factors principles and increasingly being used in health care.[44, 137, 143–146]

Studies of handoffs in other industries have been analyzed for possible implications for health care. Patterson and colleagues[2] analyzed data from four studies[147–150] and described 21 handoff strategies. According to their findings, strategies that could be applied to shift handoff

included interactive questioning, face-to-face handoff, forcing functions such as passing a pager to initiate handoff to the oncoming nurse to indicate an unambiguous transfer of responsibility, flagging critical information, and reduction of interruptions.[2] The researchers note a question remains "if the strategies can be generalized to health care"[2] (p. 132), and call for additional research in this area.

Research Implications

Following are suggested questions for future research:

- What are the best systems designs to reduce unnecessary handoffs? How can they best be implemented?
- What are best strategies for handoffs in various settings (i.e., nurse to nurse, unit to unit, agency to agency, physician to nurse)?
- What are the most effective strategies, instruments, and tools to employ to assure maximum transfer of and receipt of accurate, relevant, up-to-date information?
- How can electronic technology best be deployed to support and enhance effective handoffs, decrease errors, and improve patient safety and patient outcomes?
- What are the best techniques for assuring critical information is forwarded and not omitted or overlooked when received?
- How can handoff contributors to medication errors be addressed and decreased?
- What are the critical data elements that should be transferred by type of service, specialty, profession, and setting?

Basic to the provision of quality health care is the ability to communicate with one another and safely handoff patient care in a seamless manner so every patient can benefit from each phase of care through a well-executed handoff. This is a process that is ubiquitous but also a high-risk endeavor in many settings. More research is needed in this critical patient safety arena to promote interdisciplinary approaches to patient safety throughout the continuum of care.

Table 4. Factors, Problems, and Strategies Cited in the Literature

External & internal factors that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Handoff communication	Language problems may contribute to problems during handoffs in several ways. Different dialects, accents, and nuances may be misunderstood or misinterpreted by the nurse receiving report. Abbreviations and acronyms that are unique to certain settings may be confusing to a nurse working in a different setting or specialty. Medications may have similar sounding names, increasing risk for confusion.	• Face-to-face handoff is preferred[31, 35] to allow verbal and nonverbal exchanges and interactive communication and questions.[47, 48] • Standardize forms, checklists, or tools (customized as agreed to by clinicians for specific practice areas) so that all users will understand the information from the same context.[34] • Allow opportunity for questions and clarification during the handoff.[2, 34, 47, 48] • Use a "read back" "repeat back" to decrease communications errors.[34, 47, 49] • Use phonetic and numeric clarifications.[136] • Verify information.[47] • Implement safe practice recommendations for communicating critical test results[50] • Speak in simple, clear, straightforward manner and be specific in description of patient and situation.[34] • Avoid the use of abbreviations and jargon, which may not be understood.[34, 151] • Provide definition of ambiguous terms. • Allow receiver of handoff to review relevant summary and data (history, treatments, and services) and current information.[48] • Allow for oncoming and offgoing clinicians to assess situation.[35] • Include anticipated problems or changes in report.[31]	Arora 2005[31] Barenfanger 2004[49] Haig 2006[45] Hanna 2005[50] ISMP 2005[151] Joint Commission[47, 48] Joint Commission International Center for Patient Safety 2005[34] Simpson 2005[35] Yates 2005[136]
Distractions	Situational factors during a handoff can contribute to distractions.	• Provide handoff in a location/environment that minimizes distractions.[157]	White 2004[157]
Interruptions	Interruptions are reported to occur frequently in the health care setting.	• Limit and discourage interruptions.[2, 4, 34, 48, 108] and provide coverage of other duties during handoff to support focused transition	Beach 2006[4] Currie 2002[108] Joint Commission 2008[48] Joint Commission International Center for Patient Safety[34] Patterson 2004[2]

External & internal factors that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Noise	Background noises such as pagers, phones, overhead paging, equipment noise, alarms, and talking contribute to increased difficulty in hearing report and can lead to inaccurate interpretation of information.	• Provide handoff in a location/environment that allows those involved in the handoff to clearly hear the information.[3] • Use a "read back" to decrease communications errors.[47, 49] • Use phonetic and numeric clarifications.[136]	Barenfanger 2004[49] Joint Commission[47] Solet 2005[3] Yates 2005[136]
Fatigue	Increased errors are noted in nurses working prolonged shifts.	• Limit the amount of hours worked to reduce fatigue and errors associated with fatigue.[58, 153, 154, 155]	Hughes & Rogers 2004[153] Institute of Medicine 2004[58] Rogers 2004[154] Scott 2006[155]
Memory	Short-term memory is limited and lapses may occur when large amounts of information are communicated during a handoff.	• Design systems to reduce reliance on memory.[76, 157] • Use preprinted patient information forms for accuracy and completeness of information in handoff.[55] • Provide health care providers with access to data to reduce reliance on memory in handoff.[55, 157]	Gosbee & Gosbee 2005[76] Parker & Coiera 2000[152] Pothier 2005[55] White 2004[157]
Knowledge/ experiences in handoffs	Novice nurses and expert nurses have different needs.[158] Novice nurses may encounter issues with handoffs. Novice nurse may need supplemental information during the handoff. Staff may not have been educated on strategies for an effective handoff and discharge planning.	• Support novice nurses with orientation and preceptor programs. • Provide continuing education programs on effective handoff strategies.[45] • Provide experienced consultants to less-experienced nurses as they may not have skills in their repertoire for advanced problem-solving.[37, 84] • Provide comprehensive, pertinent information, but avoid overload during handoff.[78]	Benner 1984[158] Ebright 2004[37] Haig 2006[45] Kerr 2002[78] Taylor 2002[84]
Written communication	Trying to interpret illegible notes from another provider may create errors in communication.	• Use electronic strategies to decrease problems with illegibility.[159] • Use standardized processes (customized to a clinical area, practice setting) to assure critical information is communicated in handoff.[34, 35]	Joint Commission International Center for Patient Safety 2005[34] Simpson 2005[35] Upperman 2005[159]

External & internal factors that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Variation in processes	There may be wide variance in the way a handoff is conducted that may lead to omission of critical information and contribute to medical and medication errors.	• Adopt a standardized, consistent approach to the handoff to decrease errors.[33,34] • Adopt and use behavior-based expectations to reduce risks and promote patient safety. Tools to use during handoffs include the 5 Ps for Patient/Project, Plan, Purpose, Problems, Precautions[136] and Situation, Background, Assessment Recommendation (SBAR).[34, 44, 45] • Communicate essential patient care information.[34] • Develop and implement a systematic process for the reconciliation of patient's medications to decrease risk associated with transfers and transitions to other levels of care.[130, 131, 132]	Bomba & Prakash 2005[33] Joint Commission 2006[132] Joint Commission International Center for Patient Safety 2005, 2006[34] Haig 2006[45] Leonard 2004[44] Massachusetts Coalition for the Prevention of Medical Errors 2005[131] USP 2005[130] Yates 2005[136]

Table 5. Issues, Problems, and Strategies Cited in the Literature

Organizational/system issues that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Culture	In a culture that lacks sufficient focus on safety and learning, staff may be reluctant to report problems or may not feel comfortable asking questions.	• Support the development of a culture of safety where reporting of errors and problems is accepted and encouraged.[58, 133, 134] • Encourage the development of a "learning culture"[134] and a "just culture."[133, 134]	Institute of Medicine 2004[58] Marx 2001[133] Reason 1997[134]
Hierarchy	Hierarchical structure may impede open communication. The nurse may not feel comfortable asking questions to clarify information or may feel intimidated.	• Promote culture of safety where open communication is supported.[58, 160, 161] • Develop protocols or policies that support a culture of respect, collaboration, and collegiality among all nurses and health care providers.[161] • Provide education for all health care providers on effective communication strategies such as the use of SBAR (situation, background, assessment and recommendation) to enhance communication.[44, 45, 144]	American Association of Critical-Care Nurses 2005[161] Haig 2006[45] Institute of Medicine 2004[58] Leonard 2004[44] McFerran 2005[144] White 2004[160]

Organizational/system issues that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Systems support	Lack of time to access information and complete report will reduce time for questions and answers.	• Assure that there is time to complete the handoff report. • The receiving health care provider needs to have access to pertinent, accurate, timely patient information.[34, 48] • Recognize that a handoff requires the opportunity for interactive questions and answers.[34, 48] • Develop systems that support efficient operations in the retrieval of data in a timely manner to allow updated, current, accurate information to be provided to the receiver of the handoff.[34, 138, 141]	Joint Commission 2008[48] Joint Commission International Center for Patient Safety 2005[34] Sidlow & Katz-Sidlow 2006[141] Van Eaton 2005[138]
Infrastructure	There may be inadequate staff, tools, or equipment for effective handoffs.	• The leadership needs to promote the design and implementation of systems within an environment to provide safe patient care.[58] • Provide adequate human resources, equipment, technology, and educational opportunities to promote optimal handoffs.[58] • Involve nurses in the design of work environments.[58]	Institute of Medicine 2004[58]
Transfer of patients (within health care organization)	Increased number of transfers increases the need for handoffs.	• Consider health care delivery design models in which patient transfers are minimized.[28] • Include nursing staff in the design of handoff processes.[58]	Hendrich 2004[28] Institute of Medicine 2004[58]
Physical space limitations for handoffs	Environment may not be conducive to conducting a handoff (interruptions, noisy).	• Include health care providers in the design of work environments so adequate space requirement and configurations are identified.	Institute of Medicine 2004[58]
Technology limitations and use of manual reports and records/ difficulty accessing essential information	Lack of technology may create voluminous paper records (medication records, lab reports) with multiple reports to be referenced for handoffs to another unit, setting, or facility.	• Design electronic systems that support the easy retrieval of accurate and timely data.[34, 141, 163] • Provide for adequate planning processes, infrastructure, human resources, and education to successfully implement electronic support.[139, 162]	Ash 2003[162] Joint Commission International Center for Patient Safety 2005[34] Karsh 2004[139] Sidlow & Katz-Sidlow 2006[141] Van Eaton 2004[163]
Different cultures or organizations	Organizations may have different goals, focus, and resources.	• Develop processes between sending and receiving organizations to assure both organizations are aware of requirements for handoff.[44, 73] • Plan resource allocation to meet the patient needs.[44]	Davis 2005[73] Leonard 2004[44]

Organizational/system issues that contribute to errors	Problem/barrier associated with patient safety issues	Practice implications (strategies for reducing errors and improving safety)	References
Intra- or extra-system transfers	Transfers to a setting/facility within a single system may create fewer problems than a transfer to a different system/health care provider in which different forms and technologies are used. Transfers require efforts to assure continuity of care as the patient transitions to another level of care.	• Seek to design systems, processes, and policies that allow for collaboration and efficient transfer of essential information between organizations during handoff.[68, 69, 73, 111, 112, 115] • Complete medication reconciliation process.[129, 132] • Remove barriers to communication. • Assure a bidirectional communication process between health care providers.[110] • Communication involves verbal, written, and electronic means. • Monitor process for opportunities for improvement.[44]	Anderson & Helms 1993[69] Anderson & Helms 2000[68] Coleman & Boult 2003[110] Cortes 2004[114] Davis 2005[73] Hansen[112] Institute for Safe Medication Practices 2005[129] Joint Commission International Center for Patient Safety 2006[132] Leonard 2004[44] Nicholson 2003[74] Satzinger 2005[111] USP 2005[129] Wachter & Shojania 2004[11]
Staffing limitations	Staffing shortages may contribute to gaps in transmission of information in handoff.	• Allocate adequate human resources to support handoffs and meet patient care needs/functions.[58, 111]	Institute of Medicine 2004[58] Satzinger 2005[111]
Equipment failures	A number of devices are used in a handoff. Critical information may not be transmitted if electronic devices fail.	• Follow up on critical information to assure it was received.[2] • Monitor, replace equipment, supplies to reduce contributors to communication failures.[53] • Upgrade equipment to improve communication processes.[2]	Patterson 2004[2] Prouse 1995[53]
Lines of responsibility	Persons entering into a handoff situation may not be clear on when responsibility of patient/situation is transferred, which can lead to a “fumbled” handoff, if the responsibility for care of patient and of followup is not clearly delineated.	• Use a forcing function[2, 44] to indicate the transfer of responsibility such as by passing a pager indicating that the receiving nurse is accepting responsibly for the patient and confirming the transfer of responsibility.[2,] • Unambiguous transfer of responsibility.[2] • Clearly define responsibility at transition.[4]	Beach 2006[4] Leonard 2004[44] Patterson 2004[2]
Tight time constraints	Time constraints during handoffs (e.g., pressure to increase patient flow across the system) may contribute to a report that is rushed and incomplete.	• Assure there is time for interaction and question and answer during a handoff.[34] • Allow receiver of information to review relevant information.[48]	Joint Commission International Center for Patient Safety 2005[34] Joint Commission 2008[48]

Table 6. Issues, Problems, and Strategies Cited in the Literature

Special Issues	Problem/barrier associated with handoff	Practice implications (strategies for reducing errors and improving safety)	References
Emergency situations/critical activities	Handoffs in a critical situation present a number of challenges.	• Remain for the completion of handoff until it is clear that critical information has been received and the transfer of responsibility has occurred by the accepting health care provider team.[35] • It may be necessary to delay handoff in critical situation to assure concerns are addressed.[2,4 35] • Exercise caution and situational awareness in emergency situations to assure all information is transmitted and received and continuity of care is provided.[4]	Beach 2006[4] Patterson 2004[2] Simpson 2005[35]
Code status	Code (Do Not Resuscitate (DNR)) status may be omitted from handoff report and not documented in medical record, or information may not be accessible.	• DNR status needs to be documented and communicated so members of the health care team are aware of status.[164] • Communicate code status in handoffs.[31, 164]	Arora 2005[31] Goldstein 2006[164]
Critically ill or labile patient	Offgoing and oncoming shifts may perceive patient situation differently, and the patient situation may change during the actual shift transition.	• Bedside report, walking rounds afford both the offgoing and oncoming shifts the opportunity to observe the patient together; address and problem-solve together; clarify issues; answer questions; and assure continuity of care.[17, 22, 35]	Perry 2004[17] Richard 1988[22] Simpson 2005[35]
Variable resources on, off shifts	Transfer handoff may occur after normal business hours when resources are less available, increasing the possibility information will be omitted.	• Assure critical information is documented and transmitted. In addition allow for an interactive report so that questions can be answered and issues addressed.[44] • Assure that all medication information is documented for the receiving facility. • Reconcile medications.[129, 130, 131, 132] • Design “forcing functions” to reduce ambiguity and confirm acceptance of assignment.[2, 44] • Coordinate adequate staff coverage to support patient care handoffs.[44] • Communicate to and confirm acceptance of transfer and allow exchange of essential information.[35, 44]	ISMP 2005[129] Joint Commission International Center for Patient Safety 2006[132] Leonard 2004[44] Patterson 2004[2] Simpson 2005[35] USP 2005[130]

Search Strategy

To retrieve pertinent literature on the topic of handoffs, the following databases were reviewed: Academic Search Premier, CINAHL, Pre-CINAHL, EMBASE, Ovid's Medline, PubMed, and PsychInfo. The databases were searched for variants of the words "handover" and "handoff," "shift report," and "changeover." Additionally, the databases were searched for groups of subject terms representing the concepts of patient transfer, communication, and continuity of care. The use and combination of subject headings varied depending on the characteristics of each database. Searches for the concept of patient transfer used the following subject headings: transfer, discharge; transfer, intrahospital; patient discharge; transportation of patients; and patient transfer. The concept of communication was represented by terms such as "communication barriers," "communication," "communication skills," "communication theory," and "interpersonal communication." Subject headings focusing on the concept of overall health care delivery or quality included quality of care, health care delivery, continuity of patient care, patient safety, and medical care.

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Evidence Table. Selected Sources on Handoffs—Nursing Handoffs, Quality Improvement Activities, Interdisciplinary Handoffs

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Anderson & Helms 1993[69]	Handoff between hospital and home health agency (HHA)	Descriptive retrospective study	Inventory Referral Information (IRI) 40 items. Score 0–40 Monitor type, amount of information the HHA received from the hospital	Illinois, Iowa 300 patient records 1988–1990 Referrals of 6 hospitals to 4 HHAs	No intervention	• Scores ranged from 7 to 35 items completed • Hospital affiliated HHA received more data than nonaffiliated HHA • More information transmitted between hospital and HHA when a standard form used
Atwal 2002[122]	Discharge planning	Qualitative	Interview of nurses utilizing critical incident technique Observation of nurses and other health care providers	19 nurses Interviewed Observation at multidisciplinary meetings	No intervention	• Miscommunication of information • Observed other priorities precluded attendance at multidisciplinary meetings • Strained “interprofessional relationships”
Australian Council for Safety and Quality in Health Care 2005[1]	Handoffs	Literature review	Retrieval of literature that addresses handover and safety in both health and nonhealth literature The literature review report includes sources from 1993–2004.	777 papers reviewed Only 27 met inclusion criteria 8 non-health care 19 health care Another 21 papers did not meet criteria but were termed useful.	Studies with interventions reviewed included computerized documentation system, interdisciplinary rounds, Other reports included observational studies cases studies	• Quality of evidence on clinical handoffs deemed “extremely poor” (p. 5). • Majority are descriptive studies. • Three domains identified. • System design factors: 17 papers • Organizational/culture: 6 papers • Individual factors: 4 papers • Recommendations for each of the three domains are provided.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Bruce & Suserud 2005[107]	Experiences of emergency nurses receiving patients who are attended by ambulance nurses	Qualitative descriptive	Four themes were identified: prehospital reporting, symbolic handover, ideal handover, nonideal handover.	Sweden 6 nurses	No intervention Analyze experiences of emergency nurses and the handover and triage process	• Reportedly the first study of ambulance nurse to emergency nurse handover. • Interface between prehospital and hospital is critical. • The researchers recommend "the handover process needs to be structured and made uniform" (p. 208). • The ideal handover was described as one that was patient focused and the problems were communicated "clearly." • Authors identify questions to be asked during the handoff.
Behara 2005[106]	Emergency department (ED) transitions	Qualitative ethnographic	Observation of shift changes, and additional types of exchanges and investigations. Content analysis and grounded theory. Development of conceptual framework.	United States and Canada 5 EDs: 3 inner city 1 private tertiary center 1 community	No intervention	• Variety in types of handovers observed • "Nearly universal" attributes of ED handoffs identified. • Conceptual framework included four attributes: 1. Type of process 2. Content 3. Structure 4. Dynamic
Cahill 1998[52]	Bedside handoff (patient perceptions)	Qualitative design using a grounded theory approach	Three major categories emerged from the interviews with patients: • 'Maintaining a professional distance' • 'Establishing professional sharing' • 'Maintaining patient safety'	Nursing Unit 10 patients	No intervention	• Maintaining patient safety identified as "primary purpose" • Patients expressed concern not always understanding the terms used by nurses in report. • The patients reported handoffs were short in duration, lasting no longer than 2 minutes. • Some patients did wish to be involved in the handoff process, but not all patients did.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Currie 2002[108]	The handoff in an ED setting	Survey/ Questionnaire	Questionnaire addressed 12 topics in handoff (examples include; patient name & age, medical history & medications, vital signs, plan of care, and other topics.) Also included problems with handoff and preference for bedside or nurses' station handoff.	Emergency admissions and assessment unit. 28 nurses	No intervention	• Problems with handoffs included missing information, distractions, and lack of confidentiality. • High-priority topics included reason for admission, treatment, name, age, restrictions, plan of care, and medical history. • Recommended a standard handoff and use of clinical guideline • Suggested a strategy for handoffs using an acronym of confidential, uninterrupted, brief, accurate, and named nurse (CUBAN); however, it has not been evaluated.
Dowding 2001[95]	Shift report	Experimental factorial design	Two independent variables: 1. Type of shift report (retrospective, prospective) 2. Schema-type information (consistent, inconsistent) Dependent variables: amount of information documented, recalled and the plan of care.	Scotland Two hospitals Medical and surgical wards 48 nurses	Manipulation of a handoff (shift report). Explore the effect of manipulating information on nurse's care planning. The nurses were randomly assigned to one of the four experimental conditions.	• Type of shift report had significant effect on plan of care score. • Type of schema did have a significant effect on documentation and recall, but no effect on plan of care. • Recall of information ranged 20.1% to 34.2% depending on type of report and schema. • The study conditions used an audiotape and did not allow for "'normal' shift report" with interaction and questions. • Further research is needed in a more natural setting.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Footitt 1997[91]	Evaluation of a pilot of telephone method for shift report	Piloting a new system Quality improvement	Communications and cost effectiveness of handoff process using new telephone-based system.	United Kingdom Gynecology department of hospital Sample size not specified	Implementation of Nurse Communicator System (telephone system for reports) in spring 1995	• Reported system reduced time spent in the report (handoff) • Deemed "affordable" • Allowed reinvestment of resources • Need adequate number of phone lines to support the handoff process
Greaves 1999[90]	Bedside handoff (patient perceptions)	Qualitative	Patients were interviewed and asked questions about the handoff process. Aspects explored included likes, dislikes, privacy, experience with past handoffs, areas for improvement.	Hospital Four patients Assess patient perceptions of handoffs at the bedside	No intervention	• Four themes emerged from interviews and analysis of data 1. Access to information and a desire to be included in the handoff 2. Confidentiality of patient information 3. Continuity— the communication of information from one shift to another 4. Neglect— the staff need to be available during a handoff to care for patients so patients are not at risk for "neglect"
Haig 2006[45]	Communication	Quality Improvement	Use of SBAR <u>Outcome Measures</u> Medication reconciliation Adverse events	Bloomington, Illinois Medical center	Effort to implement situation, background, assessment and recommendation (SBAR) communication tool.	• SBAR use increased to 96% in 2005. • Use of SBAR in discharge medication reconciliation increased from 53% to 89%. • Adverse events decreased.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Hardey 2000[87]	Communication of information	Qualitative ethnographic	Communication process, specifically the use of "scraps" examined. "Scraps" are "personalized recordings of information" (p. 209) on paper or in notebooks by nurses. Grounded theory analysis.	England 5 wards (geriatric) Observation of 23 handovers Observation of interactions Interviews with 34 nursing personnel Written records	No intervention	• Scraps are used for a variety of purposes such as a 'to do' list, and record information about the patient's clinical status. • Scraps were used by nurses to augment documentation due to "perceived inadequacies." • Three themes were identified related to the use of scraps: construction and content of scraps, role and use of scraps, confidentiality and disposal.
Hendrich 2004[28]	Impact of acuity-adaptable rooms on transfers, medical errors, satisfaction	Pre-post method	12 outcomes-based questions (seven addressed in article). Outcomes studied: patient complications & mortality, sentinel events, clinician satisfaction, patient satisfaction, recruitment and retention of nurses, market impact, costs	United States Hospital 2 years baseline data 3 years postimplementation data	Use of acuity-adaptable rooms	Postimplementation • 90% decrease in patient transports • 70% decrease in medication errors • Decrease in number of patient falls • Decrease in patient dissatisfaction
Hopkinson 2002[83]	Handover related to the dying patient	Qualitative phenomenological approach	Nurses were interviewed and asked to discuss caring for a dying patient.	United Kingdom Two hospital trusts Eight hospital medical wards 28 nurses	No intervention	• Two major functions of the handoff: 1. Seen as supportive as allowed nurses a venue to discuss opinions and express feelings 2. Exchange information in order to provide care .

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Kassean & Jagoo 2005[57]	Handoff process	Quality improvement project Use of force field analysis	Evaluation of bedside handover using 6 criteria based on observation Perceptions of patients' regarding bedside handoff using a 6-item, semistructured interview	Mauritius 28-bed ward 10 nonparticipant observation handovers Semistructured interviews of 40 patients	Implementation of bedside handoff	• Observation of 10 handoffs revealed a compliance rate ranging from 90% to 100% for individual criteria. • 40 patients interviewed,100% indicate confidentiality handled with sensitivity at the beside handoff. • The "targeted" goal of 80% was exceeded on this unit.
Kelly 1999[85]	Handoff process in the critical care unit	Qualitative Ethnomethodo-logical approach	The components of the handoff were examined, including the initiation, content, the handing over to the next shift.	Critical care unit 2 handover transcripts (2 handoffs)	No intervention	• Examples of the text of the shift report are provided, and interaction of the nurses is examined in depth. • Fourteen "specimens" observed related to the handoff are delineated.
Kennedy 1999[54]	Nonverbal handoff	Qualitative Study Quality improvement	Pre Non-Verbal Handoff Nonparticipant observation of bedside handoff Post nonverbal handoff Qualitative data obtained via semistructured interview of staff, Eight months post implementation of nonverbal handoff an audit of documentation was conducted	28-bed ward 41% (9) members of nursing team Stratified sample Documentation	The implementation of a nonverbal handoff system	Post nonverbal handoff: • The documentation of information addresses reporting that one "didn't hear information in the handoff. • Disadvantage: "forgetting" to document and quality of some reports. • Team preferred the nonverbal handoff • However, interviews indicated all nursing team members still passed on information verbally in addition to the nonverbal report. • Audit results indicate there was a 60% improvement in documentation 8 months post-implementation of nonverbal handoffs.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Kerr 2002[78]	Shift "handover" (handoff)	Qualitative	The handoff was observed by researchers. An interview guide was used and focused on three issues: practice (7 questions), functions (3 questions), and problems and effectiveness (9 questions).	2 pediatric units 20 handovers per unit 12 individual per unit and 2 group interviews per unit Participants included nurses, support worker, students	No intervention	• Four main functions of handoff: informational, social, organizational, educational • Three phases of handoff: pre-handover, intershift (meeting), post-handover. • A number of tensions were identified inherent in the handoff process, including tension between being comprehensive versus information overload; confidentiality issues versus family-centered care.
Lally 1999[81]	Intershift handoff	Qualitative Observation	Research question: To what extent does the intershift handover involve social cohesion of the group/team? Observation Audiotaped the handovers, used field notes, transcribed the data, and conducted qualitative analysis.	United Kingdom One ward in a hospital in the 6 shift handovers	No intervention	• The study of shift handoff revealed 16 themes within 5 categories: nursing process, learning the ropes, them and us, model in action, foreword and appendices • A number of functions were identified in the handover, including transfer of information, teaching, and enhancement of group cohesion.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Lamond 2000[21]	Shift report	Two-by-two design comparing 2 hospitals Content analysis used on audio and written data	Multidimensional scalogram analysis (MSA) of content comparing shift report and documentation Types of information in report and documentation analyzed included general, physical, physical measures (i.e., pulse, blood pressure, etc.), psychological, social, family, nursing interventions, medical treatment, global judgments, management issues.	England 2 hospitals 2 medical 2 surgical wards 5 consecutive shift handoff reports on each ward, total of 20 reports Records documentation (medical notes, kardex, care plans, etc.) from 15 patients per ward, total of 60 patients	No intervention	• Shift reports ranged from 15 to 55 minutes in duration, average 34 minutes. • Correlation between information in documentation and report was r = 0.47, *P* < 0.001.(D.Dowding, personal communication January 3, 2008) • Shift report was provided in a certain sequence on each ward. • More information recorded in records than transmitted via report • The most frequently reported aggregated items were patient name, age, consultant, diagnosis, date of admission, surgical interventions.
Leonard 2004[44]	Communication	Quality improvement	Patient transfer to skilled nursing facilities (SNFs), communication of data checklists, Employee satisfaction scores. Turnover Wrong site surgery	Kaiser Permanente	Implementation of standardized communication process (SBAR), checklists for patient transfers, briefings	Checklist: • Improvement in communication between hospital and SNF • Improvement in patient having correct medication when transferred to SNF Briefings: • Improvement in employee satisfaction by 19% • Nursing turnover decreased • No wrong site surgeries reported after briefing implemented

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Lingard 2005[103]	Communication in the operating room (OR)	Qualitative	Ethnographic observation of implementation of checklist Informal interviews to assess the benefits and disadvantages of checklist Grounded theory approach	OR of teaching medical center 33 OR staff (surgeons, nurses, anesthesiologists, residents) 18 procedures 11 interviews	Implementation of a Preoperative Team Checklist	• Checklist used successfully • Checklist discussion duration 1–6 minutes • Some inconvenience noted • Discussions were perceived as efficient by participants • Benefits outweighed inconvenience • 6 functions of checklist identified: 1. detailed, case-related information 2. confirmation of case-specific details 3. articulation of concern or ambiguity 4. decisionmaking 5. team building 6. education
Liukkonen 1993[77]	Handoff content	Content analysis qualitative and quantitative	Identified type of information discussed in the shift handoff; a total of 28,891 statements were placed in 5 content classes.	2 wards in 2 geriatric homes Audio recording of shift reports Transcripts 1,034 pages	No intervention	• Handoff reports lasted 30–90 minutes. • Most of the content related to physical needs of the patients followed by medical treatment.
Manias & Street 2000[86]	Communication practices of nurses in a handoff	Qualitative Critical ethnography	Focus on issues and activities related to handoff, including nurses' interactions. The data was analyzed using textual analysis followed by more in-depth analysis using a 4-question guide	Australia 16 bed critical care unit 6 nurses Professional journaling, observation 3 focus group interviews 2 interviews per participant	No intervention	• First a "global" handoff was presented to all nurses. Second, after assignments of nurses to patients, bedside handoff occurred, focused on individual cases • Complex communication practices emerged. • Five specific practices were identified: global handover, examination, tyranny of tidiness, tyranny of busyness, and sense of finality.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
McKenna & Walsh 1997[88]	Shift handoffs	Action research model	Four goals were identified: 1. Assess present handoff processes, trial a handoff method. 2. Complete handoffs within 30 minutes. 3. Continue care during handoff. 4. Care continuity between shifts.	Australia 44 wards medical, surgical, high dependency unit, oncology/ palliative care Audit of duration of handoff and comments from the staff	• A variety of handoff methods were trialed on the 4 wards. • Handoff methods included bedside, verbal and bedside, verbal by nurse in charge, verbal, tape recorded.	• On average handoff length decreased to less than 30 minutes. • Challenges were encountered on different units in changing the handoff process. • Different handoff processes may be suitable for some nursing wards (units) and not for others.
Menke 2001[140]	Computerized clinical documentation system (CDS)	One group pretest–post-test design	Pre- and post-test time study of nursing care /charting, medication delivery, clinical decisionmaking, documentation quality; continuity of care (shift-to-shift report)	Pediatric intensive care unit Schedule and delivery time of medications, chart review, lab values, computer record review, and questionnaire	Implementation of a computerized CDS	• After implementation of a computerized CDS, no change in time for patient care or documentation, • Improved quality of documentation. • Unable to analyze related lab normalization information due to missing information from “paper chart.” • Improved access to medical record • Increase in reimbursement

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Miller 1998[13]	Continuity of care, types of handover (handoff)	Literature review	Review of articles addressing four types of shift handoffs: recorded, bedside, written, and verbal. Literature review included other components related to the handoff, ritual, "what to say," and quality.	Literature review nursing handoffs spanning a 15-year period (1983–1998)	Literature review	• The literature addresses the "ritual" of the handover, suggestions for the content, quality of the handover. • Issue noted with the "inconsistency of information" in the handover. • Three recommendations provided: - Formal reviews of handoffs - Develop guidelines for content of handoffs - Utilize an approved "handover sheet" for nurses
O'Connell & Penney 2001[41]	Shift handover	Qualitative Grounded theory approach	Assess how nursing care is 1. determined 2. delivered 3. communicated in the hospital Three handoff methods were studied: 1. face-to-face verbal in office 2. face-to-face at the bedside 3. tape recorded	Teaching hospital 1.Semistructured interviews (n = 27) nurses, patients, relatives 2. Field observation (5 sites) 3. Informal interviews (n > 40 nurses)	No intervention	• Strengths and limitations identified for all 3 types of handoff reports. • Handoff is forum to communicate about patient. • Forum for nurses to debrief and seek clarification. • Recommendations include develop forms to guide handoff.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Parker 1992[14]	Shift handover	Qualitative observation	Observing the process, method, and content of handovers	Critical care unit, burn unit, step down unit, medical unit, surgical units, 12 handovers	No intervention	• Handovers lasted 15–45 minutes. • A variety of processes and methods were used in the handover (e.g., use of notes, computer printout, or no notes). • Four dimensions of handover: 1. Clinical: transmission of information, including treatments, and addressing problems 2. Management: addressing "deployment" of unit resources to provide care 3. Professional: includes "peer assessment" 4. Personal: allow for debriefing
Patterson 1995[64]	Continuity of care during patient transfers	Descriptive	59-item survey of nurses, addressing patient transfers	Medical Center 197 Nurses 21 units	No intervention	• 68% satisfied with information received. • 82% received patient information via phone, but not all units use telephone report. • Critically important content items identified.
Patterson 2004[2]	Handoffs in high-risk settings	Qualitative	Observation of handoffs in four different settings based on previous research findings; 21 handoff strategies listed	4 studies: NASA mission control, nuclear power plant, railroad dispatch center, ambulance center	No intervention	• Handoffs were reported to be interactive and face to face. • Commonalties in efforts to improve handoffs' effectiveness were identified across industries. • 19 handoff strategies were observed

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Payne 2000[80]	Handover	Qualitative Ethnographic	Observation of information exchanged in handover Audio taping of handovers Interviewed staff, Review of documentation	England 5 wards in geriatric unit in hospital Observation 146 hours 23 handovers 34 interviews with nursing personnel Written records; Kardex, care plans, "scraps"	No intervention	• Reports on 20–30 patients lasted about 20 minutes. • Use of jargon and abbreviations. • Reports given quickly. • Student nurses reported difficulty understanding handover reports. • Three levels of documentation observed: 1. formal/public documents, Kardex, and care plans 2. Semiformal: ward diary 3. "Personal nursing records" 'scraps' " (p. 282) *Note: related study (Hardey, 2000[87)]
Petersen 1998[16]	Computerized sign-out	Pre- and Post-Intervention Quality improvement	Patient data included sociodemographic, severity of illness, comorbidity. Outcome Measures: adverse events.	Urban teaching hospital Boston Admissions: 3,146 baseline 1,874 Pre-intervention 3,747 intervention period	Computerized sign-outs	Decrease in the rate of adverse events reported after the implementation of computerized sign-out program when compared with the baseline information.
Priest & Holmberg 2000[94]	Illustration of ineffective shift report	Qualitative Synthesized case study	Incomplete assessment on admission, ineffective shift report, adverse drug reaction, and the consequence for patient in a psychiatric setting	Synthesized case study	Nursing care rendered is examined and critiqued in synthesized case study.	• Several deficits in shift report presented and analyzed. • Need for focus on the patient and factual information during a handoff.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Pothier 2005[55]	Data loss in the handover	Quasi-experimental	Assess three methods for handoff and the differences in information retention Retention of data (total data points) Omission of data Insertion of incorrect data	Hospital 5 nurses Handoffs of 12 fictional patients	Type of handover 3 techniques studied : • Verbal only • Written—verbal with written notes • Sheet—use of preprinted sheet with patient information and verbal exchange at handover	• 96% to 100% of information was retained using the preprinted sheet containing patient information and verbal report. • 31% to 58% of the data was retained using the note-taking style and verbal report. • 0-26% data retained with "verbal only" style.
Prouse 1995[53]	Taped shift reports	Quality Improvement Project	Pilot study Study reported on staff description of taped recorded handover postimplementation	Hospice nursing ward Early and late shift handovers Sample size not specified	• Implementation of taped handovers • Evaluated at 1 and 3 months postintervention	• After implementation of taped reports handovers, described as "organised, concise, and wholly relevant."(p. 41) • Suggestion for taping and its benefits are described. • Disadvantages of taping presented briefly
Richard 1988[22]	Congruence between patient condition and shift report	Descriptive	Handoff study for incongruence, omission, omission resulting in incongruence Data Collection of 11 items	Western U.S. 19 medical surgical units of an 800-bed hospital 57 shift reports 584 patients 2,952 entries	No Intervention	• Discrepancies were noted between the reported and actual patient condition. • Overall congruence of 70% (range 68–72%) between the patient's condition and the shift report. • Overall omission rate of information was 12% (range 9–16%). • Incongruence was 12% (range 11–14%). • Significant relationship between type of reports and lack of congruence.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Sexton 2004[42]	Handover shift report	Qualitative	Observation of handover Analysis of data from audiotaped handovers Compare handoff information with documentation Information in nursing handover categorized to where information documented	Australia 30-bed medical unit in 200-bed hospital 23 handovers	No intervention	• Shift report lasted 15–50 minutes. • Some of the handovers were reported to "promote confusion." • Nurses usually did not use care plans or other formal sources in the handover. • 84.6% of information could be communicated via documentation.
Sidlow & Katz-Sidlow 2006[141]	Electronic sign-out system	Descriptive	Surveyed nurses regarding impact on nursing care after implementation of sign-out program. Likert scale survey with option for comments	New York General medical unit, in medical center 19 nurses	• Nurses given access to computerized sign-out used by physicians • Training • Provided with computer printouts and requested to use reports	• Implementation of program rated positively by nurses. • Nurses reported improved communication between nurses and physicians. • Advantages cited integration of record used by nurses and physicians
Sherlock 1995[43]	Handover	Qualitative	Observation of handovers and interviews of nursing students to study "quality and effectiveness" (p. 33)	2 medical wards 3 nursing students	No intervention	• Handovers lasted 10–61 minutes. • Variance noted in the handover process. • Teaching did not occur in the handovers observed. • Practice implications provided

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Spee 2000[93]	Handover report	Quality improvement	Handoff shift report option trialed, staff asked to document concerns during the trial. Evaluated at staff meeting. Professional practice leader reviewed documentation on census sheets during trial period.	Nursing home Two 34-bed units	Introduction of a change process to the shift handoff. Nurses were provided with 6 shift report options. One option trialed for 3 weeks	• One method chosen initially. • Another option was chosen subsequently and adopted for use. • Nurses sought to adopt option associated with decreased report time, improved documentation, and increased patient satisfaction.
Strange 1996[82]	Handover report	Qualitative	Ethnographic analysis of the handover process	One ward	No intervention	• Practices within the handover are examined. • Technical functions of handoff include transmission of information. • The ritual in handover is described.
Strople & Ottani 2006[89]	Intershift report	Literature review	Shift report purpose, methods, formats described.	Review spans 1988–2005 63 citations	Literature review	• Analysis of deficiencies and problems with shift communication presented. • Alternate methods of communication, such as computer technology, to importance of patient safety are discussed.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Taylor 2002[84]	Handover	Qualitative	Student nurses and RNs were observed conducting patient care procedures. Taped, transcribed interviews were analyzed and coded.	Hospitals Observation and interview Three groups students year 1 students year 3 RNs 18 student (novice) nurses 15 RNs (expert) nurses	No intervention	• All sought information from at least one source prior to patient procedure. • Sources of information included: handoff, documentation, knowledge of patient, other sources • Difference in how nursing students and expert nurses accessed data • Problems that novices encounter during handoff are discussed.
Timonen & Sihvonen 2000[165]	BedsideHandoff	Descriptive	Patient and nurses perceptions of report Participation by patients in report Identification of factors that influence patient participation	Finland Six hospitals 118 nurses 74 patients 76 “bedside reporting session”	No Intervention	• Reports approximately three minutes in length • Differences in patient and nurses of perceptions bedside report • Patient reported various reasons for not participating in reports including tiredness, and not being encouraged to participate
Webster 1999[56]	Bedside handoff	Action Research Quality improvement	Questionnaire used at 3 and 6 months postimplementation. 3 months: 13 questions; 6 months: 9 questions. Access to information, patient/client orientation, confidentiality, communication (quantitative & qualitative)	Medical unit 3 months: 22 surveys 6 months: 24 surveys	Change from traditional handover to bedside handover.	6 month evaluation: • 100% reported access to resuscitation status • 92% reported could access patient information. • 58% had enough time to access information, 21% not enough time, 21% unsure. • 21% confidential information discussed at bedside (area of concern). • 67% reported enough communication of information.

Source	Safety issue related to practice	Type	Study outcome measures	Setting & study population	Intervention	Key findings
Van Eaton 2005[138]	Computerized sign-out	Randomized crossover	Observation Self-reported Patients missed in rounds Time spent in rounds Assessment of intervention on continuity of care 16-question survey administered three times to assess continuity of care.	2 teaching hospitals 14 resident teams 6-surgery 8-medicine 161 residents	Computerized sign-out system	• Decrease in patients missed on rounds. • Decrease in time spent in rounds • The majority surveyed reported an improvement in continuity of care and sign-out quality.

Chapter 35. Error Reporting and Disclosure

Zane Robinson Wolf, Ronda G. Hughes

Background

This chapter examines reporting of health care errors (e.g., verbal, written, or other form of communication and/or recording of near miss and patient safety events that generally involves some form of reporting system) and these events' disclosure (e.g., communication of errors to patients and their families), including the ethical aspects of error-reporting mechanisms. The potential benefits of intrainstitutional and Web-based databases might assist nurses and other providers to prevent similar hazards and improve patient safety. Clinicians' fears of lawsuits and their self-perceptions of incompetence could be dispelled by organizational cultures emphasizing safety rather than blame. This chapter focuses on the assertion that reporting errors that result in patient harm as well as seemingly trivial errors and near misses has the potential to strengthen processes of care and improve the quality of care afforded patients.

Reporting Errors

Reporting errors is fundamental to error prevention. The focus on medical errors that followed the release of the Institute of Medicine's (IOM) report *To Err Is Human: Building a Safer Health System*[1] centered on the suggestion that preventable adverse events in hospital were a leading cause of death in the United States. This report emphasized findings from the Harvard Medical Practice Study that found that more than 70 percent of errors resulting in adverse events were considered to be secondary to negligence, and more than 90 percent were judged to be preventable.[2, 3] The IOM report also emphasized the importance of reporting errors, using systems to "hold providers accountable for performance," and "provide information that leads to improved safety." Conceptually these purposes are not incompatible, but in reality they can prove difficult to satisfy simultaneously[1] (p. 156). Nonetheless, reporting potentially harmful errors that were intercepted before harm was done, errors that did not cause harm, and near-miss errors is as important as reporting the ones that do harm patients. Patient safety initiatives target systems-related failures that contribute to errors within the complex environment of health care. Because many errors are never reported voluntarily or captured through other mechanisms, these improvement efforts may fail.

Errors that occur either do or do not harm patients and reflect numerous problems in the system,[4] such as a culture not driven toward safety and the presence of unfavorable working conditions for nurses. To effectively avoid future errors that can cause patient harm, improvements must be made on the underlying, more-common and less-harmful systems problems[5] most often associated with near misses. Systems problems can be detected through reports of errors that harm patients, errors that occur but do not result in patient harm, and errors that could have caused harm but were mitigated in some manner before they ever reached the patient. Reporting near misses (i.e., an event/occurrence where harm to the patient was avoided), which can occur 300 times more frequently than adverse events, can provide invaluable information for proactively reducing errors.[6] Analysis of reported errors have revealed many "hidden dangers" (near misses, dangerous situations, and deviations or variations) that point to

system vulnerabilities, not intentional acts of clinician performance that may eventually cause patients harm.[7]

Opinions and experiences of hospital leaders about State reporting systems were solicited from chief executive and chief operating officers of hospitals in six States with a variety of reporting systems: mandatory, nonconfidential; mandatory, confidential; and voluntary systems.[8] Questionnaires addressed perceptions of the effect of mandatory systems on error reporting, since it was thought that they reduced the frequency of error reports. Items elicited perceptions on the likelihood of lawsuits, overall patient safety, attitudes regarding release of incident reports to the public, and likelihood of reporting incidents to the States or affected patients based on hypothetical clinical vignettes varying in type and severity of patient injury. Safety was a high priority across hospitals. Most hospital leaders reported that a mandatory, nonconfidential reporting system run by the State deterred reporting of patient safety incidents to internal reporting systems. The majority thought that a mandatory, nonconfidential system encouraged lawsuits. Over half indicated that patients should learn details of errors on request by patients or families. They preferred that individual practitioner and hospital names be kept confidential and that incidents involving serious injury be reported to the State. Most indicated that the State should not release information to patients under certain circumstances. Definitions of reportable events varied by State, bringing hospital leaders to call for specific, national definitions of errors.

Just because an error did not result in a serious or potentially serious event does not negate the fact that it was and still is an error. Since reporting both errors and near misses has been key for many industries to improve safety,[6] health care organizations and the patients they serve can benefit from enabling reporting. Reporting sets up a process so that errors and near misses can be communicated to key stakeholders. Once data are compiled, health care agencies can then evaluate causes and revise and create processes to reduce the risk of errors. As such, organizations have implemented strategies, such as staff education, elicitation of staff advice, and budget appropriations, to ease the implementation of patient safety systems and to improve internal (e.g., intrainstitutional) reporting and disclosure to patients and families.

The ramifications of errors that do cause patient harm can provide critical information to inform the modification or creation of policies and procedures for averting similar errors from harming future patients. The position taken by the Joint Commission is that once errors are identified and the underlying factors/problems or "root causes" are identified, similar errors can be reduced and patient safety increased. When both errors and near misses are reported, the information can help organizations better understand exactly what happened, identify the combination of factors that caused the error/near miss to occur, determine its frequency, and predict whether it could happen again. Underreporting and failure to report errors and near misses prevents efforts to avoid future errors and thwarts the organization's and clinicians' obligation to inform/disclose to patients about the error.

As patients become more aware of actual and potential errors, they not only want to be informed, they want to know that quality improvement efforts supported by shared learning will prevent similar future errors.[9] Patients and the public support error reporting,[10, 11] particularly mandatory reporting,[12] and want to know that clinicians and organizations acknowledge errors[13] to leaders, managers, and peers, and that errors are reported as soon as they are detected.[14]

Ethical Implications of Reporting and Disclosure

Health care providers are typically so devastated and embarrassed by their mistakes that they may attempt to conceal them or defend themselves by shifting the blame to someone or something else.[15] Some attribute failure of honestly acknowledging health care mistakes to providers' personal difficulty with admitting mistakes and incriminating other providers.[16–19] Ethical frameworks operate when health care mistakes are made.[20] Respect for patient autonomy is paramount, as is the importance of veracity. Fidelity, beneficence, and nonmaleficence are all principles that orient reporting and disclosure policies. Providers might benefit from accepting responsibility for errors, reporting and discussing errors with colleagues, and disclosing errors to patients and apologizing to them.[21]

When providers tell the truth, practitioners and patients share trust. The fiduciary responsibility of institutions exists in patients' and families' trust that providers will take care of them. If providers cover up errors and mistakes, they do not necessarily stay hidden and often result in compromising the mission of health care organizations. Consistent with their mission, institutions have an ethical obligation to admit clinical mistakes. Professional and organizational policies and procedures, risk management, and performance improvement initiatives demand prompt reporting. When patients, families, and communities do not trust health care agencies, suspicion and adversarial relationships result.[18] Likewise, the breach of the principle of fidelity or truthfulness by deception damages provider-patient relationships.[22] Fidelity and trust, implicit to the provider-patient relationship, do not coexist with deception.[23]

Physicians, nurses, and other health care providers have legal and ethical obligation to report risks, benefits, and alternative treatments through informed consent mandates. Legal self-interest and vulnerability after errors are committed must be tempered by the principle of fidelity (truthfulness and loyalty).[24–26] This ethical principle has been reinforced by practical lessons learned from errors; especially when an adverse event causes serious harm or even death, there is an ethical and moral obligation to disclose information.[27, 28] Candid reports and disclosure of errors by physicians as well as other health care providers (or institutional leadership if the physician refuses to disclose)[19] might result in greater patient trust and less litigation.[29] Furthermore, it is essential to act after errors are reported, with interventions aimed at protecting the welfare of patients by targeting iatrogenic problems and documenting the care given.

Additionally, the ethical principles of beneficence (doing good) and nonmaleficence (preventing harm) are violated when errors are not reported or disclosed. These ethical principles, beneficence and nonmaleficence, shape caring nursing practice, and caring presupposes that nurses act in the best interests of patients. For example, sharing information and preventing harm to patients through truth telling, regardless of good or bad news, build relationships between elder residents and nursing home staff.[30] Putting residents' interests first represents nurse caring and characterizes relationships in which sharing information, rather than hiding it, surrenders nurses' control related to withholding information. Thus, failure to disclose health care mistakes can be viewed from the perspective of provider control over the rights of patients or residents.

Error-Reporting Mechanisms

Traditional mechanisms have utilized verbal reports and paper-based incident reports to detect and document clinically significant medical errors; yet the correlation with actual errors

has been low.[31] The benefits of these reports are dependent upon the design of the system, how and what information is collected, and whether the information is used to inform a sophisticated investigation of specific errors to understand the nature and magnitude of the problem. Additionally, reports can reflect the clinician's ability to recognize an error and willingness to report it, whether through formal reporting mechanisms or documentation in patient records. A consistent finding in the literature is that nurses and physicians can identify error events, but nurses are more likely to submit written reports or use error-reporting systems than are physicians.

Many types of errors that involve medications, health care acquired infections, and medical devices have been targeted for reporting and dissemination mechanisms.[32] In the case of medication errors, errors made by nurses during the administration of medications to patients are more likely to be reported in incident reports than are errors made by the prescribers (e.g., physicians) or distributors (e.g., pharmacists).[33] That said, it is important to note that physicians do not necessarily use incident-reporting systems.[31]

Error-reporting mechanisms may capture only a fraction of actual errors. Research has approached potential errors using direct observation, which, while expensive and not necessarily practical in all practice settings, generates more accurate error reports.[34] More recent approaches have been focusing on increasing and simplifying error reporting, and automating the detection of errors, including creating Web-based forms or adapted standard spreadsheets to reveal patterns of errors.[35] Many of these efforts have focused on improving physician participation and emphasize voluntary[31] and confidential reporting.[36] Most have encouraged reports of errors and near misses and shared occurrences with risk managers, other agency leaders, and patient safety specialists.[37] Perhaps a combination of reporting mechanisms, both concurrent and retrospective, might improve reporting and ideally result in safer processes.

Some of the challenges in using error-reporting mechanisms are associated with the lack of standard definitions, gaining easy access to databases, and the associated cost of electronic applications.[38] The capability of health care organizations' networks and hardware, the existing policies and reporting processes, including reporting actual errors and near misses, and whether the new system will provide error details to assist quality improvement initiatives must be evaluated.

Patients can also be a source of information for reports about the occurrence of adverse effects associated with medical interventions. In institutional settings, patients can provide information on new symptoms that may not be readily detected by clinician observation or testing. In outpatient settings, it could be argued that when there is no direct communication between patients and their outpatient clinicians, some unplanned emergency department (ED) visits and hospitalizations have been used to determine patients with significant, reportable, and actionable adverse drug reactions (ADRs). Two studies of patients in an outpatient setting found that patients reported more information about ADRs, the majority of which did not warrant an ED visit or hospitalization, when specifically asked, providing clinicians the opportunity to make changes in the patient's medication therapy. Without the patient's report of an ADR, clinicians would not know about the majority of ADRs affecting patients.[39, 40]

Voluntary Versus Mandatory Reporting

The IOM differentiated between mandatory and voluntary reporting of health care errors.[41] Voluntary reports may encourage practitioners to report near misses and errors, thus producing

important information that might reduce future errors. However, there is concern that with voluntary reporting, the true error frequency may be many times greater than what is actually reported.[42] Both of these types of reporting programs can be Web-based and nationally representative. Mandatory and voluntary reporting systems differ in relation to the details required in the information that is reported.

Mandatory reporting systems, usually enacted under State law, generally require reporting of sentinel events, such as specific errors, adverse events causing patient harm, and unanticipated outcomes (e.g., serious patient injury or death. It is estimated that less than half the States have some form of mandatory reporting system for adverse events—a number that is expected to grow in the next few years. One such State-mandated system is created by Pennsylvania's Medical Care Availability and Reduction of Error (MCARE) Act of 2002 (on the Web at www.mcare.state.pa.us/mclf/lib/mclf/hb1802.pdf). Another example is the New York Patient Occurrence Reporting and Tracking System (NYPORTS), a Web-based, external, confidential, mandatory reporting system that has been in existence since 1998. The focus of NYPORTS is on serious complications of acute disease, tests, and treatments. The system has 9 occurrence categories (aspiration, embolic, burns/falls, intravascular catheter related, laparoscopic, medication errors, perioperative/periprocedural, procedure related, and other statutory events) and 54 specific event codes.[43, 44]

Sentinel events, such as serious medication errors resulting in deaths, are incidents that can be voluntarily submitted to the Joint Commission in accordance with their Sentinel Event Policy (accessible at www.jointcommission.org/SentinelEvents/PolicyandProcedures), which is based on root-cause analyses. Root-cause analysis is a systematic investigation of the reported event to discover the underlying causes. The Joint Commission's position on mandatory reporting is that providers who are forced to report errors may not describe the details of the event, since they are motivated by a requirement. Nationally, the Joint Commission's Sentinel Alerts provide electronic access to selected sentinel events, identify common underlying causes, and recommend steps to prevent future events. The alerts provide clinicians the opportunity to learn about root causes of errors. Sentinel event statistics are available for clinicians to note error trends and root causes.

An example of voluntary external reporting mechanisms, specifically a Web-based, anonymous/confidential system, is the Medication Errors Reporting Program (MERP) of the United States Pharmacopoeia and the Institute for Safe Medication Practices (assessable at www.usp.org/hqi/patientSafety/mer). Reported errors make up the MEDMARX® database, which subscribing hospitals and health care systems can use as part of their quality improvement initiatives. Employees of subscriber organizations enter, review, and release data to a central data repository that is then available for all subscribers to search. Comparisons can be made within institutions of a single health care system and across participating health care systems. The sharing of data allows medication error types, locations in agencies, level of staff involved, products, and facts contributing to errors to be known and serves to alert clinicians to safety hazards. Actual, intercepted, and potential errors are all included. MEDMARX® examines the medication use process, systems, and technologies rather than individual blame and emphasizes the Joint Commission's framework for root-cause analysis.

Barriers to Error Reporting

Many errors go unreported by health care workers.[45] The major concern they have is that self-reporting will result in repercussions.[46–48] Providers' emotional responses to errors inhibit reporting, yet some are relieved when they share the events of the error with patients.[49] Health care professionals report feeling worried, guilty, and depressed following serious errors, as well as being concerned for patient safety and fearful of disciplinary actions. They also are aware of their direct responsibility for errors.[16, 50] Many nurses accept responsibility and blame themselves for serious-outcome errors.[51] Similarly, physicians responded to memorable mistakes with self-doubt, self-blame, and shame.[52] The need of clinicians for support may be fulfilled by discussing their mistake with another person. However, many received support most often from spouses rather than colleagues. Instead of bearing the pain of mistakes in silence, clinicians should admit them, share them with peers, and dispel the myth of perfect practice. However, this support might keep disclosure within the disciplinary culture and practice of medicine rather than bringing mistakes to multidisciplinary teams.

Self-reporting errors can be thwarted by several factors. First, clinicians fear career-threatening disciplinary actions and possible malpractice litigation and liability.[22, 24, 53, 54] Health care leaders who do not protect reporters of errors from negative consequences reinforce this fear,[8, 55] as does the criminalization of fatal health care mistakes.[56, 57] Fear of these negative consequences can lead to reporting errors only when a patient is harmed or when the error could not be "covered up";[58] yet more health care providers are vulnerable to legal action if detailed error reports are documented for events that could formerly be concealed.[27, 28] Additionally, the moral residue of previous mistakes may also restrict disclosure of errors.[59] This residue could be replaced in providers' memories by efforts encouraging reporting in a nonpunitive milieu[60] and incorporating the systems improvements that follow. Clinicians do not want to intentionally harm patients; yet when they conceal errors, they place patients at increased risk of some type of harm.

Second, clinicians working in a culture of blame and punishment do not report all errors, primarily because they fear punishment. A long-held tradition in health care is the "name you, blame you, shame you"[61] mantra. Many organizations have been challenged to provide an environment in which it is safe to admit errors and understand why the errors occurred.[41] Fears of reprisal and punishment have led to a norm of silence. But silence kills, and health care professionals need to have conversations about their concerns at work, including errors and dangerous behavior of coworkers.[62] Among health care providers, especially nurses, individual blame has been the predominant reaction for errors.[63] When individuals and organizations are able to move from individual blame toward a culture of safety, where the blame and shame of errors is eliminated and reporting is rewarded, organizations are enabled to institutionalize reporting systems and increase reporting of all types of errors.[64, 65] To do so, clinicians and others must know that safety can be improved by nonpunitive reporting of error and that organizational flaws cause errors.[1] As communication, collaboration, and safety are inextricably linked in the pursuit of quality care, risk managers, safety officers, and other leaders in health care institutions are encouraging the development of a culture of safety. In a culture of safety, open communication facilitates reporting and disclosure among stakeholders and is considered the norm.[20] Yet even in organizations with a culture of safety, creating a nonpunitive environment is a work in progress.[66]

Third, there is significant variation in how errors are defined, what information is reported, and who should be involved in reporting and mitigating the effects of errors. Differing definitions of errors and near misses and significant differences in reporting—among health care providers working in the same institution and across health care systems—make it difficult to act and prevent similar errors. One of the greatest challenges confronting the patient safety movement is agreeing on standard definitions of what constitutes errors.[67] Reporting near misses can facilitate a blame-free approach (a hallmark of a culture of safety) and fewer cultural and psychological barriers. Yet, clinicians who believe that an error or near miss was unimportant or caused no harm, especially if intercepted, might decide that a report of a near miss is not warranted;[68–70] near misses are not frequently reported.[71]

Lastly, error reports are difficult to complete, and feedback about needed system changes to improve safety is not commonly given.[55] The lack of standardization in the information that is reported and collected makes comparisons and trending as well as preventing future errors difficult. Implementing and using standardized reports of error events, such as those available in hospital databases, is just one example of an open communication strategy, benefiting both clinicians and ultimately the patients they serve.[72] However, the process for reviewing events is not consistently applied nor conducted in matter conducive to providing feedback and improving safety.[73]

These and other barriers to reporting and disclosing errors must be breached to accomplish safer health care.[25] Reporting errors and near misses through established systems provides opportunities to prevent future similar, and perhaps even more serious, errors. Failure to report and speak up about errors and near misses is unacceptable because the welfare of patients is at stake. Investigations into the reporting behaviors of clinicians have found that clinicians are more likely to report an error if the patient was not harmed.[74] Clinicians would also be likely to report an error made by a colleague regardless of patient harm.[74]

Several factors are necessary to increase error reporting: having leadership committed to patient safety; eliminating a punitive culture and institutionalizing a culture of safety; increasing reporting of near misses; providing timely feedback and followup actions and improvements to avert future errors; and having a multidisciplinary approach to reporting.[64, 65] Only through reporting errors can nurses and other health care providers learn which system design and operational failures contribute to human fallibilities and subsequently improve the quality of care. Additionally, one study found that physicians, pharmacists, advanced practitioners, and nurses considered the following to be modifiable barriers to reporting: lack of error reporting system or forms, lack of information on how to report an error, and lack of feedback to the reporter.[75]

Error Disclosure

Disclosure of health care errors is not only another type of error reporting, it is also an account of a mistake. It involves an admission that a mistake was made and typically, but not exclusively, refers to a provider telling a patient about mistakes or unanticipated outcomes. Disclosure addresses the needs of the recipient of care (including patients and family members) and is often delivered by attending physicians and chief nurse executives. However, while physicians' willingness to disclose errors may be stimulated by accountability, honesty, trust, and reducing risk of malpractice, physicians may hesitate to disclose because of professional repercussions, humiliation, guilt, and lack of anonymity.[76]

Disclosure also sometimes calls for a formal verbal apology, in some institutions presented in writing by patient safety officers. Often the providers involved in the error apologize. The central element of disclosure is the trust relationship between patients (or residents of long-term care facilities) and health care providers. Agency policies specify the disclosure approach and identify the person—for example, the primary care provider or safety officer—who communicates the error, adverse event, or unanticipated outcome to the patient or resident, or family member. Some institutions make error disclosure mandatory, and some disclose errors on a voluntary basis.

Providers were concerned about disclosure. They felt shame and fear about their mistakes. "Medical missteps" were transformed into clinical mistakes after practice standards were developed; next, malpractice suits followed. As a result, mistakes were subsequently hidden, creating a negative cycle of events.[72] Furthermore, physicians' anxiety about malpractice litigation and liability and their defensive behavior toward patients have blocked individual and group strategies for preventing and reducing medical errors, thus hindering error reduction attempts.[22] Hiding errors at times resulted in providers being involved in litigation. The association between hiding errors and reducing costs seemed less certain than formerly believed.[29]

When patients' concerns are not addressed, they are more unwilling to return for future care needs[77]and follow medical advice, and are more likely to seek malpractice lawsuits.[78–80] Several surveys of patients and the general public have found that they believe health care to be only moderately safe and that they are concerned about errors affecting them if the seek care in hospitals.[54, 81–84] Specifically, patients are concerned about misdiagnoses, physician errors,[85] medication errors, nursing errors,[77, 85] wrong test/procedure errors, [85] and problems with medical equipment.[77]

Another dimension of reporting and disclosing errors is the role patients can have. Patients can understand, perceive the risk of, and are concerned about health care errors. As more is learned about errors, patients and clinicians have opportunities to improve health care quality. Patients want full disclosure[86] and to know everything about medical errors that impact them. Disclosure can avert patients seeking another physician and can improve patient satisfaction, trust, and positive emotional response to an error, as well as decrease the likelihood of patients seeking legal advice following the error.[87] Patients have the right to know; patients and the public strongly desire disclosure.[86, 87] Failure to disclose mistakes and unanticipated outcomes limits opportunities for evaluation of systems and processes, and for sharing knowledge gained by publishing safety alerts across organizations, conducting educational sessions, modifying practice, and offering opportunities for improved performance.[88] Disclosure is also an element that contributes to the creation of a culture of safety[89] and as such must be accepted as a strategy in health care institutions interested in becoming high-reliability organizations, "those in which error seldom occurs even in dangerous environments"[90] (p. 121).

A significant barrier to disclosing errors is the clinicians' willingness to do so. This may in part be due to the lack of clarity as to exactly what should be disclosed, when the discussion should take place, and who (e.g., a hospital administrator, physician, or nurse) should disclose the error. When it comes to what should be disclosed, research has found that physicians and nurses want to disclose only what had happened,[81] but there are no universal rules for doing so.[86] Decisions to disclose or not to disclose are complex and depend on how errors are defined and if they are recognized or detected. Health care providers are heavily influenced by their perceived

professional responsibility, fears, and training, while patients are influenced by their desire for information, their level of health care sophistication, and their rapport with their provider.[91]

Both health care providers and patients seem to agree that errors disclosure should take place when patients are harmed and that corrective action should involve systems improvement.[91] Other research has found that the likelihood of disclosure increased for physicians, nurses, and emergency medical technicians (EMTs) as the severity of the error increased.[92] Somewhat conflicting with this is the assertion that patients would suffer additional harm when "unnecessary" information was shared about a mistake.[30] Unfortunately, this line of reasoning has its roots in the dubious contention that patients might be more harmed when told the truth as compared with disclosing the mistake.

Physicians have argued that they should be responsible for disclosing errors to the patient.[93] This is borne out in some research that has shown that in practice, at least among emergency care providers, nurses were less likely (23 percent to 54 percent) to disclose an error than were physicians (71 percent to 74 percent).[92, 94]

Because there are instances when error disclosure has been followed by the "victims" seeking further action, the disclosure of errors in practice may not reflect all errors that have harmed patients,[95–97] nor all those that could or should have been disclosed. In many instances, patients may be less likely to seek legal action if the error is disclosed by the physician[82, 83] and if they do not suspect a cover-up.[78] However, it is not known if there is a causal relationship between disclosure of errors and adverse consequences such as litigation.[87]

Disclosure policies. Written policies on disclosing health care mistakes stand to benefit institutions because they can reduce idiosyncratic responses of reporters.[19] Specific policies and systems of error disclosure are preferred over position statements.[98, 99] This is because policies stipulate health care personnel to be notified, patient care to be given following the mistake, and the content of the disclosure notification. Plans to care for the patient are also included. "True informed consent can only be as a result of discussion between a patient and physician"[19] (p. 155). Such a policy fits within a systemwide approach to quality and safety. Underreporting may be addressed by a standardized patient safety event form, integration of databases for event reporting, ongoing education to reinforce the need for providers to report, and patient and family involvement in care delivery processes.[100]

A disclosure policy implemented by the Veterans Affairs (VA) Medical Center in Lexington, Kentucky,[91] resulted in liability payments that were more moderate than such payments at similar facilities. The policy required disclosure to patients of unanticipated outcomes (accidents or medical negligence).[101] This developing, national VA initiative continued its focus on research and policy related to health care error, error-reporting systems and analysis, and feedback methods. Improving systems of care was the target of the ongoing initiative.[102] The VA's disclosure policy included reporting details of incidents, expressing institutional regret, and identifying corrective actions. Comparable liability payments resulted when contrasted with other VA hospitals. Another solution instituted was the granting of a waiver for practitioners who reported errors. Many voluntary adverse event/health care error-reporting systems created for acute care hospitals have built on the VA reporting system.[44] Nonetheless, many health care organizations may not disclose errors to patients,[53] although virtually all have traditionally reported errors through paper incident reports that remained internal and confidential. Error-communication strategies are changing, since several States have mandated that health care institutions notify patients about unanticipated outcomes.[103]

Policies can be supported by advisories, which have historically relied on relatively few contributions from patients. Patients' responses to drafts of advisories were explored best with Medicare beneficiaries.[104] While not specifying advisory content on disclosure of health care errors, recommendations included the involvement of patients and providers. Discussions on patient roles in safety enhancement and the development of protocols for inclusion in safety advisories were encouraged.

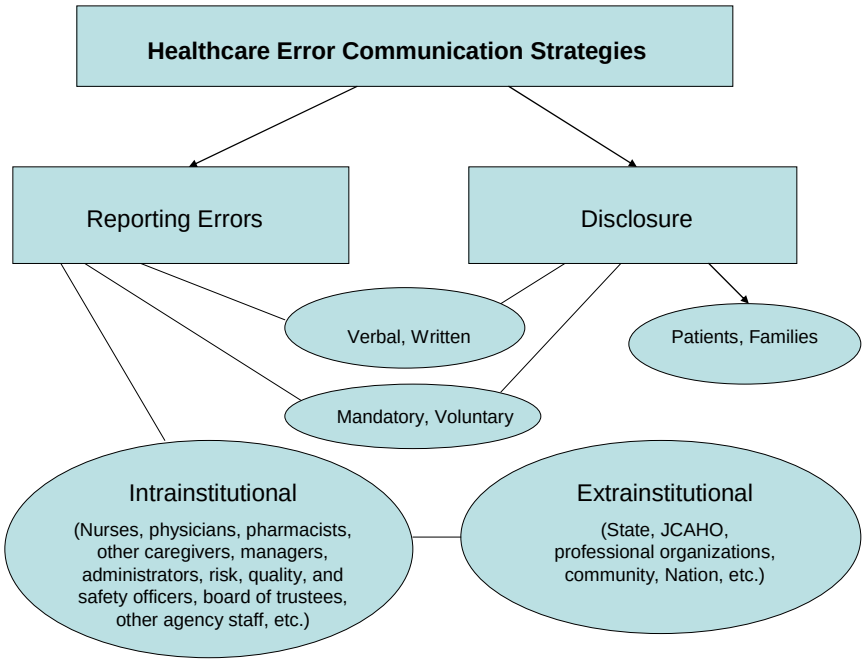
The development and implementation of disclosure policies should be part of an organization-wide effort predicated on cultural change that includes open communication, truth telling, and no blame.[20, 60] Debate regarding the assignment of blame has not negated the importance of counseling some clinicians when policies are intentionally violated—or prosecuted in the case of criminal behavior. Policies on disclosure, including apologies to patients and families, have been justified; respect for patients and their autonomy prevails as a source and support of patients' right to information about health care errors. The aforementioned changes for disclosure policies—for example, open communication, truth telling, and no blame—apply to error-reporting systems as well.

Differences between reporting and disclosure. It is important to place health care error-communication strategies, specifically definitions of reporting and disclosure, in context (see Figure 1). The process of reporting errors is sometimes referred to as disclosure of errors, causing confusion. A report of a health care error is defined as an account of the mistake that conveys details of the occurrences, at times implicating health care providers, patients, or family members in error events. Both clinicians and patients can detect and report errors.[105] Each report of a health care error can be communicated through established and informal systems existing in health care agencies (internal) and outside organizations (external), and may be written (e.g., electronic or paper) or verbal, voluntary or mandatory (policy driven). The core value supporting reporting is nonmaleficence, do no harm, or preventing the recurrence of errors.

An error report may be transmitted internally to health care agency administrators, managers, physicians, nurses, pharmacists, laboratory technicians, other caregivers, and agency legal counsel. Reporting is often directly related to risk management activities intended to prevent actual or potential threats of harm. Intrainstitutional or internal reporting examples are incident reports, nurses' notes, safety committee reports, patient care rounds, and change-of-shift reports. Intrainstitutional reports have increased since the initial IOM report and the elimination of the culture of blame in many health care agencies. Of these, the most common means of reporting serious errors for nurses has been through incident reports, a mechanism that has been criticized as being subjective and ineffective in improving patient safety.[106, 107]

Extrainstitutional or external reporting systems include accounts submitted to agencies such as the Medical Event Reporting System for Transfusion Medicine (MERS-TM), MERP, the Joint Commission, and various State departments of health, as well databases such as United States Pharmacopeia's MEDMARX® Reporting System (U.S. Pharmacopeial Convention 2006), as illustrated in Figure 1. Additional reporting methods have been called for, such as databases that allow for analysis and communication of alerts to key stakeholders in single agencies and across systems.

Figure 1. Heath Care Error-Communication Strategies



Reporting (providing accounts of mistakes) and disclosing (sharing with patients and significant others) actual errors and near misses provide opportunities to reduce the effects of errors and prevent the likelihood of future errors by, in effect, warning others about the potential risk of harm. Reporting reduces the number of future errors, diminishing personal suffering[108] and decreasing financial costs. In contrast, disclosure is thought to benefit patients and providers by supplying them with immediate answers about errors and reducing lengthy litigation.[109] Although clinicians and health care managers and administrators feel uncomfortable with disclosure, disclosure is a duty.

Error Reporting and Detecting Strategies

Several strategies have been used to improve error reporting. In a literature review of incident-reporting research published between 1990 and 2000, the effectiveness of chart reviews, computer monitoring, and voluntary reporting were compared. The investigators found that the most adverse drug events were identified through chart reviews; the least effective method was voluntary reporting. The most efficient method of understanding errors was computer-based monitoring because more adverse drug events were found than with voluntary reporting and it took less time than chart reviews.[110]

A strategy tested in another project, developed within a hospital, used an electronic, anonymous paper report to increase close call (i.e., near miss) incident reporting. Close call categories included blood/transfusions, diagnostic tests/procedures, falls, medications, other treatments, surgery, and therapeutic procedures. The final template included five main screens and was received very positively by providers. A clinical analyst assisted in communicating feedback and describing the etiology of close call situations, and urgent close calls were rapidly

communicated. The investigators found that improved reporting systems may encourage providers to report near misses. Once identified and shared with front-line providers, errors may be prevented.[111]

Several Web-based systems have also been used in hospitals to improve error reporting. One study investigated reported errors, intercepted errors, and data quality after a Web-based software application was introduced for medication error event internal reporting. The reporting system generated occurrence reports, documented anonymously submitted reports, and allowed for the possibility of real-time reporting and more rapid investigation of contributing factors. The investigators found that error reports increased as well as intercepted error threats (near misses), and intercepted nurse, physician, and pharmacist medication errors increased. The details of cause-of-error reporting also increased as did the participation of hospital leadership.[112] In another study, Wu and colleagues[113] described the use of Web-based internal reporting in the intensive care unit setting. The researchers found that analyzing and disseminating error and near miss data, so that providers are alerted to safety risks, could reduce errors. Additionally, patient safety would most likely improve when providers see the benefits of reporting through systems improvements.[113] One other project occurred when leaders at Baylor Medical Center at Grapevine partnered with DoctorQuality to create a Web-based form for reporting errors.[114] At the same time, they implemented strategies to change the culture of the organization, supported by education on the use of the reporting system, incident reporting, communication, and feedback information about errors. Investigators found that event reporting doubled, suggesting that even with increased reporting, the actual number of errors may not be identified. Proactive risk management allowed for timely followup, the percentage of errors submitted increased after implementation, and the average days from event to submission shortened.[115]

Using a voluntary, regional external reporting database and United States Pharmacopeia's MEDMARX® database increased medication error reports across critical access hospitals.[116] Most errors reported to the regional database and MEDMARX® did not result in harm to patients. However, significant differences existed in severity, phase, and types of error when comparing the two external reporting systems. More error reports from the critical access hospital database (Nebraska Center for Rural Health Research) reached patients than did MEDMARX® errors. Increased reporting of potential and near-miss errors by nursing and pharmacy personnel was associated with easily accessible pharmacist availability.

Another strategy to improve awareness of errors is the assessment of medical records to detect errors that were not otherwise reported. Two prospective, cross-sectional studies compared facilitated incident monitoring to retrospective review of patient medical records in hospitals. The first[117] compared medical record review to physician reporting prompts by daily electronic reminders for 3,146 medical patients in an urban teaching hospital. The investigators found that the physician reporting method identified nearly the same number (2.7 percent) of adverse events as did the retrospective medical record review (2.8 percent), but the electronic reminders detected more preventable adverse events (62.5 percent vs. 32.9 percent), was less costly than the record review ($15,000 vs. $54,000), and could be integrated in the daily routine through electronic health information technology. The second, smaller study[118] compared facilitated discussions to medical record review in one 12-bed intensive care unit (ICU) with 164 patients in an Australian hospital with an established incident reporting system. The investigators found that facilitated discussions, in addition to the incident reporting system, identified more preventable incidents than retrospective medical record review and was not as resource intensive

as medical record reviews (50 hours vs. 65 hours). However, medical record review detected some incidents not captured by the incident reporting system.

Research Evidence

Over the past 11 years, research on the reporting of errors among nurses targeted four key areas: (1) description of who reports errors and what errors are and perceived to be reported; (2) barriers to error reporting; (3) disclosure preferences; and (4) reporting systems and frameworks, including the development of effective reporting systems. The researchers used different methods to assess reporting preferences and what was reported, including surveys, retrospectively assessed error reports,[116, 119–128] a 2-week journal,[129] error scenarios,[81, 92, 130] and focus groups.[91, 131, 132] One study used a mixture of methods.[58] Most of the research included in this analysis involved discussions of reporting involving health care providers using existing systems, while 11 studies assessed the effects of new or revised error-reporting systems.

Who Is Reporting

Verbal, paper-based, electronic, and Web-based error-reporting mechanisms have been used to capture, record, and communicate errors. Nurses were found to report the majority of errors. The proportion of error report submitted by nurses ranged from 67.1 percent[133] to 93.3 percent.[124] Nurses reported 27 percent more errors than did physicians.[134] Physicians submitted 2 percent[135] to 23.1 percent, and 9.5 percent were submitted by others.[133] Considering the 11 surveys included in this analysis that investigated who submitted error reports, all found that nurses reported the majority of incident reports.[36, 46, 106, 120, 123, 124, 133–137]

Factors that have influenced the submission of error reports included believing it was beneficial to do so[131] and having quality management processes in place.[138] Feeling comfortable reporting, working in a climate of patient-centered care, job satisfaction, and the serious nature of the error enabled error reporting.[131] In terms of characteristics associated with those likely to report errors, nurses with more than 5 years of experience were more likely to believe there was no value in reporting near misses.[106] This contradicts findings from another survey where the frequency of error reporting was found to be higher among nurses with 5 to 10 years of experience.[139] Another finding that complicates this notion is that in one survey, nurse managers reported more errors than did staff nurses,[139] but this could have been associated with organizational structure rather than ability of staff nurses. Additional characteristics were that nurses providing direct patient care were more likely to report,[140] and that pediatric nurses reported medication errors more frequently than adult nurses.[141]

Compared to physicians, nurses seemed to have more knowledge/awareness of the reporting process/system,[106, 132] know what should be reported,[69, 142] know when the error should be reported,[142] be more likely to have submitted an error/incident report, know how to use an incident report form, and know where to submit the report.[106] One survey found that while 98.3 percent of physicians and nurses knew about incident reporting systems within their organizations, nurses were more likely to know how to submit an error report, have experience with submitting an error report, and know where to submit the report.[106] Another survey found that 54 percent of residents and 97 percent of nurses knew about their hospital's error-reporting system, and 13 percent of residents and 72 percent of nurses were likely to use the reporting system.[143] Conversely, another survey found that less than 10 percent of physicians and nurses

were aware of their State's mandatory reporting system, and only a small subset of the ones familiar with the system (less than 50 percent of nurses and 20 percent of physicians) had actually submitted a report using the mandatory system.[144]

Who reported was also be associated with their understanding of what should be reported. One survey of medication administration errors found that nurses acknowledged differences in how reportable errors were defined among staff.[145] Similar findings were found in another survey of nurses in Korea, where nurses were not clear as to what should be reported.[139]

Nurses tended to be more likely to report errors, considering it a professional obligation. One survey of nurses in rural hospitals found that nurses believed they were responsible for reporting errors, getting needed education, recommending changes in policies and procedures to prevent future errors, and participating in investigations of the causes of errors.[58] Another found that physicians believed that nurses were responsible for reporting errors.[144] Similar findings were found using error scenarios, where nurses believed that error reporting was a professional responsibility and that nurses should report the errors made by other nurses if they did not do so themselves.[130] However, another survey found that nurses were more comfortable reporting their own errors than they were of those of colleagues.[146] Another found that 54 percent of residents and 91 percent of nurses believed that they would report their own error or someone else's, and 25 percent of residents and 1 percent of nurses would report the errors of others if they did not like the person who caused the error.[143]

What Is Reported

What is reported could depend upon the understanding of nurses as to what should be reported, which is associated with how reportable errors and near misses are defined. If nurses, nurse managers, and physicians question the value of reporting because they did not see improved patient safety in practice and policies,[132] few errors may be reported. If nurses did not understand the definition of errors and near misses, they were not able to identify or differentiate errors and near misses when they occurred. For example, one very small study gave four error scenarios to 13 perioperative nurses to assess whether they could detect errors and their reporting preferences. The investigators found that 58 percent of the theoretical errors were identified as errors, but only 26.7 percent of them would have been reported.[130] However, when nurses were given definitions of errors and near misses, one study indicated that nurses reported 58 percent of errors and 59 percent of near misses.[129] Among the respondents, 61 percent reported one error and 38 percent reported making between two and five errors during a 2-week period.

The severity of errors and who is doing the reporting influence which errors are reported. One survey found that 58 percent of nurses did not report minor medication errors.[69] Another survey found that while nurses reported 27 percent more errors than physicians, physicians reported more major events and nurses reported more minor events because they had a more "inclusive view." Both physicians and nurses reported near misses.[134] Analysis of error reports in Japan found similar differences in error reporting among different types of clinicians. One study found that nurses and pharmacists submitted more reports of events that were considered minor, while physicians submitted reports when errors were detected and prevented by nurses or pharmacists.[123] The other study of error reports submitted by physicians and nurses in a hospital found that 99.5 percent of the reports—the majority of which were submitted by nurses—were for what were considered minor incidents. Additionally, the lag time for reporting major events

was 18 percent shorter than it was for minor reports, but 75 percent longer when physicians submitted the error report.[124]

Several surveys assessed whether errors that resulted in harm to patients were reported. One survey of physicians and nurses in England found that error reporting was more likely if the error harmed a patient, yet physicians were less likely to report errors than were nurses or midwives. Clinicians were less likely to report errors made by senior colleagues, and physicians in particular were unlikely to report violations of clinical protocols, whereas nurses and midwives would.[46] A review of error reports found that when an error harmed a patient, 34 percent of the reports were submitted by physicians and 27 percent of the reports were submitted by nurses. When errors did not harm patients, 31 percent of the reports were submitted by nurses and 17 percent were submitted by physicians.[133] One survey found that nurses would report errors whether they harmed the patient or not.[140] A survey in Korea found that 67 percent of nurses believed they always reported errors that harmed patients.[139] A very small study found that reporting errors that harmed patients was a secondary concern for nurses; nurses believed that errors that fell outside the scope of the nurse's practice should be reported by the responsible individual (i.e., not the nurse).[130] A related study found that errors resulting in either patient harm or worker injury were underreported.[138] Thus, events that may harm patients are at risk for not being reported.

What is reported may also be associated with whether the reports are confidential or anonymous. Informal reporting mechanisms were used by both nurses and physicians. One survey found that nurses also informally reported to physicians when a dose was withheld or omitted, but they were less likely to formally report the missed dose as an error.[142] Nurses also had a greater tendency to informally report errors to nurse colleagues.[130] Reviewers found that confidential reports were more complete than anonymous ones, but the types of patient harm did not vary between anonymous and confidential reports.[121] Since voluntary reporting depends on health care professionals to report medication errors so that the more realistic frequency and type of errors that happened can be known, several surveys encouraged anonymous responses to identify the barriers to reporting medication administration errors.[58, 69, 142, 147–149] While only brief descriptions of the survey instruments were discussed in each of the studies, the surveys did capture error reports that may not have been communicated or known otherwise.

Type of Errors Reported

An analysis of error reports found that the most serious reports involved rule violations, management practices, and nonstandardized nursing practices.[125] One study found that the majority of error reports involved delays or omissions of medications, diagnostic tests, or necessary/planned procedures; medication errors, and malfunctioning equipment. Ten percent of the reported errors required life-sustaining interventions (61 percent of which resulted from delays/omissions of prescribed nonmedication treatments and necessary planned procedures), and 3 percent might have caused the patient's death.[137]

In a study of surgical ICUs, the type of events reported were related to medications, tests, treatments, or procedures.[136] Researchers in another study found that 47 percent of reported errors were associated with diagnostic tests, 35 percent with medications, and 14 percent with both diagnostic tests and medications. The investigators believed that 71 percent of these errors were associated with communication breakdowns.[121] One study found that nurses generally were more likely to report patient falls than pressure ulcers or near-miss medication errors, and nurses

with fewer than 5 years experience were more likely to report deep vein thrombosis.[106] Another retrospective analysis of error reports in six Japanese hospitals found that reported error rates were high for prevention of problematic behavior, patient suicide, patient falls, and subcutaneous injections of insulin. A high number of error reports in some hospitals were associated with maintenance of dialysis, endoscopy preparation and assistance, administration of preoperative treatments, and blood transfusions. There were more reported errors in the elderly, hemodialysis patients, and those with problematic types of behavior.[125] Another study found that the major types of errors reported were for unsafe conditions or near misses, adverse events that harmed patients, medication/infusion errors, and patient falls.[135] In yet another study, researchers found that the majority of reports involved medication errors, surgical errors, falls, and problems with procedures.[127]

Additionally, the type of errors reported can be associated with characteristics of the patient population. For example, the findings from one survey indicated that medication error rates, which were computed from actual occurrence reports, were higher on pediatric units than adult units.[141] Children's vulnerability to adverse outcomes from medication errors was attributed to weight-based drug dosing, dilution of stock solutions, and immature physiological buffering systems, situations that are unique to children.

Estimations and Perceptions of Error Reporting

Several surveys asked nurses to estimate how many and what types of errors were reported by colleagues and themselves. There was significant variation when nurses were asked to estimate how many errors were reported. Respondents in one survey estimated that an average of 45.6 percent of errors were reported.[142] Nurses may not easily estimate how many errors are reported, as indicated in one study where staff nurses were not consistent estimators of medication administration errors.[145] Another study of medication errors in 29 rural hospitals in nine States found that less than half of nurses believed that all medication errors were reported,[58] while another study found that 44 percent of nurses estimated that 25 percent of medication errors were reported.[69] Another survey found that nurses estimated that less than half of all medication administration errors were reported,[138] an estimate that is lower than those in other surveys.[70, 150–152]

Estimation may also reflect where one works as well as one's experience. In terms of where nurses work, one survey found that nurses working in neonatal ICUs perceived higher reported errors than did those working in medical/surgical units. The mean perceived percentage of reported errors was 46 percent.[142] Another survey found that pediatric nurses estimated that 67 percent of medication errors were reported, while adult nurses estimated 56 percent. The stronger the agreement with management-related and individual/personal reasons for not reporting errors, the lower the estimates of errors reported by pediatric nurses.[141] In terms of experience, one survey found that staff nurses relied on personal experience to estimate medication administration errors on their unit.[145]

Other surveys investigated what nurses thought should be reported. One study divided nurses into high- and low-reporting rates; groups differed by definition of what makes up a reportable error, by personal experience when estimating unit error reporting, and by willingness to share occurrence data with other nurses. Also, nurses were surveyed on the perspectives of types of errors that should be reported, the proportion of errors reported, worker safety, and opinions about the work environment and job satisfaction.[138] Although nurses indicated that all errors

except near misses should be reported, less than half of medication administration errors were reported. Intravenous medication errors were the highest percentage reported events; patient falls were associated with major injuries. Not reporting medication errors was attributed to nurses' concerns about administrative responses and personal fears such as imagining the poor opinion of their coworkers. Sharps injuries, exposure to body fluids, and back injuries threatened nurse safety. Some questioned hospitals' quality management processes.

The perceived rates of error reporting may be associated with organizational characteristics. For example, the perceived rates of medication administration error reporting were compared by organizational cultures of hospitals and extent of applied continuous quality improvement (CQI) philosophy and principles.[151] As bed size increased, perceived rate of medication administration error reporting decreased. Larger hospitals tended to be more hierarchical in nature. Group-oriented hospital culture (norms and values associated with affiliation and trust, flexibility, a people-oriented culture with concerned and supportive leadership) and higher levels of CQI implementation were positively associated with the estimated overall percentage of medication administration errors reported.

Perceived Barriers to Reporting Medication Errors

There were 15 identified studies that surveyed nurses about their perceptions of what factors (e.g., organizational, process, individual) precluded them from reporting errors. Fourteen of these studies used cross-sectional surveys of nurses,[69, 70, 106, 120, 131, 138, 141, 142, 147–151, 153] and all but one of the surveys[131] were in hospitals. Of the two studies that used focus groups, one interviewed clinicians in 20 community hospitals,[132] the other in ambulatory care settings.[131] Several themes emerged from these studies, as illustrated in Table 1. The types of responses given by nurses may have depended upon the questions asked, but that is not known. In all, research findings seem to indicate that, as Wakefield and colleagues[151] found, the greater the number of barriers, the lower the reporting of errors.

One survey of nurses in the Midwest found that nurses were able to recognize errors and events associated with intentional wrongdoing related to questionable behavior. Nurses were more apt to report serious errors but not unintentional errors.[153]

Other clinicians are concerned about reporting barriers as well. In one survey of physicians and nurses, physicians identified twice as many barriers to reporting than did nurses; both identified time and extra work involved in documenting an error. However, nurses were more concerned about anonymity, "telling" on someone else, fear of lawsuits, and the necessity of reporting errors that did not result in patient harm.[149]

Additional barriers were identified as well. One survey in a State with mandatory reporting found that both physicians (40 percent) and nurses (30 percent) were concerned about the lack of anonymity of reports and that the reports would be used punitively against the individual who submitted the report.[144] Another survey of nurses in Korea found that 32 percent were worried that their errors were kept in files; 66 percent felt that their suggestions to improve patient safety were ignored; 83 percent felt that it was by chance that more errors did not happen; 52 percent believed their units had serious patient safety problems; and 56 percent reported problems talking with physicians.[139]

Table 1. Reasons why clinicians do not report and disclose errors and near misses

Reporting Barriers
Fear
Fear[69, 138, 148, 150, 151]
Fear of being blamed for negative patient outcome[70, 147]
Fear other providers will consider provider who made the error incompetent[70, 138, 141, 142, 147]
Fear of reprimand from physician(s)[70, 147, 148]
Fear patients will develop negative attitudes[70, 147]
Fear of legal liability, belief that disclosure of errors to patients results in lawsuits[149]
Fear of "telling" on someone else[149]
Fear of adverse consequences from reporting[70, 141, 147, 148]
Fear of reporting that is not anonymous[149]
Understanding
Confusion over definition of errors and near misses[70]
Disagreement with the organizations' definition of error[70, 148, 151]
Providers unaware that errors occurred[70, 142, 147]
Providers' bias about which incidents should be reported[70, 149, 153]
Some incidents, i.e., near misses, thought too trivial/unimportant to report[106]
No perceived benefit[131, 149]
Administrative/Management/Organizational
Administrative response[138, 142, 148, 150, 151]
Lack of feedback on reported errors[70, 120, 147, 148]
Persistence of the culture of blame/shame, blaming the individual[70]
Excessive emphasis on medication error rates as quality measure of care[70, 147]
Poor match of administrative response to errors with severity of errors[70, 148]
Burden of Effort[148]
Incident reports take too long to complete[70, 131, 147, 149, 151]
Verbal reports to physicians take too long or contacting the doctor takes too much time[70]
Providers forget to make a report, too busy[106, 131]
Extra work involved in reporting[149]

Five studies provided additional information about reporting barriers for nurses. In a survey of nurses in Taiwan, nurses did not vary in their concerns about the effects of reporting barriers based on factors such as the age of the nurse, type of education, length of experiences, and length of employment. Yet nurses who perceived more error reporting barriers also believed that errors were over- or underreported, compared to nurses who reported that the error reporting rates were accurate. In this study, factors that could thwart error reporting were positively correlated with the power hierarchy and face-saving concern. On the other hand, the better the work environment, quality management, and relationships with peers, the fewer the perceived barriers for error reporting.[147]

Factors about the organization's culture may be barriers to error reporting. In one survey of clinicians in rural hospitals, the majority agreed that hospital administrators did not punish error reporters. Most agreed that the hospital culture recognized that mistakes could be made (64 percent) and that error reporting could be done by all employees (86 percent). The majority felt comfortable (65 percent) or somewhat comfortable (32 percent) discussing medical errors, and

have learned and would like to continue to learn from the mistakes of others. Attempts to maintain collegiality and their belief about lacking authority prevented nurses from questioning physicians. Nonphysicians attributed many errors to nursing practices. In fact, if an error occurred, 96 percent of nurses and more than 90 percent of physicians, administrators, and pharmacists would have assigned patient safety responsibility to nurses. Only 22 percent of respondents believed that clinicians and administrators shared equal responsibility for patient safety.[58]

Three studies by Wakefield and colleagues[70, 150, 151] asked nurses about organizational and leadership/management factors that could thwart error reporting. Staff nurses believed that having an organizational culture that did not support error reporting[70] and management practices and beliefs (e.g., supervisors not viewing fear of an administrative response as a barrier to error reporting)[150] thwarted error reporting. Wakefield and colleagues[151] found in another survey that hospital culture types varied; smaller institutions tended to have group-oriented cultures while larger institutions tended to be more hierarchal (which was negatively associated with error reporting). They also found that the extent of CQI implementation increased with bed size of the hospital, and perceived rate of medication administration error reporting decreased. Considered together, the presence of a group-oriented culture and higher levels of CQI implementation were positively but not significantly associated with reporting errors.

One study surveyed physicians and nurses about barriers that could be modified to enable error reporting. The modifiable barriers they identified were the structure and processes for reporting errors and the lack of education about errors. The least modifiable barriers they reported were fear of lawsuits, fear of being blamed, and motivational issues.[149]

Error-Reporting Strategies

Thirteen studies investigated the effects of new and revised error-reporting systems on error reporting. Investigators examined a clinical pharmacist on units;[119] education, a revised reporting system, and a call center;[120] a voluntary reporting system;[121, 122] a voluntary system for near misses;[154] a voluntary, paper-based reporting system;[133, 136, 137] a confidential, electronic-based reporting system;[135] education enhanced by error report summaries;[115] education of nurse case managers;[126] a Web-based anonymous reporting system;[112] and confidential peer interviews.[36] Only one study assessed the impact of mandatory error reporting.[144]

Three of the studies introduced an “expert” to assist providers in detecting errors. In one, a clinical pharmacist was introduced on units to improve medication safety and increase medication error reporting as well as error reporting generally. Error reports remained relatively constant, yet error reports from physicians decreased. The severity of errors decreased over time, and the reporting of near misses increased from 9 percent to 51 percent.[119] Another study introduced an “expert peer” to prompt assessment of patients, using confidential peer interviews during morning rounds or via e-mail. Verbal reports of errors were confirmed with the patient medical records, but only one incident report was submitted by a house officer for a patient fall. Nurses submitted the majority of incident reports for errors involving patient slips and falls, medication errors, and other events.[36] In the third study, a hospital introduced nurse case managers to review patient medications, detect adverse drug events (ADEs), and report detected ADEs. Once the nurse case managers began reviewing medications and submitting ADE reports, the majority of which were for serious ADEs and possible ADEs, the reports of ADEs nearly doubled.[126]

Researchers in one study provided error reporting education to staff, revised their current reporting system, and introduced a call center. As a result, reporting increased throughout the hospital—more physicians in the emergency department and more nurses in medical units submitted error reports—and there were more anonymous reports compared to the hospital used as a control. More reports were submitted using the one-page form than through the call center. Nurses continued to submit the majority of reports.[120]

One study aimed to improve error reporting through educational initiatives in 10 critical access hospitals. The investigators conducted several education workshops about the nature of errors, the design of safety systems, and best practices in medication safety. Then they collected error reports from all the hospitals and provided quarterly reports from the error reports to each of the hospitals, including the results and averages from the group of hospitals. The investigators found that most of the errors were not harmful and were associated with medication administration, mostly for dose omissions. The reports helped hospitals identify and address systems factors that were conducive to errors.[116]

Five studies tested the effects of new, voluntary error-reporting systems. One study assessed the impact of introducing an error-reporting system in community, primary care research networks. Investigators found that the number of reports increased, but the confidential reports were more complete than the anonymous ones.[121] Another study also found that error reports increased after the introduction of a voluntary reporting system, that nurses submitted the majority of the errors reports, followed by pharmacists, and physicians submitted an error report only if the error was detected and prevented by the nurse.[122] A teaching hospital in New York implemented a new confidential, electronic-based error-reporting system along with an educational program. Investigators found that error reporting increased, but reporting remained low among physicians.[135] Another study assessed the effects of introducing a new Web-based anonymous reporting system. Investigators found that error reports, including those for intercepted errors, increased, and errors attributed to physicians increased while those attributed to nurses and pharmacists decreased.[112] The last of these five studies assessed the impact of using a voluntary reporting that called near misses, "close calls" and frequent feedback reports. The investigators found that after six months, the number of error reports increased by 1,468 percent.[154]

The association between voluntary error reporting and the number of error reports submitted was tested in two prospective, interrelated studies, using paper-based SAFE (Safety, Actions, Focus, Everyone) cards. One tested these cards in the medical ICU,[137] the other in the surgical ICU.[136] The SAFE report card was used over a period of 6 months to document types of events, including errors in tests, treatments, and procedures; medication; equipment; blood products; intravenous complications; behavioral/psychiatric; laboratory; surgery; and falls. This new reporting system resulted in more reported events (232 events) than what was captured by the existing hospitalwide database used to register errors and high-risk events (29 events before and 26 events during the intervention). The investigators believed that the system fostered reporting by unit team members and could reduce events proactively through improved practice.[136] The second study used similar methodology and added an additional step: the cards were withdrawn then reintroduced. The cards were reintroduced once the investigators assessed the significant drop in error reporting. The initial use of the cards increased nurse and physician reporting. After the cards were withdrawn, there was a decrease in reports by both nurses and physicians; instead, there were an increased number of reports submitted to the hospital electronic reporting system by nurses. The investigators found that a higher proportion of events reported by physicians were

for events that resulted in patient harm, whereas the higher proportion for nurses was for events that did not result in patient harm.[136] In both studies, nurses submitted the majority of reports and physician reporting increased.

Disclosure Preferences

Five studies investigated factors associated with disclosure preferences of nurses. Two studies investigated disclosure preferences of patients and clinicians. In one of these studies, which used surveys with error scenarios, patients reported wanting full disclose of errors, yet physicians and nurses wanted to disclose only what happened.[81] In the other study, which used focus groups, patients and clinicians agreed that errors should be disclosed when the patient was harmed. The degree of harm caused by errors and whether patients and others were aware of errors were related to disclosure preferences. Institutional culture (perceived tolerance for error and supportive infrastructure) was important to the disclosure decision. Relevant patient factors were health care sophistication, desire for information, and rapport with provider. Provider factors included fears of malpractice, reputation, job threat, and change in rapport with the patient, as well as perceived professional responsibility, medical training, lack of confidence in disclosure skills, and personal discomfort.[91]

Three studies used surveys to investigate disclosure preferences of EMTs, physicians, and nurses. In one study that specifically asked only nurses, nurses reported that they were less likely than physicians to want to disclose errors.[81] Another survey found that 74 percent of physicians, 23 percent of nurses, and 19 percent of EMTs had disclosed errors.[95] Physicians were also more likely to disclose (71 percent) an error than were nurses (59 percent), but nurses (68 percent) were more likely to report an error than were physicians (54 percent).[92]

Another survey found that 29 percent of physicians and 64 percent of nurses reported feeling comfortable discussing mistakes. Also, 42 percent of physicians and 44 percent of nurses reported feeling uncomfortable discussing errors with patients.[143]

Evidence-Based Practice Implications

Given the history of error reporting and the role nurses have in patient care, it is important to emphasize that nurses are pivotal in improving patient safety via error reporting. Patient safety will improve when systems effectively assure and improve safety, predicated on a culture in which the reporting of errors or near misses is considered valuable, and positive actions lead to study and change for improvement, not blame.[155] To avert underreporting of errors and to effectively learn from errors, administrators in health care agencies need to develop policies that support the routine reporting of errors, so that increased numbers of reports of actual errors and near misses are rewarded on an individual or unit basis. By easing the transition of an institution to a culture of safety, eliminating blame and the pressure of a punitive environment, error reporting will most likely increase. Additionally, it is evident that caregivers and patients profit from detailed accounts and increased reports, specifically in hospitals that act on unsafe practices identified through analysis of error reports. Systems improvements need to be communicated with all stakeholders so that they benefit from seeing the feedback loop in action.

Ethical principles—including beneficence, fiduciary responsibility, respect for autonomy, justice, and honesty—guide clinical practice and mandate reporting and disclosure.[156] These principles guide safety efforts and must be espoused by administrators and providers. Improved

safety practices begin with policy and procedure development and continue with the allocation of resources for developing reporting systems and databases as well as educating caregivers.

New systems of reporting errors are generally developed in-house or purchased by health care agencies. Electronic systems that are Web-based—that include easy reporting and standard definitions of errors, near misses, and potential root causes as well as personnel responsible for analyzing and sharing safety hazards—provide opportunities for data management and pattern identification of unsafe practices. They also save time for providers as reports are entered into databases and help to shorten the time from incident to report. Developing new systems of reporting requires administrators to budget accordingly so that additional personnel and electronic reporting systems as well as complementary software are financed. Periodic training of personnel and upgrading reporting databases are necessary, as are systems improvements that depend on error-report analysis.

Patients and families desire disclosure of health care errors by health care providers. Providers have an ethical responsibility to disclose. Generally, organizations use verbal reports, followed by written reports offered by patient safety officers, in consultation with agency attorneys, in accord with institutional reporting and disclosure policies. Refusing to disclose suggests fear and a need for provider control rather than patients' and families' need for honesty about their care. Disclosure policies must be created with honesty and respect for patient autonomy in mind; apologies must be required.

The emotional responses and perceptions of caregivers about errors are important barriers to reporting. Providers consider themselves at risk when they report errors because many providers carry the residue from previous experiences with mistakes. Anger from coworkers, shame, lack of confidence, and the like combine with guilt about the suffering of patients and fear of potential litigation to hinder reporting and disclosure. Nurses respond similarly to errors as physicians. They feel vulnerable to disciplinary action and legal repercussions; thus errors go underreported. Providers must experience changes in institutional culture, where systems improvements are targeted rather than individual blame.

Teamwork training improves error reporting and reduces clinical errors. Teamwork principles include increased communication among health care providers. One element of a teamwork training program, cross-monitoring, might result in decreased errors as providers observe each other, identify unsafe behaviors, and act to correct each others' mistakes. Status barriers must be penetrated. Cross-monitoring involves interdisciplinary/caregiver observations, identifying unsafe behaviors, and acting to correct unsafe behaviors. The challenge is how this team training element might be successfully initiated and consistently reinforced in acute care hospitals, critical access hospitals, nursing homes, long-term care facilities, and other agencies. Along these lines, nurse educators are challenged to include teamwork strategies and exercises aimed at increasing safety practices in health care agencies in undergraduate and graduate nursing courses, taking into account content on existing status issues among health care providers.

Research Implications

The majority of the research on error reporting has occurred within the past 10 years. While the studies included in this analysis provide important insight into what is being reported, they were primarily descriptive and none were nonrandomized or randomized controlled trials. Thus, additional well-designed studies are called for. Teamwork training holds promise as an

intervention that might affect frequency and severity of reported errors. Emphasizing cross-monitoring and increased communication as team training strategies might also affect outcomes. Teamwork training could include scenarios that challenge clinicians to determine how and what to report. Multisite team training programs should be investigated. The benefit of team training is in the development of expertise in reporting and disclosure among front-line providers. However, additional research is needed on the effect of team training on error frequency and reporting and disclosure skills, especially among nurses. Examples of research questions might be, Are there differences in patient and family member satisfaction when disclosure of errors is provided by team-trained versus usual-approach health care providers? Does team training affect error and near-miss reporting rates?

Additional studies could be conducted in which disclosure of errors to patients and families is linked to differences in outcomes, for example, claims reports and monetary awards. More research is needed on the impact of Web-based reporting systems on time used for reporting via data entry, time from incident to report, time to systems improvement, as well as a classification of systems improvement strategies and the effect of strategies on error outcomes. Examples of research questions might be, Are there differences in severity scores following errors when Web-based versus incident-report methods of reporting are used by health care providers? Are there differences in frequency of error reports when Web-based versus incident reporting systems are used? Comparisons also might be made between physician and administrator methods of disclosure to patients and families in which simplicity or complexity of disclosure events are examined. Examples of research questions might be, Are there differences in patient and family satisfaction when physician/administrator disclosers are trained using standard, simple script versus unscripted (usual) disclosure communication approaches? Are there differences in the number of liability claims and monetary awards when mandatory versus voluntary disclosure policies are used?

Notable in the reviewed literature was the dearth of studies on reporting and disclosure regarding the variety of adverse events, for example, blood transfusion errors, device malfunctions, health care acquired infections, and others. Most addressed were medication errors. Data are needed across all settings; most research on reporting is hospital-based. Community settings, nursing homes, free-standing short-procedure units, and primary care offices also require additional study regarding error reporting and disclosure. Consequently, there are many research opportunities for nurse investigators. Research is needed describing initial patterns of errors across various settings and focusing on other events, including blood transfusions, surgical incidents, device malfunctions, etc. Comparisons might also be made in liability lawsuit statistics between institutions that have disseminated and acted on the no-blame cultural approach versus those that have initially instituted this approach.

Conclusions

Sustained and collaborative efforts to reduce the occurrence and severity of health care errors are required so that safer, higher quality care results. To improve safety, error-reporting strategies should include identifying errors, admitting mistakes, correcting unsafe conditions, and reporting systems improvements to stakeholders. The greater the number of actual errors and near misses reported, the more reliable a health care organization or system could be, from a safety viewpoint, when systems improvements are consistent with error patterns.

Clinicians appreciate seeing the results of the reports they submitted transformed into systems improvements. Understanding and communicating the root causes of errors and near misses can decrease the risk of future errors, and support the concept that health care errors are often systemic and multifactorial. Reporting errors and near misses may increase through voluntary reporting systems, because voluntary systems provide additional evidence that the blame/shame patterns are being eliminated in health care organizations and systems.

Electronic error-reporting systems can possibly make the time required to report shorter, shorten the time for correcting unsafe conditions, and alert providers to emerging unsafe patterns. Some systems can also facilitate quality improvement initiatives through enhanced error-reporting systems. The benefits of Web-based health care reporting systems that clinicians find easy to use and see the effects of their reporting in changes to systems might ultimately reduce the incidence of serious errors, and significantly improve the safety and quality of health care afforded patients.

Search Strategy

Various databases were searched to locate studies and related literature on reporting and disclosing health care errors, including CINAHL®, PubMed®, and Psycharticles. Search terms included "medical errors" and "medical error reports." Published results in a non-English language, expert opinions, case reports, and letters were excluded. Studies specifically assessing rates, types, and causes of reported medication administration errors were excluded as well. To be included in the analysis, each article had to involve nursing and report findings specific to nurses. Most of the articles identified in the literature search were primarily descriptive.

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Evidence Table

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Balas 2004[129]	Error reporting Reporting near errors	Cross-sectional study	Qualitative, voluntary, anonymous, self-reported recording of 14-days of shift work, sleep, and errors using a journal (Level 4)	119 full-time hospital registered nurses (RNs). Note: subset of the larger study with 393 full-time RNs described in other articles.	None	58% of reported errors and 59% of near misses were medication related. 73 nurses reported 1 error, while 45 reported making between 2 and 5 errors during the study period.
Blegen 2004[138]	Barriers to reporting medication administration errors (MAEs) and near misses	Cross-sectional study	Survey, including falls and MAEs, near misses, staff injury, and reporting barriers (Level 4)	1,105 RN respondents in 25 acute care hospitals nationally	None	Reporting rates varied, with 47% errors reported overall; intravenous MAEs highest rate overall. Reporting inhibited by fear of being blamed, peer reactions, patients becoming negative, reprimands by physicians, losing license, and public reporting. Reporting of MAEs was higher in units with quality management processes. Errors resulting in patient and staff injuries were underreported.
Chiang 2006[147]	Barriers to error reporting	Cross-sectional study	Self-administered survey of barriers to reporting MAEs (Level 4)	597 nurses in 1 hospital in Taiwan	None	Fear was the main barrier to reporting MAEs, significantly associated with organizational power hierarchy and face-saving concerns.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cook 2004[58]	Responsibility for errors Defining medical errors	Cross-sectional study	Assessed hospital data and administered the "Close Call Pilot Culture Assessment," error reports, staff patient safety instrument, e-mailed questionnaires, staff patient-safety survey, case studies, and telephone interviews (Level 4)	485 clinicians (305 nurses, 49 physicians, and others) in 29 hospitals in 9 States	None	Majority agreed that hospital administrators did not punish error reporters. Staff have learned and would like to continue to learn from mistakes of others. Most agreed that the hospital culture recognized that mistakes could be made (64%) and that error reporting could be done by all employees (86%). Majority felt comfortable (65%) or somewhat comfortable (32%) discussing medical errors. Attempts to maintain collegiality and their belief about lacking authority prevented nurses from questioning physicians. Pharmacists were more confident in their ability to recognize errors. Nurses reported most frequent problem was unclear or confusing patient orders. Nonphysicians attributed many errors to nursing practices. 96% of nurses and more than 90% of physicians, administers, and pharmacists assigned patient safety responsibility to nurses. 22% of respondents believed that clinicians and administrators shared equal responsibility for patient safety. Nurses reported that they were responsible for reporting errors (99%), educating themselves (98%), recommending changes in procedures (88%) and policy (86%), reviewing reported events (79%), and participating in investigations of errors (72%). However fewer than half had participated in investigating, reviewing, or analyzing errors.

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Costello 2007[119]	Error reporting	Pretest and post-test	Retrospectively assessed error reports, then again assessed error reports after several interventions (Level 4)	Physicians and nurses in a pediatric critical care center	Introduction of clinical pharmacists to raise awareness of medication safety and encourage reporting of all errors	Medication error reporting increased overall, but reports from nurses remained relatively constant and the reports from physicians decreased. The pharmacist did not change the error reporting culture.
Day 2004[134]	Reporting adverse events	Cross-sectional study	Administered a retrospective questionnaire about experience in reporting errors (Level 4)	32 physicians, 175 nurses, and 44 others (a 43% response rate) in 1 hospital in Utah	None	Physicians and nurses reported similar reporting experiences, but nurses reported 27% more. 34% of ICU staff reported errors. Physicians reported more major events while nurses reported more minor events; nurses had a more "inclusive view." Physicians and nurses reported more near misses. 47% reported time and 27% reported fear of punitive actions as the major barriers to reporting.
Elder 2007[131]	Barriers to error reporting Reasons to report errors	Cross-sectional study	Conducted focus groups on errors related to testing, issues involved in error reporting, and the effects of error reporting on office systems (Level 4)	Physicians, nurse practitioners, physician assistants, office staff, and nurses in 8 family physicians offices	None	Majority of reporting barriers were a lack of time, forgetfulness, and confusion about what to and who should report. Most common reported reason for reporting errors was a perceived benefit.
Espin 2006[81]	Error disclosure and reporting	Cross-sectional study	Questionnaire using 4 scenarios	9 surgeons, 9 nurses, 10 anesthesiologists in operating rooms at 2 teaching hospitals	None	Patients want full disclosure, while physicians and nurses want to disclose only what happened. Nurses (the only clinician type asked) were less likely to want to report errors than patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Espin 2007[130]	Error reporting	Cross-sectional study	Administered 4 error scenarios to nurses	13 perioperative nurses at 1 hospital in Canada	None	58% of theoretical errors were identified as errors, only 26.7% of which would have been reported by the nurses. Nurses perceived error reporting as a profession-specific responsibility; nurses should report errors made by nurses. The presence of a negative outcome appeared to be a secondary consideration for nurse error reporting. Nurses had a greater tendency to report errors informally with a nurse colleague or nurse manager.
Evans 2006[106]	Barriers to error reporting	Cross-sectional study	Anonymous survey of physicians and nurses about their knowledge of their organizations' reporting system, how often they reported errors, and reasons why errors were not reported (Level 4)	70.7 response rate for physicians and 73.6% for nurses in hospitals in southern Australia	None	98.3% of physicians and nurses were aware of the incident reporting system. Nurses were more likely to know how to submit an error report (88.3%), to have completed an error report (89.2%), and to know where to submit an error report (81.9%).
Evans 2007[120]	Error reporting	Nonrandomized trial	Comparison of incident reporting rates between 1 control and 1 intervention hospital (Level 3)	2 hospitals in Australia	Educational intervention was combined with a revised reporting system, with an option for a call center.	Reporting increased throughout the hospitals. More reports were initiated by physicians in EDs and were anonymous. Nurses generated 84% of error reports.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fein 2005[91]	Error disclosure	Case control study	Focus group interviews, on ethical perceptions and details of error disclosure (Level 4)	Hospital personnel and former patients (n = 240), 25 focus groups: separate stakeholder groups of attending physicians, residents, nurses, administrators, former patients	None	All agreed that errors should be disclosed when patients are harmed. Degree of harm caused by error and whether patients and others were aware of errors were characteristics related to disclosure. Institutional culture (perceived tolerance for error and supportive infrastructure) was important to disclosure decision. Patient factors were health care sophistication, desire for information, and rapport with provider. Provider factors included fears of malpractice, reputation, job threat, and change in rapport with the patient, as well as perceived professional responsibility, medical training, lack of confidence in disclosure skills, and personal discomfort.
Fernald 2004[121]	Error reporting in ambulatory settings	Cross-sectional study	Collected and analyzed error reports from clinicians and staff, using a voluntary reporting system (Level 4)	2 practice-based research networks	Implemented a voluntary reporting system	47% of reported errors were associated with diagnostic tests, 35.4% with medications, and 13.6% with both medication and a diagnostic test; 70.8% of error reports were associated with communication errors. Confidential reports were more complete than anonymous reports. Reporting different types of patient harm did not vary between anonymous and confidential reports.
France 2003[122]	Reporting system	Quality improvement	Assessed utilization of a voluntary reporting system and provider-initiated improvements (Level 4)	1 hospital in Tennessee	Implemented a voluntary reporting system	Nurse reporting significantly decreased after implementation, while pharmacy reporting significantly increased.
Furukawa 2003[123]	Reporting medication errors	Cross-sectional study	Errors reported using a Web-based system during a 2-year period (Level 4)	Physicians, nurses, pharmacists, technologists, and others in 1 hospital in Japan	None	Nurses reported 78% of errors, an average of 2.2 reports per nurse. The majority of error reports submitted by nurses and pharmacists were considered minor. Physicians were found to report errors only when detected and prevented by nurses or pharmacists.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Harper 2005[144]	Barriers to error reporting	Cross-sectional study	Self-report survey (Reporting Culture Survey) on mandatory reporting system in hospitals transitioning to close-call reporting system: scaled and open-ended items (Level 4)	858 nurses and physicians (a 41% response rate) at 2 hospitals in Texas	None	Less than 10% of respondents had knowledge of the mandatory reporting system, but less than half of nurses and 20% of physicians reported using the system. Physicians and nurses were not positive about the effectiveness of a hospital-based reporting system. Physicians reported that nurses were responsible for reporting errors. 40% of physicians and 30% of nurses were concerned about the anonymity of reporters, yet 86% of nurses and 81% of physicians favored feedback on corrective action taken in response to the report. 40% of physicians and 30% of nurses were concerned that the reporting system would be used punitively.
Harris 2007[133]	Error reporting	Prospective cohort study	Assessment of error reports once a new reporting system had been put in place (Level 4)	3 ICUs in a 1,371-bed urban teaching hospital	A new, card-based reporting program to encourage anonymous reporting of errors	Nurses submitted 67.1% of error reports, followed by 23.1% by physicians and 9.5% by other reporters. Of the reports where errors did not reach the patient, 31.1% were from nurses, 36.2% from other staff, and 17% from physicians. Of the reports were errors harmed patients, 33.9% were from physicians, 27.2% from nurses, and 13% from other staff.
Hirose 2007[124]	Error reporting	Cross-sectional study	Evaluation of lag time of submission of 6,880 reports filed by nurses and physicians during a 3-year period (Level 3)	Reports submitted by nurses and physicians in 1 hospital in central Japan	None	Nurses filed 93.3% of the reports, 99.5% of which were categorized as minor incidents. Physicians submitted 32 reports (an annual reporting rate of 0.26 per physician), while nurses submitted 31 reports (an annual reporting rate of 3.43 per nurse) for major errors. Lag time was 18% shorter for major events than minor, and 75% longer for physicians.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hobgood 2004[100]	Error disclosure Error reporting	Cross-sectional study	Retrospective survey of health care providers' experiences with disclosing medical errors (Level 4)	41 EMTs, 33 RNs, and 42 physicians in 1 tertiary care academic medical center	None	Disclosure to patients was associated with provider type (19% EMTs, 23% RNs, and 74% physicians). 59% of physicians reported observing another provider disclose an error.
Hobgood 2006[92]	Error disclosure Error reporting	Cross-sectional study	Survey using 10 clinical vignettes (Level 4)	40 physicians, 26 nurses, and 35 EMTs in 1 tertiary care academic emergency department	None	Physicians were more likely (71%) to disclose an error than were nurses (59%), but nurses were more likely (68%) to report the error than were physicians (54%).
Inoue 2004[125]	Types of error reports	Cross-sectional study	Retrospective analysis of errors reported through incident reports (Level 4)	Incident reports submitted by nurses in 6 urban hospitals in Japan	None	Error rates were high for prevention of problematic behavior, prevention of suicide, safeguarding against falls, and subcutaneous injections of insulin. Error rates that were high in some hospitals, but not all, were maintenance of dialysis, endoscopy preparation and assistance, administration of preoperative treatments, and blood transfusions. Error rates were higher in hemodialysis patients, those with problematic types of behavior, and the elderly. Incidence of errors was associated with rule violations, management practices, and nonstandardized nursing practices.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Jeffe 2004[132]	Perceptions of error reporting Barriers to error reporting	Cross-sectional study	Verbatim transcribed focus groups, recommendations for systems change to improve reporting, including awareness of provider status, benefits of feedback, and culture change (Level 4)	9 focus groups with 49 nurses, 10 nurse managers, and 30 physicians in 20 community and academic hospitals	None	Culture change might be accomplished as providers' concern and responses were considered in systems changes to improve reporting and policy revisions; how best to improve error reporting and disseminate information about errors might benefit when considering perceived barriers to reporting and including front-line providers' perspectives on clear guidelines on what to report, education on reporting mechanisms, anonymous reporting mechanisms, personnel, and routine followup of error reports for education and hospital action. Nurses were more knowledgeable about how to report errors. All mentioned barriers—fear of reprisals, lack of confidentiality, time, and feedback after an error—are reported. Both physicians and nurses agreed that reporting was intended to change practice and policy to promote patient safety.
Jones 2004[116]	Error reporting	Quality improvement	Standardized voluntary medication reporting form and database, compared with MEDMARX; NCC MERP severity index was used to categorize severity of harm to the patient (Level 4)	10 critical access hospitals	Conducted education workshops about nature of errors, the design of safety systems, and best practices in medication safety; provided quarterly reports from the error reports the hospitals	Most errors were not harmful; greater availability of pharmacists associated with reporting greater proportions of Category A errors (circumstances have the capacity to cause error) and Category B errors (an error occurred, but the error did not reach the patient). Nurses submitted 97% of error reports.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kim 2006[157]	Electronic error reporting	Cross-sectional study	Structured interview (Level 4)	Chairs of nursing departments (a 35% response rate) throughout Korea	None	Only 3% of hospitals used health information technology (HIT); HIT mainly used for medication administration, order entry, and radiology.
Kim 2007[139]	Error reporting Barriers to error reporting	Cross-sectional study	AHRQ's patient safety culture survey (Level 4)	886 nurses (a 92.3% response rate) in 8 teaching hospitals in Korea	None	67% of nurses reported always reporting errors resulting in patient harm. About half were unclear about what should be reported. 32% worried that their errors were kept in files. 52% reported having been given feedback and informed about errors made. 48% reported speaking out if they saw something negative, and 38% would voice opinions that differed from those in authority. 66% felt that their suggestions to improve patient safety were ignored. 83% felt that more errors should have happened than did, and 52% reported their units had serious patient safety problems. 56% reported problems talking with physicians. Frequency of reporting errors was higher among nurses with 5 to 10 years experience. Head nurses reported errors more frequently than did staff.
King 2001[153]	Error reporting	Cross-sectional study	Mailed surveys of error scenarios to RNs to elicit error reporting behaviors (Level 4)	372 nurses in the Midwest	None	Nurses were able to differentiate between intentional wrongdoing, which was related to questionable behavior. The perception of severity determined whether the error was reported. Unintentional errors would not be reported.
Lata 2004[126]	Improving adverse drug event (ADE) reporting	Cross-sectional study	Determine whether nurse case managers and pharmacists increase reporting of serious ADEs (Level 4)	1 community hospital in rural Wisconsin	Nurse case managers were educated that they were expected to report ADEs.	Nurse case managers reported 62% of ADEs, compared to 17% by pharmacists, and 75% of serious adverse drug reactions.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lawton 2002[46]	Barriers to error reporting	Cross-sectional study	Questionnaire about willingness to report errors of others; included error scenarios (Level 4)	73 physicians, 145 nurses, and 92 midwives (a 53% response rate) in 3 NHS trusts in England	None	Reporting was more likely if there was a bad outcome. Physicians were less likely to make a report than were nurses or midwives. Health care professionals were less likely to report errors of senior colleagues. Physicians were unlikely to report violations of clinical protocols, whereas nurses and midwives were more likely.
Mayo 2004[142]	Error reporting	Cross-sectional study	Random sample of RNs surveyed about perceived causes of medication errors, percentage of medication errors reported to nurse managers, types of reportable incidents, and reporting behaviors, including medication errors scenarios (Level 4)	983 RNs (20% response rate) in the United Nurses Association of California/ Union of Health Care Professionals	None	When the dose was withheld or omitted, the majority would report the event to the physician, but few would have completed an incident report for the withheld medication, compared to about half for the omitted dose. Nurses working in neonatal intensive care units perceived higher reported errors (52.5%) than did those working in medical/surgical units (35.3%). The mean perceived percentage of reported errors was 45.6%. 92.6% reported knowing what a medication error was, and 91.3% reported knowing when to use an incident report. Reporting barriers were fear of manager reactions (76.9%), fear of coworker reactions (61.4%), and considering error was not serious enough to warrant reporting (52.9%).
Mick 2007[154]	Reporting Errors	Cross-sectional study	Assessed error reports	300 employees (out of a possible 800) in 5 inpatient units	New close call error reporting program, called the Good Catch Program with periodic feedback to staff.	The new program resulted in a 1,468% increase (from 175 before to 2,744 afterwards) in the number of reports. Reports facilitated the targeting of interventions to improve patient safety.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Nuckols 2007[127]	Reporting errors	Cross-sectional study	Analyzed 3,875 reports from 2 hospitals (Level 4)	1 academic tertiary referral hospital and 1 affiliated community hospital in Southern California	None	The majority of reports were for errors involving medications, operations, falls, and procedures. 89% of incident reports were from nurses. 48% of incidents occurred on general floors, 21% in ICUs, and 14% in operating rooms. Nurses were involved in 43% of the potentially preventable events, while physicians were involved in 16%.
Osborne 1999[69]	Perceptions of errors Reporting medication errors Barriers to error reporting	Cross-sectional study	Survey to RNs about perceived causes of medication errors (Level 4)	57 RNs (61.9% response rate) on medical-surgical units in a 700-bed community hospital in South Florida	None	43.9% of respondents reported that only 25% of medication errors were reported. 84.2% of respondents indicated that they knew what defined an error, and 86% that medication errors were not reported because of fear. 57.9% reported that they did not report a medication error when they did not consider it serious. There was no difference in perceptions associated with age, years of experience, or level of education.
Osmon 2004[137]	Reporting errors	Cross-sectional study	Prospective analysis following implementation of a new error reporting process, specific to the hospital (Level 4)	1 urban teaching hospital in Missouri	Implementation of new hospital-based error reporting system using the SAFE reporting cards	Reporting rate for medical events was 31.9 per 100 ICU patient admissions. Nurses reported the majority of events (59.1%), followed by medical students (27.2%) and ICU attending physicians (2.6%). Most reports involved delays or omissions (e.g., medications, diagnostic tests, or necessary/planned procedures (36.5%)), medication errors (20.2%), and malfunctioning equipment (7.9%). 9.9% of events required life-sustaining interventions, and 3% may have led to the patient's death. 60.9% of life-sustaining interventions were a result of delays/omission of prescribed nonmedication treatments and necessary planned procedures.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rathert 2007[146]	Reporting errors	Cross-sectional study	Survey measuring patient-centered climate, perceived medication error frequency, job satisfaction, comfort reporting own errors and pointing out the errors of others (Level 4)	307 nurses (a 57% response rate) in 3 acute care hospitals in the eastern United States	None	Nurses are more comfortable reporting their own errors in a patient-centered care climate than they are pointing out the errors made by others.
Rudman 2005[112]	Error reporting systems	Cross-sectional study	Comparative description of baseline paper-based medication errors with postintervention Web-based reports; increased medication error reports, increased intercepted medication error threats, and staff access to post error interventions (Level 3)	Hospital reported errors: pre (average = 434.5/mo.) vs. post (average = 79.9/mo.)	Web-based, anonymous medication error reporting system on all personal computers and work stations	Staff accessed reports, noting immediate actions taken. Error reports and intercepted error threats increased. Intercepted nurse, physician, and pharmacist medication errors increased. Errors attributed to physicians increased as nurses' and pharmacists' decreased. Details of cause-of-error reporting.
Schuerer 2006[136]	Error reporting systems	Prospective cohort study	Assessment of error reporting using a prospective analysis following implementation, withdrawal, and then reintroduction of a new error reporting process, specific to the hospital (Level 4)	Nurses, physicians and other health care workers in 1 24-bed surgical ICU	A card-based reporting system (SAFE)	Physician reporting increased from 0.3 to 5.8 reports per 1,000 patient days, and nurses from 18 to 39 reports per 1,000 patient days. When reporting cards were removed, physician reporting decreased to 0 per 1,000 patient days, then increased to 8.1 reports when the cards were reintroduced. A higher proportion of events reported by physicians were for events that caused harm, while the higher proportion of events reported by nurses were for events that did not cause harm to patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Stratton 2004[141]	Perceptions on error reporting	Cross-sectional study	Survey of pediatric and adult hospital nurses on their perceptions of the proportion of reported medication errors and why errors are not reported (Level 4)	57 pediatric and 227 adult nurses (a 40% response rate) in 33 acute care units in 11 hospitals (in rural Midwestern States, urban areas in the Rocky Mountain region of the United States)	None	Pediatric nurses estimated that 67% of medication errors were reported; adult nurses estimated 56%. Error rates per 1,000 patient-days were 14.80 in pediatric units and 5.66 in adult units. Medication errors are underreported by pediatric and adult nurses, with more reported on pediatric units. The more strongly nurses on pediatric units agreed with management-related and individual/personal reasons for not reporting errors, the lower the estimates of errors reported. Pediatric nurses agreed that nurses fear consequences from reporting and believe peers will think of the reporters as incompetent.
Throckmorton 2007[140]	Error reporting	Cross-sectional study	Survey about the environment and reasons why nurses do not report errors (Level 4)	435 nurses (a 10% response rate) licensed to practice in Texas	None	Knowledge of the nurse practice act was not associated with intent to report. Nurses providing direct care to patients were more likely to report. Nurses would report both errors that harmed patients and those that did not.
Tuttle 2004[135]	Error reporting system	Prospective cohort study	Implementation of a voluntary, electronic reporting system (ERS) for safety events involving patients or visitors (Level 4)	1 teaching hospital in New York	Implemented new confidential ERS for safety events and provided multifaceted education program to promote safety awareness and how to use the ERS.	Nurses reported 73% of the 2,843 safety events; physicians reported 2%. Of the events reported: - 16% were unsafe conditions or near misses; 22% were adverse events where patient was harmed; and 39% were not reported correctly. - 40% were medication/infusion events, 30% were adverse clinical events, and 24% were falls.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Uribe 2002[149]	Barriers to reporting errors	Cross-sectional study	Survey on perceived barriers to reporting and likelihood they could be modified (Level 4)	56 physicians and 66 nurses (17.3% response rate) in a Midwest academic hospital	None	Major barriers to error reporting were time and work involved in documenting an error; not being able to report anonymously; thinking that errors with no negative outcomes should not be reported; fear of legal actions; and hesitancy to "tell" on someone else. Modifiable barriers were identified as the structure and processes for reporting errors and education. Least modifiable barriers were fear of lawsuits, fear of being blamed, and motivational issues. Physicians identified twice as many barriers to reporting than did nurses; both identified time and extra work involved in documenting an error. Nurses were more concerned about anonymity, "telling" on someone else, fear of lawsuits, and the necessity of reporting errors that did not result in patient harm.
Vojir 2003[145]	Error reporting	Cross-sectional study	Surveyed nurses about their estimates of reported medication administration errors (Level 4)	1,214 nurses in 205 adult patient care units in 26 hospitals	None	Differences in staff definitions of reportable error, occurrence data not widely shared with staff nurses, staff nurses rely on personal experience to estimate unit medication administration errors.
Wakefield 1996[70]	Barriers to reporting medication errors	Cross-sectional study	Survey of medication administration errors and reasons nurses do not report errors, oriented to reporting process (Level 4)	RNs (n = 1,384) in 24 acute care hospitals; nonrandomly selected convenience sample	None	Fear, disagreement over whether an error occurred, administrative responses to medication errors, and effort required to report MAE are reasons nurses may not report errors. Fear inhibits reporting; organizational culture change needed to support reliable, valid, complete error reporting; too much emphasis placed on medication errors as measure of quality nursing care.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wakefield 1999[150]	Barriers to reporting MAEs Perceived causes of MAEs Estimated MAEs reported	Cross-sectional study	Survey assessing perceived reasons for not reporting MAEs (Level 4)	Staff nurses and supervisors in 29 acute care hospitals in Iowa	None	There was some agreement on fear and administrative response as barriers to error reporting, but the barriers are associated with individual characteristics and management practices. The degree of agreement between staff and their supervisors about why errors are not reported varied considerably. Supervisors were more likely to view fear of administrative response as a barrier to error reporting, whereas staff nurses did view fear as a barrier**.**
Wakefield 2001[151]	Barriers to reporting MAEs	Cross-sectional study	Questionnaire on organizational culture, implementation of clinical quality improvement (CQI), and nurses' perceptions of MAE reporting (Level 4)	292 nurses from 6 Midwest hospitals	None	Hospital culture types varied: smaller institutions tended to have group-oriented cultures, larger institutions tended to be more hierarchal in nature. The extent of CQI implementation increased with bed size of the hospital, and perceived rate of MAE reporting decreased. The greater the number of barriers, the lower the reporting of errors. The presence of a group-oriented culture and higher levels of CQI implementation were positively but not significantly associated with reporting errors. Hierarchical or rational-type cultures were negatively associated with reporting errors.
Wakefield 2005[148] (Note: This includes findings of Wakefield 1996, 1999, 2001[70, 150,151])	Barriers to reporting medication errors	Cross-sectional study	Scale development, content validity (face), construct validity (factorial), concurrent validity; internal consistency, and test-retest reliability (Level 4)	RNs (n =1,384 in 1994, 1,428 in 1996, 862 in 1998, and 295 in 2001) in hospitals (n = 24 in 1994, 29 in 1996, 21 in 1998, and 16 in 2001)	None	The reported reasons why MAEs were not reported were due to disagreement with the definitions, the burden of the reporting effort, fear (e.g., judgment from peers, patients, and their families, physician reprimand, adverse consequences, and being blamed for patient harm), and administrative response (e.g., no positive feedback, individual blame, and response not matching the severity of the error).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weingart 2000[36]	Error reporting	Cross-sectional study	Compared house officer reports with incident reports and patients' medical records, using confidential peer interviews to identify errors and substandard quality care (Level 3)	Medical house officers, nurses, social workers, physical therapists, and case managers in 1 hospital in Boston	None	Of the errors verbally reported by the house officer and confirmed in the patient's medical record, only one was recorded in the hospitals' incident reporting system. Nurses recorded the majority of incident reports, whereas only 1 incident report was submitted by a house officer.
Wild 2005[143]	Perceptions and attitudes about error reporting Knowledge and use of error reporting systems	Cross-sectional study	Self-administered survey on the knowledge and use of the hospital error reporting system and attitudes and perceptions about hospital culture regarding error reporting (Level 4).	24 resident physicians (a 96% response rate) and 36 nurses (a 60% response rate) in 1 community hospital in Connecticut	None	54% of residents and 97% of nurses knew of the hospital's error reporting system; 13% of residents and 72% of nurses were likely to use it. Residents were more likely to perceive the culture as more threatening and nonsupportive; 29% of residents and 64% of nurses reported being comfortable discussing mistakes. 42% of residents and 44% of nurses were uncomfortable discussing errors with patients. 64% of nurses were comfortable discussing mistakes with supervisors. 54% of residents and 91% of nurses reported being more likely to report an error, either their own or someone else's. 25% of residents and 1% of nurses were more likely to report an error if they did not like the person who caused the error.
Yamagishi 2003[128]	Reporting adverse events Reporting method	Cross-sectional study	Adverse event data obtained from incident reports, logs, checklists, nurse interviews, medication error questionnaires, urine leucocyte tests, patient interviews, and medical records. Patients were interviewed about the events (Level 3).	Event reports by 115 staff nurses in 6 wards in 1 hospital in Tokyo, Japan	None	Actual events and reported events were similar when using incident reports, checklists, nurse interviews, urine leucocyte tests, and questionnaires of medication errors. Falls were not always reported, depending on whether patients were independent with activities of daily living or under standardized care protocols. Restraint use was usually not documented in patient record.

Chapter 36. Wrong-Site Surgery: A Preventable Medical Error

Deborah F. Mulloy, Ronda G. Hughes

Background

Surgery is one area of health care in which preventable medical errors and near misses can occur. However, until the 1999 Institute of Medicine report, *To Err Is Human,*[1] clinicians were unaware of the number of surgery-associated injuries, deaths, and near misses because there was no process for recognizing, reporting, and tracking these events.[2] Of great concern is wrong-site surgery (WSS), which encompasses surgery performed on the wrong side or site of the body, wrong surgical procedure performed, and surgery performed on the wrong patient.[3] This definition also includes "any invasive procedure that exposes patients to more than minimal risk, including procedures performed in settings other than the OR [operating room], such as a special procedures unit, an endoscopy unit, and an interventional radiology suite"[4] (p. 11). WSS is also defined as a sentinel event (i.e., an unexpected occurrence involving death or serious physical or psychological injures, or the risk thereof) by the Joint Commission (formerly called the Joint Commission on Accreditation of Healthcare Organizations), which found WSSs to be the third-highest-ranking event.[5]

Causes and Consequences of Wrong-Site Surgery

WSS can be a devastating experience for the patient and have a negative impact on the surgical team.[6, 7] State licensure boards are imposing penalties on surgeons for WSS,[8] and some insurers have decided to no longer pay providers for WSS or wrong-person surgery, nor for leaving a foreign object in a patient's body after surgery.[9] Surgery performed on the wrong site or wrong person has also often been held compensable under malpractice claims. Indeed, 79 percent of wrong-site eye surgery and 84 percent of wrong-site orthopedic claims resulted in malpractice awards.[10, 11]

WSSs are rare events, but we are learning more about their prevalence. Because reporting of sentinel events to the Joint Commission is voluntary, it could be that only 10 percent of actual WSSs are reported.[12] Researchers have confirmed that the Joint Commission's numbers are low, finding wide variations in the number of WSSs: 1 out of 27,686 cases,[6] or 1 out of every 112,994 surgeries,[13] or 1 in 5 hand surgeons during their career,[7] or 1 out of 4 orthopedic surgeons with 25 years' experience.[14] Regardless of the exact number of WSSs, they are seen as a preventable medical error if certain steps are taken and standardized procedures are implemented in the perioperative setting.[15, 16]

The incidence of reported WSS has increased in recent years. From the inception of the Joint Commission's Sentinel Event program, the number of WSSs reported has increased from 15 cases in 1998, to a total of 592 cases reported by June 30, 2007.[17] Of these, WSSs most commonly occur in orthopedic or podiatric procedures,[5] general surgery, and urological and neurosurgical procedures.[17] In response to the occurrence of these preventable errors, the Joint

Commission issued two National Patient Safety Goals on January 1, 2003 to target wrong-site surgery:

Goal 1—to improve the accuracy of patient identification by using two patient identifiers and a "time-out" procedure before invasive procedures.

Goal 4—to eliminate wrong-site, wrong-patient, and wrong-procedure surgery using a preoperative verification process to confirm documents, and to implement a process to mark the surgical site and involve the patient/family.[40]

Both of these goals continue to be an ongoing priority for the Joint Commission. Yet with many surgical procedures traditionally performed only in acute care settings now being performed in freestanding surgical centers and physician offices—not necessarily all under the purview of the Joint Commission—surgeons, surgical teams, and patients need to be vigilant with all surgeries, particularly when the level of oversight and scrutiny may not be as high as in hospitals.

WSS is generally caused by a lack of a formal system to verify the site of surgery or a breakdown of the system that verifies the correct site of surgery.[18] In using root-cause analysis, a process that determines the underlying organizational causes or factors that contributed to an event, the Joint Commission found the top root causes of WSS to be communication failure (70 percent), procedural noncompliance (64 percent), and leadership (46 percent).[16] Other system and process causes are listed in Table 1. Risk factors associated with WSS were identified as emergency cases, multiple surgeons, multiple procedures, obesity, deformities, time pressures, unusual equipment or setup, and room changes.[17]

Table 1. Causes of Wrong-Site Surgeries[5, 18, 19, 20]

System Factors	Process Factors
♦ Lack of institutional controls/formal system to verify the correct site of surgery ♦ Lack of a checklist to make sure every check was performed ♦ Exclusion of certain surgical team members ♦ Reliance solely on the surgeon for determining the correct surgical site ♦ Unusual time pressures (e.g., unplanned emergencies or large volume of procedures) ♦ Pressures to reduce preoperative preparation time ♦ Procedures requiring unusual equipment or patient positioning ♦ Team competency and credentialing ♦ Availability of information ♦ Organizational culture ♦ Orientation and training ♦ Staffing ♦ Environmental safety/security ♦ Continuum of care ♦ Patient characteristics, such as obesity or unusual anatomy, that require alterations in the usual positioning of the patient	♦ Inadequate patient assessment ♦ Inadequate care planning ♦ Inadequate medical record review ♦ Miscommunication among members of the surgical team and the patient ♦ More than one surgeon involved in the procedure ♦ Multiple procedures on multiple parts of a patient performed during a single operation ♦ Failure to include the patient and family or significant others when identifying the correct site ♦ Failure to mark or clearly mark the correct operation site ♦ Incomplete or inaccurate communication among members of the surgical team ♦ Noncompliance with procedures ♦ Failure to recheck patient information before starting the operation

Universal Protocol for Preventing Wrong-Site Surgery

Early attempts to address the occurrence of WSS started with the American Academy of Orthopedic Surgeons (AAOS) and the North American Spine Society (NASS). After reviewing of 10 years of malpractice claims and polling its members,[21] AAOS developed an awareness campaign to encourage the marking of the right surgical site, called "Sign Your Site."[22] But in practice, adding an additional warning such as "No" on the incorrect site and having the surgical team work together to verify the correct site helped the Sign Your Site program to be effective.[23] The NASS further refined the Sign Your Site process by adding more detail for the appropriate level and site of the spine in its "Sign, Mark, and X-ray" program, calling for marking the exact site and side of the spine with a radiopaque indicator, and put forth a checklist for patient and procedure verification.[24]

In 2003, the Joint Commission convened a summit, including the AAOS and leaders from 23 other organizations, to address the continued escalation of reported WSS cases (i.e., sentinel events reported to the Joint Commission); and the impact of WSS on patients, their families, and health care professionals; and associated health care costs. The summit was specifically designed to bring health care professionals and others together to address and develop strategies to lessen or eliminate WSS.[14] A major outcome of the summit was creation of a protocol, *The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery* ™ (see Text Box 1).[20] This protocol was designed to be used in all areas where invasive procedures are performed within health care organizations, including nonoperating-room settings. The goal was to drastically reduce or eliminate completely the incidence of WSS by using a standardized routine and acceptable preoperative process of verifying the patient and the correct site, as well as the physician marking the site with his or her initials before the patient is sedated.

The Universal Protocol for WSS is based on prevention theories that drive safety practice in high-risk industries, such as aviation and development of nuclear weapons. The operating room is complex with "tight coupling" of processes that happen very quickly and cannot be turned off once started; failed parts cannot be isolated from other parts—resulting in an unsafe process. A model most often used to demonstrate this is the one described by Reason[25] as the Swiss cheese model, where error defenses breakdown or are not in place, resulting in patient harm. (See the chapter on human factors for more information on Reason's model.)

By implementing a systems change required by the WSS protocol, the possibility of a WSS should be prevented. The three key elements of the Universal Protocol for WSS are (1) preoperative verification process, (2) marking the operative site, and (3) taking a time out. The Universal Protocol is to be used in ambulatory care, hospitals, critical access hospitals, and office-based settings.[20] Implementing and adhering to this protocol should eliminate WSS errors that can be attributable to interruptions, distractions, and too many forms or procedures. On July 1, 2004, the Joint Commission began to include these three key Universal Protocol elements in its accreditation process for health care organizations and also provided further guidance on its implementation (see Text Box 2).

Text Box 1. The Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™

Wrong site, wrong procedure, wrong person surgery can be prevented. This Universal Protocol is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations.

In developing this protocol, consensus was reached on the following principles:

- Wrong site, wrong procedure, wrong person surgery can and must be prevented.
- A robust approach—using multiple, complementary strategies—is necessary to achieve the goal of eliminating wrong site, wrong procedure, wrong person surgery.
- Active involvement and effective communication among all members of the surgical team is important for success.
- To the extent possible, the patient (or legally designated representative) should be involved in the process.
- Consistent implementation of a standardized approach using a universal, consensus-based protocol will be most effective.
- The protocol should be flexible enough to allow for implementation with appropriate adaptation when required to meet specific patient needs.
- A requirement for site marking should focus on cases involving right/left distinction, multiple structures (fingers, toes), or levels (spine).
- The Universal Protocol should be applicable or adaptable to all operative and other invasive procedures that expose patients to harm, including procedures done in settings other than the operating room.

In concert with these principles, the following steps, taken together, comprise the Universal Protocol for eliminating wrong site, wrong procedure, wrong person surgery:

- **Preoperative verification process**
  - **Purpose:** To ensure that all of the relevant documents and studies are available prior to the start of the procedure and that they have been reviewed and are consistent with each other and with the patient's expectations and with the team's understanding of the intended patient, procedure, site, and, as applicable, any implants. Missing information or discrepancies must be addressed before starting the procedure.
  - **Process:** An ongoing process of information gathering and verification, beginning with the determination to do the procedure, continuing through all settings and interventions involved in the preoperative preparation of the patient, up to and including the "time out" just before the start of the procedure.

- **Marking the operative site**
  - **Purpose:** To identify unambiguously the intended site of incision or insertion.
  - **Process:** For procedures involving right/left distinction, multiple structures (such as fingers and toes), or multiple levels (as in spinal procedures), the intended site must be marked such that the mark will be visible after the patient has been prepped and draped.

- **"Time out" immediately before starting the procedure**
  - **Purpose:** To conduct a final verification of the correct patient, procedure, site and, as applicable, implants.
  - **Process:** Active communication among all members of the surgical/procedure team, consistently initiated by a designated member of the team, conducted in a "fail-safe" mode, i.e., the procedure is not started until any questions or concerns are resolved.

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Text Box 2. Implementation Expectations for the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™

These guidelines provide detailed implementation requirements, exemptions, and adaptations for special situations.

Preoperative verification process

- Verification of the correct person, procedure, and site should occur (as applicable):
  - At the time the surgery/procedure is scheduled.
  - At the time of admission or entry into the facility.
  - Anytime the responsibility for care of the patient is transferred to another caregiver.
  - With the patient involved, awake, and aware, if possible.
  - Before the patient leaves the preoperative area or enters the procedure/surgical room.
- A preoperative verification checklist may be helpful to ensure availability and review of the following, prior to the start of the procedure:
  - Relevant documentation (e.g., history and physical, consent).
  - Relevant images, properly labeled and displayed.
  - Any required implants and special equipment.

Marking the operative site

- Make the mark at or near the incision site. Do NOT mark any nonoperative site(s) unless necessary for some other aspect of care.
- The mark must be unambiguous (e.g., use initials or "YES" or a line representing the proposed incision; consider that "X" may be ambiguous).
- The mark must be positioned to be visible after the patient is prepped and draped.
- The mark must be made using a marker that is sufficiently permanent to remain visible after completion of the skin prep. Adhesive site markers should not be used as the sole means of marking the site.
- The method of marking and type of mark should be consistent throughout the organization.
- At a minimum, mark all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). Note: In addition to preoperative skin marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.
- The person performing the procedure should do the site marking.
- Marking must take place with the patient involved, awake, and aware, if possible.
- Final verification of the site mark must take place during the "time out."
- A defined procedure must be in place for patients who refuse site marking.

Exemptions

- Single organ cases (e.g., Cesarean section, cardiac surgery).
- Interventional cases for which the catheter/instrument insertion site is not predetermined (e.g., cardiac catheterization).
- Teeth–but, indicate operative tooth name(s) on documentation or mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Premature infants, for whom the mark may cause a permanent tattoo.

"Time out" immediately before starting the procedure
Must be conducted in the location where the procedure will be done, just before starting the procedure. It must involve the entire operative team, use active communication, be briefly documented, such as in a checklist (the organization should determine the type and amount of documentation), and must, at the least, include:

- Correct patient identity.
- Correct side and site.
- Agreement on the procedure to be done.
- Correct patient position.
- Availability of correct implants and any special equipment or special requirements.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

Procedures for non-OR settings, including bedside procedures

- Site marking must be done for any procedure that involves laterality, multiple structures, or levels (even if the procedure takes place outside of an OR).
- Verification, site marking, and "time out" procedures should be as consistent as possible throughout the organization, including the OR and other locations where invasive procedures are done.
- **Exception:** Cases in which the individual doing the procedure is in continuous attendance with the patient from the time of decision to do the procedure and consent from the patient through to the conduct of the procedure may be exempted from the site marking requirement. The requirement for a "time out" final verification still applies.

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The Association of periOperative Registered Nurses (AORN), realizing the importance of the Universal Protocol for WSS, worked collaboratively with the Joint Commission to develop a Correct Site Surgery Tool Kit. The tool kit, designed to assist health care providers to implement the Universal Protocol for WSS in their facilities, was endorsed by the American College of Surgeons, American Society of Anesthesiologists, American Society for Healthcare Risk Management, American Hospital Association, and the American Association of Ambulatory Surgery Centers.

The AORN Correct Site Surgery Tool Kit contains a variety of resources to educate health care providers about the Universal Protocol for WSS and to assist them with its implementation. The resources include (1) an educational program on CD-ROM; (2) a pocket reference card outlining the steps necessary to promote patient identification, site marking, and the time out; (3) a template to facilitate development of a facility policy to implement the Universal Protocol for WSS; (4) a copy of the Universal Protocol for WSS and Guidelines for Implementing the Universal Protocol; (5) frequently asked questions of the Joint Commission and AORN; (6) letters to nurses, physicians, facility chief executive officers, and health care risk managers encouraging standard implementation of the Universal Protocol across all facilities; and (7) information for patients about the Universal Protocol for WSS and health care safety. This tool kit is available from AORN at http://www.aorn.org/PracticeResources/ToolKits/CorrectSiteSurgeryToolKit. In addition, AORN Standards, Recommended Practices, and Guidelines has a position statement on Correct Site Surgery that has additional information on preventing wrong site surgery.[39]

Several other organizations have set forth tools and policies to prevent WSS. The Veterans Affairs National Center for Patient Safety put forth the Ensuring Correct Surgery and Invasive Procedures directive, based on root-cause analysis, that adds two steps to the Joint Commission's

Universal Protocol: ensuring the consent form is administered and used properly, and having two members of the surgical team review patient information and radiological images prior to the start of the surgery.[26] The OR briefing tool used at Johns Hopkins Hospital expands the time-out part of the Universal Protocol by prompting additional dialogue between the anesthesia care team, nursing, and the surgical team.[27] Additionally, the British National Patient Safety Agency has introduced a risk management tool, setting forth a process for double-checking and identifying who is accountable at each stage for ensuring surgical markings on the right site to avoid WSS.[28]

Research Evidence

There is limited research on wrong-site surgery. The majority of studies have been retrospective, chart reviews, case studies, and surveys of various professional organizations. The evidence table summarizes the most recent evidence related to WSS, specifically the three components of the Universal Protocol.

In two of the retrospective studies that investigated WSS broadly, Meinberg and Stern,[7] in a study relating to the Universal Protocol, found that nearly half of surgeons changed their preoperative practices in response to the Sign Your Site campaign. Since the campaign targeted orthopedic surgeons, they were more knowledgeable about the campaign and were more likely to have changed their practices. Kwaan and colleagues[6] identified 62 percent of WSS cases that could have been prevented had providers adhered to the Universal Protocol. In this study, the authors concluded that the Universal Protocol would not have prevented the remaining one-third of WSS documented cases because of errors initiated in weeks before surgery (e.g., wrong documentation, inaccurate labeling of radiological reports). In an analysis of quality improvement efforts, similar findings also indicated implementation challenges associated with staff nonadherence because the issue of laterality was not addressed in the policy and the process was vulnerable to communication failures during handoffs.[29]

Preoperative Verification

In verifying that the right patient is to have the right surgery in the right location, one study found that when discrepancies occurred among clinicians, a review of the patient's information could resolve the discrepancy.[30] Published guidelines assert the need for a checklist to itemize exactly what should be checked, but do not specify what should happen if a discrepancy occurs.[31]

Marking the Site

Three different studies and one quality improvement project assessed aspects of site marking, included two different approaches in who actually marks the right site. All found challenges in ensuring that each surgical patient had the right site marked, therefore exposing patients to possible WSS. One study that surveyed a small number of surgeons on their site-marking practices following the establishment of national guidelines, found that their practices ranged from no marking to marking every patient, with some relationship to the type of surgery.[32] In approaching site marking from the point of view that it is the patient's responsibility, instead of the surgeon having complete responsibility, DiGiovanni and colleagues[33] sought to have patients

mark the right site after being given a set of instructions. They found that when patients (instead of someone from the surgical team) were asked preoperatively to mark "no" on the wrong foot or ankle, 60 percent of patients marked the site correctly.

The last study and quality improvement project assessed whether marking would cause other errors, because of the permanence of the ink, thereby discouraging site marking. The study found that marking the surgical site with a pen marker did not affect sterility or place a patient at a higher risk for infection.[34] The quality improvement project found that staff were not marking the right site because the ink upset breast cancer patients and was indelible on premature infants, and the policy did not address laterality.[29]

Time Out

Two studies found that the time out component can prevent the majority of WSS, but not all.[6, 13, 35] Another study found that when surgeons, anesthesiologists, and nurses were trained in doing a standardized 2-minute briefing prior to surgery, there were specific improvements in communication on the surgical site and side operated on.[36]

Evidence-Based Practice Implications

In response to continued WSS sentinel event reports, one of the Joint Commission's National Patient Safety Goals continues to be to eliminate wrong-site, wrong-patient, and wrong-procedure surgery. Eliminating WSS errors requires a systems approach, institutionalizing robust systems to verify the correct site that adequately addresses potential causes of breakdowns in the system. Hospital and surgery center leaders and managers should evaluate their policies and procedures regarding WSS and marking the right site to ensure that no WSSs occur under any circumstances.

Adoption of the Universal Protocol standardizes preoperative preparations, improves function of the health care team, and should avert any potential for WSS. All health care personnel must be knowledgeable about the Universal Protocol and consistently adhere to the three key elements—patient identification, site mark, and time out—as outlined in the Universal Protocol to reduce the number of WSSs occurring in the United States.

The Universal Protocol for WSS should be adhered to on all applicable cases, as the operating room and procedural areas are highly coupled and complex areas that would be unlikely to be completely error proof. Measures should be taken that require less reliance on memory. For example, a surgical site mark is a measure to prevent reliance on memory. However, when involving patients in marking the surgical site, one needs to assess their physical, cognitive, and emotional ability.[31]

All health care professionals have an obligation to comply with the Universal Protocol and to speak up if they feel patient safety is being compromised in any way.[37] Nurses, specifically perianesthesia nurses, should function as the patient's advocate and foster procedures that ensure right-site surgery.[38]

Research Implications

There is little empirical evidence regarding prevention of WSS or quantitative evaluation of implementation of strategies to prevent WSS. Part of the problem with research in this area has

been that the medical-error data are not easy to extract, and error data are often transferred to medical claims data and medical liability, further preventing the sharing of such data. Mandatory reporting of these data has just recently been required in some States. Consequently, there are gaps in the current evidence on wrong-site surgery. For example, there were no randomized controlled studies to evaluate the effect of the Universal Protocol on WSS. Research is needed to determine whether the patient's risk for WSS is associated with the organization following the Joint Commission's Universal Protocol or other standardized process, or with the effectiveness of the surgical team in communicating with each other. It is unknown how effective surgical teams are in complying with the protocol on a daily basis, and it is unknown what factors or barriers exist to implementing the Universal Protocol for WSS in facilities across the country.

Conclusion

The reported number of WSS cases continues to increase as health care organizations become more transparent to medical error. Many health care organizations, drawing on error-prevention theories and the experience of the aviation industry, recognize that through such transparencies, systems can change and result in better patient outcomes. However, it is unlikely that WSS will fully be reported because of industrywide report cards, fear of litigation, and difference of opinions. Although absolute numbers of WSS may not be striking, the consequences to the patient on whom it occurs are dire.

Search Strategy

Both PUBMED® and CINAHL® databases between 1990 and March 2007 were searched, using wrong site surgery[keyword] OR wrong site surgery[subject heading]. This identified 239 citations. Citations were excluded for the following reasons: non-English, dealt only with disclosing errors or patient preferences, opinion/editorial pieces, news articles, or announcements. This left 68 articles for consideration in this review, 10 of which were considered as evidence.

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Evidence Table. Summary of Evidence Related to Wrong-Site Surgery

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cronen 2005[34]	Sterility of surgical site marking	Nonrandomized control study	Test the sterility of the site mark after using a surgical marking pen	20 volunteers. The right forearm was used as the experimental (marked) arm, and the left forearm as the control arm. The experimental forearms were marked with a surgical marker as described by the protocol.	Both upper extremities were sterilized from the antecubital fossa to the phalanges with a 7.5% povidone-iodine scrub followed by the application of a 10% povidone-iodine paint. Swabs were used to obtain samples from the experimental and control arms, as well as from the marker. Swabs were sent for microbiological culture and analysis.	No growth was seen in the cultures of the swabs used on the experimental or control arms or on the marking pens. Preoperative marking of surgical sites in accordance with the Universal Protocol did not affect the sterility of the surgical field, a finding that provides support for the safety of surgical site marking.
DiGiovanni 2003[33]	Surgical site marking	Pretest and post-test study	Evaluated the responses of 100 elective patients undergoing foot and ankle surgery to participating in marking the surgical site. (Level 3)	Prospective study. 100 consecutive patients in a private foot-and-ankle practice followed the explicit preoperative instruction, before they underwent elective orthopedic surgery, to mark "NO" on the extremity that was not to be operated on.	Patients were instructed on how to mark the site	59 patients correctly marked the surgical site, 27 made no mark, 4 were considered partially marked, as the mark was different from the “NO” they were instructed to do. 70% of noncompliant patients had a worker compensation claim.
Giles 2006[32]	Surgical site marking	Noncomparative study	Retrospective qualitative semi-structured surveys. (Level 4)	In person or telephone interview of 38 surgeons in 14 hospitals in the U.K.		Surgeon’s practices and methods of site marking varied, as did their value of the need for marking.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
JCAHO 2003[20]	Surgical site identification protocol	Published guidelines based on a consensus report		Universal Protocol is applicable to all JCAHO accredited facilities commencing on July 1, 2004.	Preoperative strategy to verify the correct patient, type of procedure, and site of intervention	3-step Universal Protocol: • Preoperative verification process • Marking the operative site • Time out immediately before starting the procedure
Kwaan 2006[6]	Wrong-site surgery	Case series	Incidence, characteristics, cause of WSS. Characteristics of site verification protocols (Level 2)	Malpractice liability insurer data from 20-year period from one-third of Massachusetts physicians and approximately 30 hospitals. Site verification protocols in 2004 from 28 hospitals covered by 4 malpractice insurers in New England and Texas. Retrospective medical records reviewed on 13 of 24 identified cases of WSS.		Wrong-site surgery is rare as is major injury from WSS. Current protocols for site verification could have prevented only 2/3 of examined cases.
Makary 2007[36]	Communication	Pretest and post-test study	Survey	306 operating room (OR) staff (e.g., surgeons, nurses, and anesthesiologists) at one academic medical center (85% response rate)	Administered a version of the Safety Attitudes Questionnaire before and after initiation of an OR briefing program.	OR briefings reduced perceived risk for WSS, improved perceived collaboration/teamwork among OR staff, and promoted using team discussions.
Mawji 2002[29]	Surgical site identification protocol	Quality improvement project	Root-cause analysis of near misses, for project implementation using the Plan-Do-Study-Act method.	800-bed, 3-site academic hospital and network	Implementation of surgical site policy, marking “yes” on the surgical site and “no” on the other side.	Surgical site marking policy was not being followed. • Handoffs were missing critical information. • Nature of marking was problematic. • Laterality of markings not included in policy.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Meinberg 2003[7]	Incidence of wrong-site surgery in hand surgeons	Noncomparative study	Survey	1,560 active members of the American Society for Surgery of the Hand (ASSH) were polled by mail. Return rate of 67%.	29-question survey to determine incidence of WSS	Estimated number of WSS was 1 in 27,686 hand procedures. 21% hand surgeons reported performing wrong-site surgery at least once during their career; wrong finger occurred 63% of the 242 reported events.
Rogers 2004[31]	Barriers to implementing Wrong Site Surgery Guidelines	Changing practice projects/ research	Observational study of surgical cases at 4 facilities: 2 outpatient surgical units 1 large metropolitan teaching university 1moderate-size Federal facility	October 2001 to February 2002 Field observation and semi-structured interview questions. Total of 40 observational hours.		Surgical process is tightly coupled, complex system that includes multiple layers of interaction. Unlikely to error proof completely the process in such a dynamic environment, but measures can enhance the resiliency, such as having data available to all practitioners that is updated for everyone to see to prevent overreliance on memory. Avoid hidden assumptions, for example, that encourage patients to be involved in site-marking process as it assumes the patient is physically, cognitively, and emotionally able to correct any errors.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sexton 2006[30]	Teamwork climate in OR – preverification process	Noncomparative study	Safety Attitudes Questionnaire Survey	2,135 OR caregivers in a 60-hospital health system, including surgeons, surgical technicians, anesthesiologists, CRNAs, and OR nurses.		A high level of teamwork was perceived by the attending surgeons (64%) and residents (74%), which was markedly different from the attending anesthesiologists (39%), surgical nurses (28%), anesthesia nurses (25%), and anesthesia residents (10%). When attending surgeons were asked about a fellow, resident, or medical student questioning their decision, 45% of attending surgeons indicated that hierarchical systems should be in place, compared to 94% of airline crew members who preferred no hierarchies (Sexton et al., 2000). When asked the question, "Even when fatigued, I perform effectively during critical times," the surgical team response ranged from 47% to 70% in agreement, compared with 26% of pilots who agreed with this statement (Sexton et al., 2000).

Chapter 37. Medication Administration Safety

Ronda G. Hughes, Mary A. Blegen

Background

The Institute of Medicine's (IOM) first Quality Chasm report, *To Err Is Human: Building a Safer Health System*,[1] stated that medication-related errors (a subset of medical error) were a significant cause of morbidity and mortality; they accounted "for one out of every 131 outpatient deaths, and one out of 854 inpatient deaths"[1] (p. 27). Medication errors were estimated to account for more than 7,000 deaths annually.[1] Building on this work and previous IOM reports, the IOM put forth a report in 2007 on medication safety, *Preventing Medication Errors*.[2] This report emphasized the importance of severely reducing medication errors, improving communication with patients, continually monitoring for errors, providing clinicians with decision-support and information tools, and improving and standardizing medication labeling and drug-related information.

With the growing reliance on medication therapy as the primary intervention for most illnesses, patients receiving medication interventions are exposed to potential harm as well as benefits. Benefits are effective management of the illness/disease, slowed progression of the disease, and improved patient outcomes with few if any errors. Harm from medications can arise from unintended consequences as well as medication error (wrong medication, wrong time, wrong dose, etc.). With inadequate nursing education about patient safety and quality, excessive workloads, staffing inadequacies, fatigue, illegible provider handwriting, flawed dispensing systems, and problems with the labeling of drugs, nurses are continually challenged to ensure that their patients receive the right medication at the right time. The purpose of this chapter is to review the research regarding medication safety in relation to nursing care. We will show that while we have an adequate and consistent knowledge base of medication error reporting and distribution across phases of the medication process, the knowledge base to inform interventions is very weak.

Defining Medication Errors

Shared definitions of several key terms are important to understanding this chapter. Drugs are defined as "a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; and a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device."[3] Medications include, but are not limited to, any product considered a drug by the Food and Drug Administration (FDA).[3] Given the number and variety of definitions for medication errors, the IOM has recommended that international definitions be adopted for medication error, adverse drug events, and near misses.[2]

Medication Errors

One commonly used definition for a medication error is:

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.[4]

Some of the factors associated with medication errors include the following:

- Medications with similar names or similar packaging
- Medications that are not commonly used or prescribed
- Commonly used medications to which many patients are allergic (e.g., antibiotics, opiates, and nonsteroidal anti-inflammatory drugs)
- Medications that require testing to ensure proper (i.e., nontoxic) therapeutic levels are maintained (e.g., lithium, warfarin, theophylline, and digoxin)

Look-alike/sound-alike medication names can result in medication errors. Misreading medication names that look similar is a common mistake. These look-alike medication names may also sound alike and can lead to errors associated with verbal prescriptions. The Joint Commission publishes a list of look-alike/sound-alike drugs that are considered the most problematic medication names across settings. (This list is available at www.jointcommission.org/NR/rdonlyres/C92AAB3F-A9BD-431C-8628-11DD2D1D53CC/0/lasa.pdf.)

Medication errors occur in all settings[5] and may or may not cause an adverse drug event (ADE). Medications with complex dosing regimens and those given in specialty areas (e.g., intensive care units, emergency departments, and diagnostic and interventional areas) are associated with increased risk of ADEs.[6] Phillips and colleagues[7] found that deaths (the most severe ADE) associated with medication errors involved central nervous system agents, antineoplastics, and cardiovascular drugs. Most of the common types of errors resulting in patient death involved the wrong dose (40.9 percent), the wrong drug (16 percent), and the wrong route of administration (9.5 percent). The causes of these deaths were categorized as oral and written miscommunication, name confusion (e.g., names that look or sound alike), similar or misleading container labeling, performance or knowledge deficits, and inappropriate packaging or device design.

Adverse Drug Events and Adverse Drug Reactions

Adverse drug events are defined as injuries that result from medication use, although the causality of this relationship may not be proven.[8] Some ADEs are caused by preventable errors. ADEs that are not preventable are often the result of adverse drug reactions (ADRs), which are defined as "any response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease, or the modification of physiological function, given that this noxious response is not due to medication error."[9] Potential ADEs or near misses/close calls are medication errors that do not cause any harm to the patient because they are intercepted before they reach the patient or because the patient is able to physiologically absorb the error without any harm.

An adverse drug reaction is defined as "an undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both."[10] ADRs can be manifested as diarrhea or constipation, rash, headache, or other nonspecific symptoms. One of the challenges presented by ADRs is that prescribers may attribute the adverse effects to the patient's underlying condition and fail to recognize the patient's age or number of medications as a contributing factor.[11] According to Bates and colleagues,[12] more attention needs to be directed to ADEs—including both ADRs and preventable ADEs—which range in severity from insignificant to fatal.

Black Box Warnings and High-Alert Medications

In 1995, the FDA established the black box warning (BBW) system to alert prescribers to drugs with increased risks for patients. These warnings are intended to be the strongest labeling requirement for drugs or drug products that can have serious adverse reactions or potential safety hazards, especially those that may result in death or serious injury.[13] While the FDA does not issue a comprehensive list of drugs with BBWs,[14] some of the BBW drugs are celecoxib (Celebrex), warfarin, rosiglitazone (Avandia), methylphenidate (Ritalin), estrogen-containing contraceptives, and most antidepressants.[15] One study funded by the Agency for Healthcare Research and Quality found 40 percent of patients were taking a medication with a BBW and that many of those patients did not receive the recommended laboratory monitoring. The authors concluded that BBWs did not prevent the inappropriate use of high-risk medications.[16]

Medication errors can be considered a sentinel event when they are associated with high-alert medications. According to the Institute for Safe Medication Practices (ISMP), "High-alert medications are those likely to cause significant harm when used in error." The top five high-alert medications are "insulin, opiates and narcotics, injectable potassium chloride (or phosphate) concentrate, intravenous anticoagulants (heparin), and sodium chloride solutions above 0.9 percent"[17] (p. 339). ISMP's list of high-alert medications is available at: www.ismp.org/tools/highalertmedications.pdf.

The Prevalence and Impact of Medication Errors

In the Harvard Medical Practice Study, Leape and colleagues[18, 19] examined more than 30,000 hospital discharges selected at random from 51 hospitals in the State of New York in 1984. The researchers found that 3.7 percent of hospitalizations involved adverse events that prolonged hospital stay or were manifested as a new disability at the time of discharge. About one in four of these adverse events were judged to be attributable to negligence, and 58 percent were judged to be preventable.

It is difficult to reduce or eliminate medication errors when information on their prevalence is absent, inaccurate, or contradictory. Bates[20] put forth the notion that for every medication error that harms a patient, there are 100, mostly undetected, errors that do not. Most medication errors cause no patient harm or remain undetected by the clinician.[20, 21] The low rate of detected errors makes assessing the effectiveness of strategies to prevent medication errors challenging.

Rates of medication errors vary, depending on the detection method used. For example, among hospitalized patients, studies have shown that errors may be occurring as frequently as one per patient per day.[5, 22] In pediatric intensive care unit (ICU) studies, reported medication error rates have ranged from 5.7[23] and 14.6 per 100 orders[24] to as high as 26 per 100 orders.[25]

The impact of medication errors on morbidity and mortality were assessed in a case-control analysis of ADEs in hospitalized patients during a 3-year period.[26] The investigators found significant increases in (a) the cost of hospitalization from increased length of stay, ranging from $677 to $9,022; (b) patient mortality (odds ratio = 1.88 with a 95% confidence interval); and (c) postdischarge disability. The impact was less in male patients, younger patients, and patients with less severe illnesses and in certain diagnosis-related groups.

Without an infrastructure to capture and assess all medication errors and near misses, the real number is not known. These rates could be expected to be higher once patient safety organizations begin to collect nationwide errors and health care clinicians become more comfortable and skilled in recognizing and reporting all medication errors. The concern raised in *To Err Is Human*[1] about the potential prevalence and impact of ADEs—2 out of every 100 hospitalized patients—was just the beginning of our understanding of the potential magnitude of the rates of medication errors. The concern continues, as is seen in the most recent IOM report, *Preventing Medication Errors*,[2] which states that "a hospital patient is subject to at least one medication error per day, with considerable variation in error rates across facilities" (pp. 1–2). Yet, despite numerous research findings, we cannot estimate the actual rates because they vary by site, organization, and clinician; because not all medication errors are detected; and because not all detected errors are reported.

Error-Prone Processes

There are five stages of the medication process: (a) ordering/prescribing, (b) transcribing and verifying, (c) dispensing and delivering, (d) administering, and (e) monitoring and reporting.[2] Monitoring and reporting is a newly identified stage about which there is little research. Some of the most noted and early work on medication safety found hospitalized patients suffer preventable injury or even death as a result of ADEs associated with errors made during the prescribing, dispensing, and administering of medications to patients,[12, 27–29] although the rates of error in the stages of the medication process vary. A few studies have indicated that one of every three medication errors could be attributed to either a lack of knowledge about the medication or a lack of knowledge about the patient.[30]

Prescribing/ordering. Of the five stages, ordering/prescribing most often initiates a series of errors resulting in a patient receiving the wrong dose or wrong medication. In this stage, the wrong drug, dose, or route can be ordered, as can drugs to which the patient has known allergies. Workload, knowledge about the prescribed drug, and attitude of the prescriber—especially if there is a low perceived importance of prescribing compared with other responsibilities—are significantly associated with ADEs.[31, 32] Furthermore, if nurses or pharmacists question a prescriber about an order, they can be confronted with aggressive behavior, which may inhibit future questioning and seeking clarification.[33] The proportion of medication errors attributable to the ordering/prescribing stage range from 79 percent[29] to 3 percent.[34] Examples of the types of errors committed in this stage include illegible and/or incomplete orders, orders for contraindicated medications, and inappropriate doses. Similar results have been found in mandatory adverse event reporting systems. An analysis of 108 reports associated with significant harm or death reported to the State of New York noted that, when the error occurred during the prescribing stage, written prescriptions accounted for 74 percent of the errors, and verbal orders accounted for 15 percent.[6]

While the preponderance of the research focuses on physician prescribing, there is a brief discussion about the role of advanced practice nurses in prescribing to ensure safety. One

investigation of the occurrence of ADRs in outpatient veterans found no difference in ADR events between physicians and nurse practitioners.[11] Prescribers may make changes in medication therapy (e.g., change the dosage or discontinue the medication) in response to ADRs (e.g., constipation, rash) or other indications communicated to them by nurses or patients.

Transcribing, dispensing, and delivering. In some settings, medication orders are transcribed, dispensed, and then delivered for nurse administration. In certain circumstances and settings, both nurses and pharmacists are involved in transcribing, verifying, dispensing, and delivering medications. Yet errors of these two stages (transcribing and verifying, dispensing and delivering) have been predominately studied for pharmacists. Pharmacists can have an important role in intercepting and preventing prescribing/ordering errors.[35] One study found that while dispensing errors were 14 percent of the total ADEs, pharmacists intercepted 70 percent of all physician ordering errors.[27] Pharmacy dispensing errors have been found to range from 4 percent to 42 percent of errors.[36] Examples of errors that can be initiated at the transcribing, dispensing, and delivering stages include failure to transcribe the order, incorrectly filling the order, and failure to deliver the correct medication for the correct patient.

Medication administration. Nurses are primarily involved in the administration of medications across settings. Nurses can also be involved in both the dispensing and preparation of medications (in a similar role to pharmacists), such as crushing pills and drawing up a measured amount for injections. Early research on medication administration errors (MAEs) reported an error rate of 60 percent,[34] mainly in the form of wrong time, wrong rate, or wrong dose. In other studies, approximately one out of every three ADEs were attributable to nurses administering medications to patients.[21, 28] In a study of deaths caused by medication errors reported to the FDA from 1993 to 1998, injectable drugs were most often the problem;[7] the most common type of error was a drug overdose, and the second most common type of error was administering the wrong drug to a patient. The 583 causes of the 469 deaths were categorized as miscommunication, name confusion, similar or misleading labeling, human factors (e.g., knowledge or performance deficits), and inappropriate packaging or device design. The most common causes were human factors (65.2 percent), followed by miscommunication (15.8 percent).

Nurses are not the only ones to administer medications. Physicians, certified medication technicians, and patients and family members also administer medications. Part of the challenge in understanding the impact of nursing in medication administration is the need for research that clearly differentiates the administrators of medications. Several studies have reported medication administration errors that have included nonnurses.[37, 38] Among many reasons for the prevalence of nurse involvement in medication errors is that nurses may spend as much as 40 percent of their time in medication administration.[39]

A large-scale study by the U.S. National Council of State Boards of Nursing assessed whether there were any identifiable characteristics common to those nurses who committed medication administration errors. The most significant finding was that "the age, educational preparation and employment setting of RNs disciplined for medication administration errors are similar to those of the entire RN population"[40] (p. 12).

The "rights" of medication administration include right patient, right drug, right time, right route, and right dose. These rights are critical for nurses. A survey of patients discharged from the hospital found that about 20 percent were concerned about an error with their medications, and 15 percent of them were concerned about being harmed from mistakes by nurses compared to 10 percent who were concerned about mistakes by physicians.[41] However, the complexity of

the medication process has led to the formulation of the rights of nurses in the area of medication administration. The essential environmental conditions conducive to safe medication practices include (a) the right to complete and clearly written orders that clearly specify the drug, dose, route, and frequency; (b) the right to have the correct drug route and dose dispensed from pharmacies; (c) the right to have access to drug information; (d) the right to have policies on safe medication administration; (e) the right to administer medications safely and to identify problems in the system; and (f) the right to stop, think, and be vigilant when administering medications.[42]

Types of Medication Errors

Leape and colleagues[27] reported more than 15 types of medication errors: wrong dose, wrong choice, wrong drug, known allergy, missed dose, wrong time, wrong frequency, wrong technique, drug-drug interaction, wrong route, extra dose, failure to act on test, equipment failure, inadequate monitoring, preparation error, and other. Of the 130 errors for physicians, the majority were wrong dose, wrong choice of drug, and known allergy. Among the 126 nursing administration errors, the majority were associated with wrong dose, wrong technique, and wrong drug. Each type of error was found to occur at various stages, though some more often during the ordering and administration stages.

Since the study by Leape and colleagues, research has captured some of the types of error identified by Leape and added yet others (e.g., omission due to late transcription,[43] wrong administration technique,[24, 44, 45] and infiltration/extravasation.[46] Reporting incidences by type of error, rather than the stage it was associated with, leads to equivocal implications for nursing practice. The categorization approach used determines whether the implication can be targeted to stage, and therefore discipline, or to types of error. For example, 11 studies reported rates of types of medication errors using institution-specific and national databases, yet not specifying whether the error occurred during the prescribing, dispensing, or administration stage of the medication process or not clearly specifying administration errors associated with nurse administration. One of these studies analyzed deaths associated with medication errors, finding that the majority of deaths were related to overdose and wrong drug[7]—again, not specified by stage. Yet among these, it may be possible to see that wrong dose, dose omission, wrong drug, and wrong time are the most frequent type of medication error. Even then, comparisons and practice implications are challenging due to the lack of standardization among the types of categories used in research.

Working Conditions Can Facilitate Medication Errors

Following the release of *To Err Is Human*,[1] the focus on deaths caused by medication errors targeted system issues, such as high noise levels and excessive workloads,[47] and system interventions, such as the need for computerized order entry, unit dose (e.g., single-dose packaging), and 24-hour pharmacy coverage.[48] The IOM's report, *Crossing the Quality Chasm*,[49] put forth the concept that poor designs set the workforce up to fail, regardless of how hard they try. Thus, if health care institutions want to ensure safer, higher-quality care, they will need to, among other things, redesign systems of care using information technology to support clinical and administrative processes.

We are at the beginning stage of assessing and understanding the potential association between working conditions/environment and medication errors. Early research in this area found a relationship between characteristics of the work environment for nurses and medication

errors.[30, 50, 51] For example, Leape and colleagues[27] found an association between the occurrence of medication errors and the inability to access information and failure to follow policies and guidelines. Also, research has found that health care clinicians should be aware of the repeated patterns of medication errors and near misses to provide insight on how to avoid future errors.[52]

The system approach to safety emphasizes the human condition of fallibility and anticipates that errors will occur, even in the best organizations with the best people working in them. This approach focuses on identifying predisposing factors within the working environment or systems that lead to errors.[53] Reason's[53] model of accident causation describes three conditions that predicate an error:

1. *Latent conditions*—Organizational processes, management decisions, and elements in the system, such as staffing shortages, turnover, and medication administration protocols.
2. *Error-producing conditions*—Environmental, team, individual, or task factors that affect performance, such as distractions and interruptions (e.g., delivering and receiving food trays), transporting patients, and performing ancillary services (e.g., delivery of medical supplies, blood products).[49]
3. *Active failures*—errors involving slips (actions in which there are recognition or selection failures), lapses (failure of memory or attention), and mistakes (incorrect choice of objective, or choice of an incorrect path to achieve it), compared to violation, where rules of correct behavior are consciously ignored.

Threats to medication safety include miscommunication among health care providers, drug information that is not accessible or up to date, confusing directions, poor technique, inadequate patient information, lack of drug knowledge, incomplete patient medication history, lack of redundant safety checks, lack of evidence-based protocols, and staff assuming roles for which they are not prepared. An additional risk is a hospital without 24-hour pharmacy coverage, especially when procedural barriers to offset the risk of accessing high-risk drugs are absent.[6]

Recognizing and Reporting Medication Administration Errors

Error reporting strategies are critical to the implementation of effective system-level approaches to reduce medication errors and ADEs.[54] However, the usefulness of many reporting strategies depends directly on the level of response.[55] To be effective, medication error reporting needs to be ongoing and part of a continuous quality improvement process.[56, 57]

Previous research has found that when nurses voluntarily report medication administration errors, as few as 10 to 25 percent of errors are reported.[28] As discussed in the chapter on error reporting, there were numerous surveys of hospital nurses' perceptions of what constitutes an MAE, why these types of errors occur,[58–61] and what the barriers to reporting are.[58–72] The three most significant barriers to reporting were (a) a hierarchical hospital culture/structure where the nursing staff disagreed about the definition of reportable errors, (b) fear of the response and reaction of hospital management/administrators and peers to a reported error, and (c) the amount of time and effort involved in documenting and reporting an error. Together these studies indicate that the medication errors that are reported do not represent the actual incidence of medication errors.

Without reporting, many errors may not be known. Based on a survey of nurses on barriers to reporting, Wakefield and colleagues[62] suggested several strategies to increase the reporting of MAEs: agreement on the definition of error; supporting and simplifying reporting of errors; institutionalizing a culture that rewards and learns from error reporting (i.e., a culture of safety, where learning is encouraged and blaming discouraged); capitalizing on feedback reports to

determine system factors contributing to error; and ensuring positive incentives for MAE reporting.

Incident reports, retrospective chart reviews, and direct observation are methods that have been used to detect errors. Incident reports, which capture information on recognized errors, can vary by type of unit and management activities;[73] they represent only a few of the actual medication errors, particularly when compared to a patient record review.[74] Chart reviews have been found to be most useful in detecting errors in ordering/prescribing, but not administration.[75, 76] Direct observation of administration with comparison to the medication administration record detects most administration errors; however, it cannot detect ordering errors and, in some systems, transcribing and dispensing errors. There were two studies that compared detection methods. One of these studies of medication administration in 36 hospitals and skilled nursing facilities found 373 errors made on 2,556 doses.[77] The comparison of three detection methods found that chart review detected 7 percent of the observed errors, and incident reports detected only 1 percent. Direct observation was able to detect 80 percent of true administration errors, far more than detected through other means. A second study compared detection methods and found that more administration errors were detected by observation (a 31.1 percent error rate) than were documented in the patients' medical records (a 23.5 percent error rate).[78] Therefore, no one method will do it all. When automated systems that use triggers are not in place, multiple approaches such as incident reports, observation, patient record reviews, and surveillance by pharmacist may be more successful.[79]

The wide variation in reported prevalence and etiology of medication errors is in part attributable to the lack of a national reporting system or systems that collect both errors and near misses. State-based and nationally focused efforts to better determine the incidence of medication errors are also available and expanding (Patient Safety and Quality Improvement Act of 2005). The FDA's Adverse Event Reporting System (AERS), which is part of the FDAs' MedWatch program (www.fda.gov/medwatch), U.S. Pharmacopeia's (USP's) MEDMARX® database (www.medmarx.com), and the USP's Medication Errors Reporting Program (MERP; www.ismp.org/orderforms/reporterrortoISMP.asp), in cooperation with the ISMP, collect voluntary reports on actual and potential medication errors, analyze the information, and publish information on their findings.

Research reported to date clearly reveals that medication errors are a major threat to patient safety, and that these errors can be attributed to all involved disciplines and to all stages of the medication process. Unfortunately, the research also reveals that we have only weak knowledge of the actual incidence of errors. Our information about ADEs (those detected, reported, and treated) is better, but far from complete. With this knowledge of the strengths and limitations of the research, this chapter will consider the evidence regarding nurses' medication administration.

Research Evidence—Medication Administration by Nurses

The research review targeted studies involving medication administration by nurses. This excluded several studies that assessed medication administration errors without differentiating whether the errors were associated with physicians, assistants, or nurses. None of these studies included interventions.

Rates and Types of Medication Administration Errors

Thirteen studies explicitly reported types of MAEs associated with nurses. The incidence of MAEs was detected either formally through incident reports, chart reviews, or direct observation, or informally through anonymous surveys. Two studies conducted retrospective assessments, one using medical records[43] and the other malpractice claims.[80] Seven studies assessed self-reported MAEs from a nationally representative database[44, 81–83] or self-reported errors using a nationally representative sample.[84–86] None of these self-reported MAEs were verified. Eight studies assessed MAEs using direct observation of the medication administration process.[24, 37, 78, 87–91]

The incidence of MAEs varied widely with the different research designs and samples. Using chart reviews, Grasso and colleagues[43] found that 4.7 percent of doses were administered incorrectly. Direct observation studies placed the estimate of total incorrect doses between 19 percent and 27 percent,[87] and when an extra review was done to separate the errors into stages of the medication process, between 6 percent and 8 percent of doses were in error because of administration. The majority of types of MAEs reported were wrong dose, wrong rate, wrong time, and omission. All of the studies reviewed here reported wrong drug and dose, but varied across the other types of MAE categories (see Evidence Table 1); this was dependent upon the study methodology.

Five studies evaluated self-reported MAEs, involving incident reports and informal reports.[38, 44, 81, 82] The most common types of reported errors were wrong dose, omission, and wrong time. Four of these studies[38, 81–83] assessed a large secondary, nationally representative database containing MAEs reported to the MEDMARX database over five years.[38, 81, 82, 44] found in the error reports submitted by nursing students that the majority of MAEs were associated with omission, wrong dose, wrong time, and extra dose. Of the reported contributing factors, 78 percent were due to the inexperience of the nurse. The Beyea and Hicks[81, 82] studies looked at errors associated with the operating room, same-day surgery, and postanesthesia; they found the majority of errors attributable to administration but did not classify them by error type. The other study reviewed 88 incident reports from a long-term care facility submitted during a 21-month period. It found that the majority of MAEs were associated with errors involving interpreting or updating the medication administration record, delayed dose, wrong dose, or wrong drug.[92] A separate component of this study surveyed administrative and clinical nurses and found that they believed the majority of medication errors occurred at either the administration or dispensing stage.

Two other studies assessed the type of MAEs reported by nurses in nationwide surveys.[84, 85] While the majority (57 percent) of errors reported by critical care nurses involved MAEs, an additional 28 percent of reported errors involved near misses. Medication administration errors involving wrong time, omission, and wrong dose accounted for 77.3 percent of errors, while wrong drug and wrong patient accounted for 77.8 percent of near misses. The most frequent types of medication errors were wrong time (33.6 percent), wrong dose (24.1 percent), and wrong drug (17.2 percent), and the three most frequent types of near misses were wrong drug (29.3 percent), wrong dose (21.6 percent), and wrong patient (19.0 percent).[85] Many of the reported MAEs in ICUs involved intravenous medications and fluids.[84] In these surveys, the nurses who reported making errors described between two and five errors during a 14-day period.

At the more advanced stage of incident reports, one study reviewed 68 malpractice cases involving MAEs in Sweden.[80] Among the cases reviewed, the majority of MAEs made by nurses

involved wrong dose. When the nurses delegated the drug administration to subordinate staff, the majority of MAEs involved wrong drug or wrong concentration of a drug. Errors, which were reported to the immediate supervisor, were also reported to the physician in 65 percent of cases. The reported causes of MAEs were lack of administration protocols, failure to check orders, ineffective nurse supervision when delegating administration, and inadequate documentation.

One study assessed medication errors using 31 medical records of patients discharged from a psychiatric hospital and found a total of 2,194 errors.[43] Of these, 997 were classified as MAEs (4.7 percent of all doses, and 66 percent of all errors). Of these, 61.9 percent were due to scheduled doses not documented as administered, 29.1 percent as drugs administered without an order, 8 percent as missed doses because of late transcription, and 3 percent resulting from orders not being correctly entered in the pharmacy computer.

Table 1. Comparison of the Incidence of Medication Administration Errors by Type Categories

	Buckley 2007[24] n = 15	Tang 2007[93] n = 72	Balas 2006[84] n = 127	Kopp 2006[45] n = 132	Wolf 2006[44] n = 1,305	Prot 2005[78] n = 538	Handler 2004[92] n = 88	Colen 2003[88] n = 1,077	Tissot 2003[91] n = 78	Flynn 2002[77] n = 457	Kapborg 1999[80] n = 37
	Percentages (%)										
Wrong patient	-	-	4.7	-	9.2	-	4.5	0		-	16.2
Wrong drug/unauthorized drug	0	26.4	10.2	0	8.4	12	11.3	0.46	13	3.7	13.5
Wrong dose	26.7	36.1	20.5	12	17.2	15	19.3	1.0	12	18.4	51.4
Wrong route	0	8.3	3.9	0	3.6	19	-	0.19		1.3	-
Wrong time/frequency	26.7	18.1	37.8	10	16.9	36	29.5	20.0	26	42.9	-
Wrong form	0	-	-	0	0.4	8	-	0.09		3.9	-
Wrong administration technique	20	-	-	14	3.4	3	-	0.19	4	0.4	-
Omission	0	-	22.0	48	19.0	5	-	3.3	16	27.6	2.7
Extra dose	26.7	-	-	14	14.1	0	-	-	-	1.8	-
Deteriorated drug	-	-	-	-	-	2	-	-	-	-	-
Drug past expiration date	-	-	-	-	-	-	-	-	-	-	5.4
Drug reaction/allergy	0	-	-	0	-	-	-	-	-	-	-
Infiltration/extravasation	-	-	-	-	-	-	-	-	-	-	-
Maintenance intravenous fluid/total parenteral nutrition	0	-	-	2	-		-	-	-	-	-
Wrong concentration	-	-	-	-	-	-	-	-	-	-	8.1
Wrong drug preparation	-	-	-	-	3.1	-	-	0.09	4	-	-
Wrong rate	-	-	-	-	-	-	-	-	19	-	-

Wrong solution	-	-	-	-	-	-	-	0	-	-	-
Wrong storage	-	-	-	-	-	-	-	-	-	-	2.7
Other/Not specified	-	-	0.8	-	-	-	35.2	1.5	6	-	-

Note: "-" represents variable not included in analysis or not reported.

The number of studies using direct observation of medication administration is increasing in response to the concern about the accuracy of other sources of data. Ten studies were found, only three of which were done in the United States. While we attempt to summarize across these studies, it is difficult to determine consistency across studies as each focused on different sets of errors (some only intravenous errors, some included gastrointestinal tube technique) and were conducted in different settings. In many of the non-U.S. studies, nurses dispensed drugs from ward stock and prepared many of the intravenous solutions for administration.

Three observational studies were conducted in pediatric units—one in France,[78] one in Switzerland,[25] and one in the United States.[24] Buckley[24] reported 52 of the 263 doses (19 percent) observed to be in error, but only 15 (6 percent) of those were in the administration stage. Those 15 were nearly evenly divided among wrong dose, wrong time, wrong technique, and extra dose categories. Prot[78] reported nearly 50 percent more MAEs. Of the 1,719 observed doses, 467 (27 percent) were in error, including wrong time; excluding wrong-time errors, the error rate was 13 percent of doses. The categories with the most MAEs in Prot's study were wrong time, wrong route (GI tube versus oral), wrong dose, unordered drug, wrong form, and omissions. Schneider and colleagues[25] reported an overall 26.9 percent error rate with wrong-time errors, and an 18.2 percent rate excluding wrong-time errors. Common errors in addition to wrong time were wrong dose preparation and wrong administration technique.

The incidence of intravenous drug errors was observed in three studies, one in England,[89] one in Germany,[90] and one in both countries.[37] About 50 percent of the doses were determined to contain at least one error. Compared to other studies, this rate is surprisingly high, and it included preparation technique errors (selection of diluent/solvent) as well as administration errors (rate of bolus injection and infusion rate). Part of the explanation may come from institutional (type of pharmacy support available) and professional training factors. (German nurses are not trained to do intravenous medications.)

Three studies focused on medication administration in ICUs in the United States,[45] in France,[91] and in the Netherlands.[94] Kopp and colleagues[45] looked at all medication errors and report that 27 percent of doses were in error; of these 32 percent could be attributed to the administration stage. Within the MAEs, most were omitted medications; the rest were evenly distributed among wrong dose, extra dose, and wrong technique. Few wrong-time errors were noted. Tissot[91] and van den Bernt[94] examined only administration stage errors and reported very different rates. Tissot reported 6.6 percent of the 2,009 observed doses were in error, most from wrong dose, wrong rate, and wrong preparation technique. Excluding wrong-time errors, van den Bernt reported a 33 percent error rate that included preparation errors with diluent/solvent issues, infusion-rate errors, and chemical incompatibility of intravenous drugs. It is likely that the differences in rates across these studies are due to the range of error types observed in each study as well as the varying responsibilities of nurses in the three countries.

The most extensive observation study, by Barker and colleagues,[87] conducted observations of medication administration in 36 randomly selected health care facilities (acute and long-term care) in two States in the United States. Of the 3,216 doses observed, 605 (19 percent) contained at least one error. Nearly half of those errors were wrong-time errors. Other common types of errors included omission, wrong dose, and unauthorized (unordered) drug. In a much smaller study conducted in the Netherlands, Colen, Neef, and Schuring[88] found an MAE rate of 27 percent, with most of these wrong-time errors. The rate of MAEs without wrong time was approximately 7 percent, and most of those were omissions.

Information from these research studies forms a consistent picture of the most common types of MAEs. These are wrong time, omissions, and wrong dose (including extra dose). Rates of error derived from direct observation studies ranged narrowly between 20 and 27 percent including wrong-time errors, and between 6 and 18 percent excluding wrong-time errors. The alarming exception to this was the nearly 50 percent error rate in observation of intravenous medication in ICUs in Europe.

Evidence Table 1. Types of Reported and Observed Medication Administration Errors (MAEs)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Balas 2004[85]	Type of MAEs	Cross-sectional study	Voluntary, self-reported recording of 14 days of shift work, sleep, and errors using a journal	393 full-time registered nurses (RNs) in hospitals responded to the survey.	37.8% of nurses reported medication errors and near errors; made on average between 2 and 5 errors. Reported top types of medication errors were wrong time (33.6%), wrong dose (24.1%), and wrong drug (17.2%), compared to the top three types of near errors, which were wrong drug (29.3%), wrong dose (21.6%), and wrong patient (19.0%).
Balas 2006[84]	Types of MAEs or near errors	Cross-sectional study	Voluntary, self-reported recording of 14 days of shift work, sleep, and errors using a journal	502 RNs in critical care units throughout the United States	Of the 224 errors and 350 near errors, 56.7% involved medications. Wrong time, omission, and wrong dose accounted for 77.3% of MAEs, and wrong dose, wrong drug, and wrong patient accounted for 77.8% of near misses.
Barker 2002[87]	Types of MAEs	Cross-sectional	Observation of 3,216 doses administered by nurses in 36 randomly selected institutions	12 accredited hospitals, 12 nonaccredited hospitals, and 12 nursing homes	19% of doses were in error including wrong time, 11% excluding wrong time. The most frequent errors besides wrong time were omissions and wrong dose in all three types of institutions.
Buckley 2007[24]	Types of MAEs	Prospective cohort study	Direct observation over 6 months of medication process, determining actual and potential errors. Observers would intervene if error was considered harmful to patient.	In a 16-bed pediatric medical/surgical ICU at a tertiary care academic medical center	263 doses observed and 19% were in error. Only 6% of the doses were affected by an MAE. Common errors during administration were wrong dose, wrong time, extra dose, and wrong technique. Proximal causes of administration errors were slips and memory lapses, lack of drug knowledge, and rule violations.
Colen 2003[88]	Types of MAEs	Prospective cohort study	One phase of a study of the evaluation of a medication distribution system involving direct observation of administration. Observers would intervene if error was considered harmful to patient.	1,077 doses were observed in 1 teaching hospital in the Netherlands	The MAE rate was 27.2% including wrong time, and 7.2% excluding wrong time. The major types of MAEs included wrong time (20.0%) and omissions (3.3%).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Grasso 2003[43]	Types of MAEs	Retrospective cohort study	Review of patient records for patients discharged from the Augusta Mental Health Institute in Maine, during a period of 14 weeks	2,194 medication errors, of which 1,432 were MAEs, from 31 patient records	MAEs represented 65.3% of all medication errors. 61.9% of MAEs were due to a scheduled dose not documented as administered, 29.1% as drugs administered without an order, 8% as missed dose because of late transcription, and 3% resulting from order not being correctly entered in the pharmacy computer.
Kapborg 1999[80]	Types of MAEs	Retrospective cohort study	Analysis of malpractice cases and small interview survey with 8 nurses working in nursing homes and home care setting using semistructured questions	68 cases of MAEs occurring in several types of home care settings and nursing homes during a 4-year period, reported to a regional supervisory unit of the National Board of Health and Welfare in Sweden	The majority of MAEs made by nurses involved dosing above what was prescribed and when the drug administration was delegated to subordinate staff; the majority of MAEs involved wrong drug or wrong concentration of a drug.
Kopp 2006[45]	Types of MAEs	Prospective cohort study	Direct observation over 6 months by 2 pharmacy residents specializing in critical care pharmacy. Pharmacy residents would intervene if MAE would have resulted in patient harm.	1 16-bed medical/surgical ICU in a tertiary care academic medical center in Arizona	Overall, 27% of doses were in error. Of the 132 ADEs, 42 (32%) were attributed to medication administration. About half of those (48%) were errors of omission. Other common error types were wrong dose, extra dose, and wrong technique. Thirty seven (34%) of ADEs attributed to medication administration were considered potential ADEs, and only 3 of those were intercepted.
McCarthy 2000[86]	Types of MAEs	Cross-sectional study	Voluntary, randomly selected survey of members of the National Association of School Nurses	649 school nurses (64.9% response rate) in the United States	48.5% of respondents reported medication errors, and the majority of the types of errors were missed doses and undocumented doses.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Prot 2005[78]	Types of MAEs	Prospective cohort study	Direct observation of nurses administering medications to patients. Observers would intervene if MAE would have resulted in patient harm.	1,719 doses were observed on 4 units at a pediatric teaching hospital in Paris, France.	27% of doses were in error (538 MAEs). Wrong-time errors were 36% of MAEs, wrong route was 19%, wrong dose was 15%, and unordered drug was 10%. The risk of an MAE increased if the medication was administered by a nurse intern, a temporary staffing agency nurse, or a pool nurse (OR = 1.67, *P* = 0.03) and if the medication had been prepared by the pharmacy (OR = 1.66, *P* = 0.02).
Schneider 1998[25]	Frequency and types of MAEs	Cross-sectional	Direct observation	275 doses were observed on a pediatric ICU in Switzerland	26.9% of the doses were in error including wrong-time errors, 18.2% excluding wrong-time errors. The other common error types were wrong dose preparation and wrong administration technique.
Taxis 2003[89]	Types of MAEs in Intravenous (IV) drug administration	Cross-sectional	Ethnographic—direct observation of nurses administering medications	430 IV drug doses were observed for nurses working in 10 wards in 2 hospitals in the UK.	Overall error rate was 49%; wrong-time errors were not counted. Of the 212 errors observed, 38% involved administering a bolus dose too fast, and preparation errors accounted for 15%. Majority of preparations errors by nurses involved doses requiring multiple-step preparations, specifically preparing the wrong dose or selecting the wrong solvent.
Taxis 2003[90]	Types of MAEs in IV drug administration	Cross-sectional	Ethnographic—direct observation of nurses administering medications	22 staff nurses on 2 units in a German hospital were observed administering 122 IV doses.	Overall error rate was 48%. Wrong-time errors were not counted. Of the errors, the largest proportion occurred during a multiple-step drug preparation procedure, and the second largest was administering incompatible drugs through the same line. Majority of preparations errors by nurses involved preparing the wrong dose or selecting the wrong solvent.
Tissot 2003[91]	Type of MAEs	Prospective cohort study	Direct observation of nurses administering medications to patients by a pharmacist	Medical ICU in France	Of the 2,009 nursing acts observed, 132 (6.6%) were in error. Wrong dose was the most frequent error, followed by wrong rate of administration, errors in preparation, and physicochemical incompatibility.
Ven den Bernt 2002[94]	Frequency and type of MAEs	Cross-sectional	Direct observation of nurses administering medication to patients	233 drug administrations in 2 Dutch hospitals	Overall, 104 doses had errors (44.6%) including wrong time, 77 (33%) excluding wrong time. The most common error types were wrong dose preparation and wrong administration technique.
Wirtz 2003[37]	Types of MAEs in IV drug administration	Cross-sectional	Ethnographic—disguised observation of nurses preparing and administering medications	337 drug preparations and 278 drug administration were observed in 2 German and one UK hospital.	Across the three sites, the rate for preparation errors was 26%, and the rate for administration errors was 34%. The most common errors were wrong administration rate, omissions, and wrong dose. The types of errors varied across the hospitals, which had different pharmacy systems, although nurses prepared and administered IV meds on the wards.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Wolf 2006[44]	Types of MAEs	Retrospective cohort study	Analysis of MAEs reported January 1, 1999, to December 21, 2003, by nursing students during the administration phase	MAEs reported by 1,305 nursing students in the USP MEDMARX program	Majority of MAEs were associated with omission (19%), wrong dose (17%), wrong time (17%), and extra dose (14%). The major causes of MAEs were reported as performance (human) deficit (51%), procedure/protocol not followed (32%), and knowledge deficit (27%). Of the reported contributing factors, 78% were due to the inexperience of staff. When an MAE occurred, 55% of the staff who made the error were informed and 44% received education/training.

Impact of Working Conditions on Medication Errors

Medication safety for patients is dependent upon systems, process, and human factors, which can vary significantly across health care settings. A review of the literature found 34 studies that investigated some aspect of working conditions in relation to medication safety.

Systems factors. Systems factors that can influence medication administration include staffing levels and RN skill mix (proportion of care given by RNs), shift length, patient acuity, and organizational climate. There were 13 articles presenting research findings and three literature reviews. The major systems/organizational factors included nurse staffing, workload, organizational climate/favorable working conditions, policies and procedures, and technologies enabling safety or contributing to MAEs.

Nurse staffing: Medication administration is a key responsibility of nurses in many settings, and three studies assessed the relationship between nurse staffing, hours of nursing care in hospitals, RN skill mix, and medication errors. Two studies associated the total hours of care and the RN skill mix at a patient care unit to reported medication error rates in those units; one study used 42 units in a large Midwestern hospital[95] and the other used 39 units in 11 small hospitals.[96] Rates of MAEs, when the number of doses was the denominator, were highest in medical-surgical and obstetric units; when patient days were the denominator, the highest rate was in ICUs. In both studies the type of unit was controlled and the rate of reported medication errors declined as the RN skill mix increased up to an 87 percent mix. A third study of nurses in ICUs in 10 hospitals found an inverse relationship between rates of medication errors and staffing work hours per patient day in specific settings (e.g., cardiac ICUs and noncardiac intermediate care settings). A little over 30 percent of the variance in medication error rates resulted from the variance in staffing work hours per patient day.[97]

Other studies conducted prior to 1998 did not find a relationship between staffing and medication errors. Three literature reviews,[30, 39, 98] concluded that the direct evidence for a relationship between staffing and MAE rates was inconsistent. Nurses' perceptions of the impact of staffing or workload on medication errors, however, is quite consistent.

Workloads: These findings are consistent with three studies and two literature reviews on the impact of heavy workloads, a component of nurse staffing, on errors. In one survey of nurses in 11 hospitals, both pediatric and adult nurses reported staffing ratios and the number of medications being administered as being the major reasons why medication errors occur.[58] A second survey found that nurses from Taiwan also indicated that workload was a major factor in medication errors.[93] Beyea, Hicks, and Becker[81, 82] and Hicks and colleagues[38] analyzed MEDMARX data for medication errors in the operating room, postanesthesia, and in same-day-surgery units. Most of these errors involved nurses (64–76 percent) and medication administration (59–68 percent). In all three sets of error reports, workload increases and insufficient staffing were noted to be causes of errors.

The effect of heavy workloads and inadequate numbers of nurses can also be manifested as long workdays, providing patient care beyond the point of effective performance. In a national survey by Rogers and colleagues,[99] self-reported errors by nurses found that the likelihood of a medication error increased by three times once the nurse worked more than 12.5 hours providing direct patient care. Among nurses working more than 12.5 hours, the reported errors, 58 percent of actual errors and 56 percent of near misses were associated with medication administration.

Other findings support the importance of adequate nurse staffing and understanding the impact of shift work in decreasing medication errors. A review of incident reports found that the major contributing factors to errors were inexperienced staff, followed by insufficient staffing, agency/temporary staffing, lack of access to patient information, emergency situation, poor lighting, patient transfers, floating staff, no 24-hour pharmacy, and code situations.[44] Certain aspects of shift work can also impact medication safety, as shown in a review of research conducted in the 1980s and early 1990s that indicated that there was a difference in the number of errors by shift, but no difference in the number of hours worked (8 versus 12 hours). However, there were more errors with nurses working rotating shifts.[30]

Organizational climate: Other systems/organizational issues include the presence of favorable working conditions, effective systems, policies and procedures, and technologies that enable safety or contribute to MAEs. An assessment of medication administration behaviors of 176 nurses in rural Australia, using structural equation modeling to test the association between organizational climate and the administration behaviors of nurses, found that the variable "violations" was the only variable with a direct contribution to MAEs, but there was no direct linkage to actual errors. While it was not possible to determine the effect of organizational climate on violations, distress was positively associated with violations, while quality of working life, morale, and organizational climate had a negative association. The organizational climate was found to be linked with safety behavior.[100] Hofmann and Mark[101] did find that the safety climate on patient care units was linked to the rate of harm-producing medication errors in a study using data collected from 82 units in 41 hospitals. Higher overall safety climate was related to lower rates of medication errors and urinary tract infections.

Policies, procedures, and protocols: Lack of appropriate policies, procedures, and protocols can impact medication safety, as seen in a few small studies. In a study of malpractice cases, medication errors were associated with lack of administration protocols and ineffective nurse supervision in delegating administration.[80] However, even when policies are in place, they may not necessarily improve safety. For example, a review of two studies in the literature found that medication errors did not necessarily decrease with two nurses administering medications (e.g., double-checking).[30] In addition, appropriate policies may not be followed. Double-checking policies are commonly used as a strategy to ensure medication safety. When errors occurred under such policies, failure to double-check doses by both pediatric and adult nurses [58] and nurses in a Veterans Affairs (VA) hospital[102] were reported. However, research presented in two literature reviews offers somewhat conflicting information. In the first review of three studies, following double-checking policies did not necessarily prevent errors.[39] Yet in the other review, failure to adhere to policies and procedures was associated with errors.[30]

Process factors. Process factors that influence medication administration include latent failures that can instigate events resulting in errors, such as administrative processes, technological processes, clinical processes, and factors such as interruptions and distractions. These factors reflect the nature of the work, including "competing tasks and interruptions, individual vs. teamwork, physical/cognitive requirements, treatment complexity, workflow."[103] A review of the literature found 18 studies and 2 literature reviews that contained process factors and their association to medication errors by nurses.

Distractions and interruptions: Factors such as distractions and interruptions, during the process of delivering care can have a significant impact on medication safety. Nine studies, four with nationwide samples, and two literature reviews present information on the association between MAEs and distractions and interruptions. One survey of nurses in three hospitals in

Taiwan found that they perceived distractions and interruptions as causes of errors.[93] In three other surveys in the United States, nurses ranked distractions as major causes for the majority of medication errors.[58, 61, 102] In a small, five-site observational study of medication administration among 39 RNs, licensed practical nurses (LPNs) and certified medical technicians/assistants (CMT/As), Scott-Cawiezell and colleagues[104] found an increase in medication errors attributable in part to interruptions, and when wrong-time errors were excluded, the error rate actually increased during medication administration.

These finding are furthered by research concerning self-reported errors from a nationwide sample of nurses.[84] The nurses believed the cause of their reported medication errors and near errors were interruptions and distractions. In a secondary analysis of the MEDMARX® data base, distractions and interruptions were prominent contributing factors to medication errors.[81–83] Furthermore, these findings are supported by three reviews of the literature: one found that distractions and interruptions interfered with preparing and administering medication, potentially causing errors;[30] interruptions were perceived as causing medication errors in the second review;[98] and the third indicated that rapid turnover and changes as well as distractions and interruptions contributed to errors.[39]

Documentation of the medication administration process: One small study investigated nurse adherence to a hospital policy to document medications administered and their effects on patients. From a sample of 12 nurses in one hospital, one-third of progress notes were found to contain information about administered medications, yet only 30 percent of those progress notes included medication name, dose, and time of administration, and only 10 percent documented information about desired or adverse effects of medications. Medication education, outcomes of administered medication, and assessment prior to administering were not documented in any progress note. Only half of withheld medications were documented.[105] In a review of records to detect medication errors, Grasso and colleagues[43] found that 62 percent did not document doses as administered.

Communication: Five studies and one literature review assessed the relationship between communication failures and medication errors. A small observational study of 12 nurses found that they communicated with other nurses about information resources on medications, how to troubleshoot equipment problems, clarification in medication orders, changes in medication regimens, and patient assessment parameters when handing over patients.[106] Nurses communicated with physicians informally to exchange information, about the absence of other physicians, and in both unstructured and structured ward rounds. Nurses also communicated with pharmacists about information on medication administration and organizing medications for patient discharge. Another direct observational study of medication administration found opportunities for errors associated with incomplete or illegible prescriptions.[91] This finding was supported by two related literature reviews that indicated that illegible and poorly written drug prescriptions and breakdowns in communication led to errors.[30, 39] Another survey found that nurses ranked difficult/illegible physician handwriting as a cause of the majority of medication errors, but did not consider withholding a dose because a lab report was late or omitting a medication while the patient was sleeping as something that should have been communicated to physicians or others.[61]

A small survey of 39 nurses in three hospitals in Nova Scotia about communication failures during patient transfers found that more than two-thirds of nurses reported difficulty in obtaining an accurate medication history from patients when they were admitted; 82 percent reported patients were unable to provide accurate medication histories. When patients were transferred

from across units, 85 percent of nurses reported that medication orders were rewritten at transfer, 92 percent that medication orders were checked against electronic medical records, 62 percent that it was time consuming to clarify medication orders, 66 percent that the reasons for medication changes were made at transfer, and 20 percent that blanket orders are often written as transfer orders.[107]

Complexity: Three studies investigated the impact of complexity on medication safety. In a small, five site observational study of medication administration of 39 RNs, LPNs and CMT/As in long-term care settings, Scott-Cawiezell and colleagues[104] found that even though RNs administered fewer medications they had more MAEs, compared to LPNs and CMT/As. The suggested explanation was that the mediations RN must administer in long-term care are those with more complexity. Another survey of 284 RNs in 11 hospitals found that pediatric and adult nurses reported numbers of medications being administered as a major reason on why medication errors occur.[58] Also, another survey of nurses found that they perceived that complicated doctor-initiated orders (24 percent) and complicated prescription were the major causes of MAEs related to the medication administration process.[93]

Equipment failure while administering medication: Three studies found that systems and process factors can interfere with medication administration when equipment used in administration does not perform properly, exposing the nurse and patient to safety risks. In two ICU studies, infusion pump problems were involved in 6.7 percent of 58 MAEs in one study[24] and 12 percent of the 42 MAEs in the other sutdy.[45] Another investigation of smart pumps with integrated decision-support software found that half of the ADEs were considered preventable (2.12 of 100 patient-pump days), and 72 percent of preventable ADEs were serious or life-threatening.[108] Given the number of ADEs, the fact that the drug library was bypassed in 24 percent of the infusions, and the frequency of overriding alerts, the investigators concluded that use of the smart pumps did not reduce the rate of serious medication errors—but possibly could if certain process factors could be modified, such as not allowing overrides.

Monitoring and assessing: An essential component of the medication process related to the administration of medications is monitoring and assessing the patient by the nurse. Only two studies provided information in this area, offering scant evidence. In the first, based on a small sample of nurses in one unit in one hospital, a qualitative analysis of observed medication administration found that participants monitored patients before, during, and after medication administration.[109] Nurses assessed vital signs, lab values, ability to swallow, and patients' self-report of health. They also felt responsible for timing medication administration and providing as-needed (e.g., PRN) medications. In the second study, where ICU nurses were surveyed, no administration errors were found to be associated with inadequate monitoring or lack of patient information.[24]

Effects of Human Factors on Medication Administration Errors

There are a wide range of system-related human factors that can impact medication administration. These factors include characteristics of individual providers (e.g., training, fatigue levels), the nature of the clinical work (e.g., need for attention to detail, time pressures), equipment and technology interfaces (e.g., confusing or straight-forward to operate), the design of the physical environment (e.g., designing rooms to reduce spread of infection and patient falls), and even macro-level factors external to the institution (e.g., evidence base for safe practices, public awareness of patient safety concerns).[103] There were 10 studies that assessed the

association of human factors with MAEs. Four major themes emerged in the review: fatigue, cognitive abilities, experience, and skills.

Effects of fatigue and sleep loss: Five studies assessed the association between fatigue and sleep loss with MAE errors. The first specifically investigated the effects of fatigue and sleep loss on errors using a national sample of nurses over a 2-week period. In this study, the rate of errors increased after working 12.5 hours.[99] A subpopulation of critical care nurses reported forgetfulness, heavy workload, distractions, and high patient acuity as causes for their medication errors or near errors.[84] Fatigue and sleep loss was also a factor in a subpopulation of ICU nurses, who reported errors with high-alert medications (e.g., morphine, chemotherapeautic agents).[85] The other two studies assessed fatigue along with other variables associated with medication errors. In one of these, a survey of 57 nurses, respondents reported that the majority of medication errors were attributable to fatigue.[70] The other study, a survey of 25 nurses in one hospital, found that one of the most frequently perceived causes of medication errors for nurses was being tired and exhausted (33.3 percent).[102]

The thought processes of nurses during medication administration was assessed in two studies. A semistructured, qualitative interview of 40 hospital nurses prior to implementation of a bar-coding system explored the thinking processes of nurses associated with medication administration.[110] Their thought processes involved analyzing situations and seeking validation or a solution when communicating about patients; using knowledge, experience, and understanding of patients' responses to anticipate problems; integrating their knowledge of lab values and patterns of pathophysiological responses to determine possible need to change dosage or administration timing; checking orders for validity and correctness; assessing patients' responses for possible side effects and effectiveness of the drug; using cues from patients or family members about need for explanations about drugs; bypassing protocols or procedures, some taking a risk, to get drugs to patients or use time more efficiently; anticipating needs for future problem solving; and applying professional knowledge during drug administration. The other study of nurses, using direct observation in a medical and surgical unit in Australia, found that participants used hypothetico-deductive reasoning to manage patient problems.[111] Graduate nurses used pattern recognition of patient characteristics and medications during decisionmaking. Intuition and tacit knowledge was used in relation to changes in patients' vital signs and to objectively monitor patients.

Thought process can also be distorted by distractions and interruptions. One study employed direct observation of medication administration to determine the effects of human factors on MAEs.[24] The investigators found that slips and memory lapses were associated with 46.7 percent of MAEs. During both the prescribing and administration of medications, the causes of errors were attributable to slips and memory lapses (23.1 percent during prescribing vs. 46.7 percent during administration), lack of drug knowledge (46.2 percent during prescribing vs. 13.3 percent during administration), and rule violations (30.8 percent during prescribing vs. 13.3 percent during administration). Another study using direct observation found causes associated with MAEs to include slips and memory lapses (40 percent), rule violations (26 percent), infusion pump problems (12 percent), and lack of drug knowledge (10 percent).[45]

Experience and skills also impact thought processes. In one study of 40 student nurses and 6 nurses using a computerized program to assess the impact of dyslexia found that the greater the tendency towards dyslexia, the poorer the potential cognitive ability to effectively provide the skills associated with effective drug administration.[112] Similarly, in two reviews of the literature,

a number of medications errors were found to be caused by poor mathematical skills,[30] especially if mathematical skills were needed to properly administer drugs.[39]

Lack of medication knowledge is a constant problem, and there is a need to continually gain more knowledge about current and new medications.[30] Nurses with more education and experience may have greater knowledge of medications.[39] However, experience has not been found to mitigate the effect of poor mathematical skills nor frequency of MAEs.[30] Those new to a unit or profession may be at risk for errors.[39] In a survey of nurses working in three hospitals in Taiwan, nurses reported causes of MAEs as new staff (37.5 percent), unfamiliarity with medication (31.9 percent), unfamiliarity with patient's condition (22.2 percent), and insufficient training (15.3 percent).[93] Inexperience may also contribute to performance (human) deficit, willingness to follow a procedure/protocol, and knowledge deficit. Of these reported contributing factors, 78 percent were due to the inexperience of staff.[44] Blegen, Vaughn, and Goode[113] found that medication errors rates were inversely related to the proportion of nurses on a unit with greater experience, but were not related to the educational level of the staff on the unit.

Evidence Table 2. Working Conditions Associated With Medication Administration Errors and Adverse Drug Events

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Aitken 2006[105]	*Process Factors*: Documentation of medication administered by nurse	Cross-sectional study	Review of patient medication charts and progress notes for one working shift. Each participant was interviewed.	47 nurses in one urban teaching hospital in Australia	None	34% of progress notes contained information about administered medications. 30% of progress note entries included medication name, dose, and time of administration. Medication education was not documented in any progress note. Outcomes of administered medications were not documented, nor was assessment prior to administering. 10% of progress notes documented information about desired or adverse effects of medications. Only half of withheld medications were documented.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Armitage 2003[39]	*System Factors:* Workload *Process Factors:* Lack of double-checking Failure to follow policies and procedures Distractions and interruptions Communication processes *Human Factors:* Individual characteristics and abilities associated with medication administration errors (MAEs)	Literature review	Expanded upon the O'Shea (1999)[30] review	Literature on drug administration, drug error, and nursing was reviewed.	None	Workload—4 studies indicated equivocal findings on the relationship between workload and errors. Lack of double-checking—3 studies indicated that double-checking did not necessarily prevent errors. Failure to follow policies and procedures—6 studies indicated that failure to adhere to policies has been associated with errors. Distractions and interruptions—6 studies indicated that rapid turnover and changes as well as distractions and interruptions contributed to errors. Communication failures—7 studies indicated that illegible and poorly written drug prescriptions led to errors. Mathematical skills of nurses—5 studies indicated that poor mathematical skills may put nurses at risk for errors, especially if they need complex mathematical skills to administer drugs. 3 additional studies indicated weight-base dosing and mathematical calculations of dosing resulted in potential risk of errors. Knowledge of medications—3 studies indicated that knowledge of medication may be greater in nurses with more education and experience. Length of nursing experience—6 studies indicated that those new to a unit or profession may be at risk for errors.
Balas 2006[84]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions	Cross-sectional	Qualitative 14-day self-reported record of shift work and errors	502 RNs in critical care units	None	Nurses reported forgetfulness, heavy workload, distractions, and high patient acuity as causes for their medication errors or near errors.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Beyea 2003[81]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Secondary analysis	179 reported medication errors in same-day surgery	MEDMARX® data	None	Workload increase in 11.2% reports, insufficient staffing in 8.4%. Distraction associated with 56.4% of errors. Inexperienced staff with 14.5% of error reports.
Beyea 2003[82]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Secondary analysis	731 reported medication errors in the operating room	MEDMARX® data	None	Workload increase in 11.5% reports, insufficient staffing in 4.8%. Distraction associated with 48% of errors. Inexperienced staff with 17% of error reports.
Blegen 1998[95]	*System Factors:* Staffing and RN skill mix	Cross-sectional	Administrative data for nurse staffing and medication errors at the patient care unit level	42 units in 1 large tertiary care hospital	None	Rates of medication errors were inversely associated with RN skill mix up to an RN proportion of 87.5%. Rates of medication errors were positively correlated with falls (0.192).
Blegen 1998[96]	*System Factors:* Staffing and RN skill mix	Cross-sectional study	Analysis of event reports and nurse staffing patterns for 10 quarters	39 units in 11 hospitals	None	Rates of MAEs by 10,000 doses were highest in medical-surgical and obstetric units; they were highest by 1,000 days in ICUs. Units with RN proportions greater than 85% had higher rates of MAEs per 10,000 doses.
Blegen 2001[113]	*Human Factors:* RN education and experience	Cross-sectional study	Secondary data analysis	80 units in 12 hospitals	None	MAEs were inversely related to RN experience but were not related to RN education.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Buckley 2007[24]	*Process Factors*: Communication processes Medication administration process *Human Factors:* Individual characteristics associated with MAEs	Prospective cohort study	Anonymous survey of pediatric ICU nurses about the medication process, followed by a direct observation over 6 months of medication process, determining actual and potential errors. Observers of medication administration would intervene if error was considered harmful to patient.	In a 16-bed pediatric medical/surgical ICU at a tertiary care academic medical center	None	Faulty interaction with other services (6.7%) and infusion pump problems (6.7%); no administration errors were found to be associated with drug stocking and delivery, inadequate monitoring, or lack of patient information. Majority of MAEs were associated with slips and memory lapses (46.7%), lack of drug knowledge (13.3%), rule violations (13.3%).
Carlton 2006[98]	*System Factors*: Length of work shift Staff skill mix Patient acuity *Process Factors*: Interruptions Unclear orders Medications received late *Human Factors*: Skill/education/ experience Knowledge of medications	Literature review	Medication administration literature published before 2005		None	5 studies reviewed the association of nurse skill mix with MAEs; found that the research on skill mix is conflicting. 1 study reviewed a neonatal care unit and found increasing number of medication errors (MEs) associated with increasing acuity of newborns. Many MAEs are not recognized as an error. 1 study of a cross-sectional survey of nurses found that nurses perceived MEs to be caused by late arrival of medications from pharmacy, RNs too busy, RNs forgetful or failure in oversight, and unclear medical administration records. 1 study found lack of knowledge and skill/experience, failure to adhere to policies and procedures, and communication failures as active errors by nurses resulting in MEs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Chevalier 2005[107]	*Process Factors*: Nurse management of the medication administration process	Cross-sectional study	Retrospective survey on safety culture	39 nurses (35% response rate) in 3 hospitals in the Capital Health district of Nova Scotia	None	69% of nurses reported difficulty in obtaining an accurate medication history from patients when they were admitted; 82% reported patients were unable to provide accurate medication histories (e.g., reconciliation). When patients were transferred from another unit, 85% of nurses reported that medication orders were rewritten at transfer, 92% that medication orders were checked against electronic medical records, 62% that it was time consuming to clarify medication orders, 66% that the reasons for medication changes made at transfer, and 20% that "blanket" orders are often written as transfer orders.
Eisenhauer 2007[110]	*Human Factors:* Individual characteristics associated with MAEs	Cross-sectional study	Semistructured, retrospective, qualitative interview of nurses; then used basic content analysis of the narrative data.	40 staff nurses in one northeastern U.S. hospital where bar-coding was being implemented	None	Nurses' thought processes in relation to medication administration included - Analyzed situations and sought validation or a solution when communicating about patients. - Used knowledge, experience, and understanding of patients' responses to anticipate problems. - Integrated their knowledge of lab values and patterns of pathophysiological responses to determine possible need to change dosage or administration timing. - Checked orders for validity and correctness. - Assessed patients' responses, the possible presence of side effects, and effectiveness of drug. - Used cues from patients or family members about need for explanations about drugs. - Bypassed protocols or procedures, some taking a risk, to get drugs to patients or use time more efficiently. - Anticipated need for future problem-solving. - Applied professional knowledge during drug administration.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fogarty 2006[100]	*System Factors:* Organizational climate	Cross-sectional study	Survey included a 6-item quality of work life, satisfaction with working conditions, positive and negative affect, organizational climate, and a procedure violation scale.	176 nurses in rural Australia working in 11 public sector hospitals	None	"Violations" was the only variable with a direct contribution (24%) to MAEs. Distress was positively associated with violations, while quality of working life, morale, and organizational climate had a negative association. It was not possible to determine if the effect of organizational climate on violations is direct or mediated by stress and morale, but organizational climate is linked with safety behavior.
Hicks 2004[38]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Retrospective cohort study	645 reported medication errors in postanesthesia care unit	MEDMARX® data	None	Workload increase in 15.5% reports; insufficient staffing in 4.3%. Distraction associated with 47% of errors. Inexperienced staff associated with 14.9% of error reports.
Hofmann 2006[101]	*System Factors:* Safety climate	Cross-sectional study	Survey and administrative data from 82 units in 41 hospitals		None	Increased safety climate scores associated with lower rate of medication errors causing harm.
Kapborg 1999[80]	*Process Factors:* Policies and procedures Supervision Documentation of administration	Retrospective cohort study	Analysis of malpractice cases and small interview survey with 8 nurses working in nursing homes and home care setting using semistructured questions	68 cases of MAEs occurring in several types of home care and nursing home settings	None	Reported causes of MAEs were lack of administration protocols, failure to check orders, ineffective nurse supervision in delegating administration, and inadequate documentation.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kopp 2006[45]	*Process Factors:* Equipment malfunction during medication administration *Human Factors:* Individual characteristics associated with MAEs	Prospective cohort study	Voluntary survey of nurses on the medication use process followed by direct observation over 6 months by 2 pharmacy residents specializing in critical care pharmacy. Pharmacy residents would intervene if MAE would have resulted in patient harm.	1 16-bed medical/surgical ICU in a tertiary care academic medical center in Arizona	None	12% of the 42 MAEs were caused by infusion pump problems. Causes associated with MAEs included slips and memory lapses (40%), rule violations (26%), lack of drug knowledge (10%).
Manias 2004[109]	*Process Factors:* Medication management and patient monitoring	Prospective cohort study	Qualitative participant observation and questioning of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	To monitor patients before, during, and after medication administration, nurses assessed vital signs, lab values, ability to swallow, and patient self-report of health. Participants felt responsible for timing medication administration and providing as-needed medications.
Manias 2004[111]	*Human Factors:* Cognitive reasoning	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Participants used hypothetico-deductive reasoning to manage patient problems. Graduate nurses used pattern recognition of patient characteristics and medications during decisionmaking. Intuition and tacit knowledge was used in relation to changes in patients' vital signs and objective monitoring of patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Manias 2005[114]	*Process Factors:* Communication with health care providers	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Nurses communicated with other nurses about information resources on medications, how to troubleshoot equipment problems, clarification in medication orders, changes in medication regimens, and patient assessment parameters when handing over patients. Nurses communicated with physicians informally to exchange information, about the absence of other physicians, and in both unstructured and structured ward rounds. Nurses communicated with pharmacist about information on medication administration and organizing medications for patient discharge.
Manias 2005[106]	*Process Factors:* Adhering to protocols for medication administration	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Protocols were used to check that practices were acceptable, obtain information on medications, provide patient care without seeking additional information from physicians, and provide key information when working in another unit. Nurses examined the patient's identity 27% of the time before medication administration; double-checked certain medications before administration with another nurse 80% of the time; did not complete incident reports for medication errors (only 2 medication errors were observed); sought information on unfamiliar medications 86% of the time; sought clarity on unclear medication orders 100% of the time; and observed patients taking oral medications 90% of the time.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mayo 2004[61]	*Process Factors:* Lack of order clarity Communicating missed doses	Cross-sectional study	Random sample of RNs surveyed about perceived causes of medication errors; percentage of medication errors reported to nurse managers; types of reportable incidents; and reporting behaviors, including medication errors scenarios.	983 RNs (a 20% response rate) in the United Nurses Association of California/Union of Health Care Professionals		Nurses ranked difficult/illegible physician handwriting, distractions, and being tired and exhausted as causes for the majority of medication errors. Nurses would not communicate to physicians or others when a routine morning dose of medication was withheld because a lab report was late (91.8%) or a dose omitted while the patient was sleeping (55.5%).
Millward 2005[112]	*Human Factors:* Cognitive skills involved in drug administration	Prospective cohort study	Used a computerized program to assess the presence of dyslexia and its effects on drug administration skills	40 students and 6 qualified nurses	None	The greater the tendency to dyslexia, the poorer the potential cognitive ability to effectively provide skills associated with drug administration.
Osborne 1999[70]	*Process Factors:* Distractions Failure to comply with procedures *Human Factors:* Confusion Fatigue	Cross-sectional study	Self-reported perception of nurses on medication errors, their causes, and how medication errors should be reported	57 full-time and part-time RNs (a 62% response rate) in a medical-surgical unit in a 700-bed community hospital in south Florida		Main cause of medication errors was failure to identify the right patient (35.1%), and 24.6% indicated the effects of fatigue.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
O'Shea 1999[30]	*System Factors:* Workload Nurse staffing Medication delivery systems *Process Factors:* Shift and hours worked Single nurse drug administration Adherence to policy and procedures Distractions and interruptions *Human Factors:* Mathematical skills Knowledge of medications Experience	Literature review	Retrospective review of 97 articles published in 1995 and earlier, involving the definition and contributing factors to MAEs	Studies involving nurses and medication administration	None	Staffing—2 studies indicated contradictory implications on the effect of staffing levels on the incidence of medication errors. Shift and hours worked—3 studies indicated that there was a difference in the number of errors by shift; and 2 studies indicated that there was no difference in the number of hours worked (8 vs. 12), but there were more errors with nurses working rotating shifts. Workload—3 studies indicated that the effect of a heavy workload can be compounded by distractions; use of temporary staff and inadequate skill mix are associated with more errors. Medication delivery systems—1 study indicated that the error rate was higher in units using a medication nurse to administer medications. Single nurse drug administration—2 studies indicated that medication errors did not necessarily decrease with two nurses administering medications (e.g., double-checking). Adherence to policy and procedures—8 studies indicated that MAEs can be caused by failure to adhere to policies. Distractions and interruptions—5 studies indicated that distractions and interruptions interfere with preparing and administering medication, potentially causing errors. Mathematical skills—8 studies indicating that a number of medications errors are caused by poor mathematical skills. Knowledge of medications—8 studies indicated that not only is lack of knowledge a constant problem, but there is a need to continually gain more knowledge about current and new medications.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
O'Shea 1999[30] (cont.)						Length of experience—2 studies indicated that experience did not mitigate the effect of poor mathematical skills nor frequency of MAEs
Rogers 2004[99]	*System Factors:* Nurse staffing Shift work	Cross-sectional study	Qualitative 14-day self-reported record of shift work and errors	Nationwide sample of 393 nurses (a 40% response rate)	None	The risk of medication administration errors was nearly three times higher once a nurse worked more than 12.5 hours during a 24-hour period. In over 80% of shifts, nurses reported leaving after their scheduled shift, working on average 55 minutes longer than scheduled each day. Work duration, overtime, and number of hours worked in a week was directly associated with errors.
Rothschild 2005[108]	*Process Factors:* Using smart pumps to decrease medication administration errors	Randomized clinical trail	Prospective, randomized time-series trial comparing the rate of serious medication errors with and without decision support during 11 months.	1 cardiac surgical intensive care and 2 step-down units in a hospital in Boston	Implementation of new intravenous infusion pumps with decision support (i.e., alerts, reminders, and unit-specific drug rate limits) used during medication administration	During the trial, half of ADEs were preventable (2.12 of 100 patient-pump days); 72% of preventable ADEs were serious or life-threatening. During the intervention, bypassing the drug library (24% of infusions) and overriding alerts were frequent. Use of the smart pumps did not reduce the rate of serious medication errors.
Scott-Cawiezell 2007[104]	*Process Factors:* Distractions and interruptions	Prospective cohort	Naïve, direct observation of medication administration	8 RNs, 12 LPNs, 19 CMT/As in 5 Midwestern nursing homes	None	RNs administered 15.3% of observed doses, LPNs 23.3%, and CMT/As 61.43%. The MAE rate for RNs was 34.6%, LPNs 40.1%, and CMT/As 34.2%. RNs had more interruptions (39.9%), and LPNs had more distractions (41.6%).
Stratton 2004[58]	*System Factors:* Workload *Process Factors:* Distractions and interruptions	Cross-sectional study	Nurses were surveyed to assess the perceived causes of MAEs.	284 RNs (227 adult and 57 pediatric nurses) in 11 hospitals in 2 States (40% response rate)	None	Pediatric and adult nurses reported distractions and interruptions (50% of pediatric nurses and 47% of adult nurses), RN-to-patient ratios (37% and 37%), numbers of medications administered (35% and 31%), and not double-checking doses (28% and 28%) as the most important causes of MAEs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Tang 2007[93]	*System Factors:* Workload *Process Factors:* Complicated orders Distractions and interruptions *Human Factors:* Experience Knowledge and skills	Cross-sectional study	A semistructured questionnaire was used to assess MAE events, background of the nurse, and perceived contributing factors.	72 female nurses at 3 acute care hospitals (80% response rate)	None	Nurses reported personal neglect (86%), heavy workload (38%), complicated doctor-initiated order (24%), and complicated prescription as the major causes of MAEs related to the medication administration process. Personal neglect included distraction, interruptions, not double-checking, and poor mood. Nurses reported causes of MAEs as new staff (37.5%), unfamiliarity with medication (31.9%), unfamiliarity with patient's condition (22.2%), and insufficient training (15.3%).
Tissot 2003[91]	*System Factors:* Workload *Process Factors:* Incomplete/illegible orders	Prospective cohort study	Direct observation of nurses administering medications to patients by a pharmacist	A geriatric unit and a cardiovascular-thoracic surgery unit within a hospital in France	None	Opportunities for errors were associated with incomplete/illegible prescriptions and nurse workload (OR = 2.44, 95% CI = 1.30–4.60; *P* = 0.006).
Ulanimo 2007[102]	*Process Factors:* Perceived causes of MAEs *Human Factors:* Distractions	Cross-sectional study	Survey on perceived causes of medication errors and percentage of all medication errors that are reported to the nurse manager, completing an incident report.	25 nurses (44% response rate) in a VA hospital in Northern California	None	The most frequent perceived causes of medication errors for nurses were failing to check patient name band with medication administration record (45.8%); being tired and exhausted (33.3%); miscalculating the dose (29.2%); confusion between 2 look-alike drugs (29.2%); distractions (25%); different infusion devices being used (25%); unclear medication labeling/packaging (25%); and wrong infusion device set up/adjustment (24%).
Whitman 2002[97]	*System Factors:* Nurse staffing	Prospective cohort study	Secondary data analysis of a prospective, observational cohort study	95 patient care units in 10 adult acute care hospitals in an integrated health care system in the eastern United States	None	Rates of medication errors were inversely associated to staffing work hours per patient day in cardiac ICU (r = -0.53) and noncardiac intermediate (r = -0.55) care settings. 30.3% of the variance in medication error rates resulted from the variance in staffing work hours per patient day.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wolf 2006[44]	*Process Factors:* Distractions *Human Factors:* Knowledge deficit Inexperience	Retrospective cohort study	Analysis of MAEs reported January 1, 1999, to December 21, 2003, by nursing students during the administration phase	MAEs reported by 1,305 nursing students in the USP MEDMARX® program; 763 reports included contributing factors.	None	The major contributing factors to MAEs were inexperienced staff (78%) and distractions (20%). The other, significantly fewer causes of errors were insufficient staffing, agency/temporary staffing, lack of access to patient information, emergency situation, poor lighting, patient transfer, floating staff, no 24-hour pharmacy, and code situation. The major causes of MAEs were reported as performance (human) deficit (51%), procedure/protocol not followed (32%), and knowledge deficit (27%).

Strategies To Improve Medication Administration Safety

Strategies to improve medication safety focused on acute care settings. Twenty-six studies and descriptions of quality improvement projects were identified. Strategies used included recommendations from a nationwide voluntary organization to improve safety, education of nurses and other providers in safe practices, and system change and technology.

Nationwide voluntary efforts. Lucian Leape and colleagues[116] reported on a 15-month Institute for Healthcare Improvement Breakthrough Series Collaborative intended to reduce ADEs. Eight types of strategies were successfully used, including documentation of allergies, nonpunitive reporting, and standardizing medication administration times. Effective leadership and appropriateness of intervention were associated with successful change implementation. The converse was associated with failure, as were unclear aims, poorly designed interventions, lack of focus on underlying system failures, unclear measures, too much focus on data collection, involvement from only some stakeholders, opposition from physicians and nurses, and conflicting time demands for team members. The findings were limited by the lack of an analysis of the relationship between established safety policies and practices and the success of implementing new strategies, as well as the relationship between the implementation and the occurrence of ADEs.

A survey of 148 hospitals about the characteristics and barriers associated with adoption of the National Quality Forums' 30 safe practices was done by Rask and colleagues.[117] These practices included unit dosing, adopting computerized physician order entry (CPOE), and having a culture of safety. Of the recommended practices, there was high adoption of standardized labeling and storage of medications (90.5 percent), identification of high-alert medications (81 percent), and use of unit doses (81 percent). For-profit hospitals were more likely than not-for-profit hospitals to have unit-dose medication distribution systems (93.1 percent vs. 78.2 percent) and policies on reading back verbal orders (83.1 percent vs. 58.4 percent). There were greater distractions affecting medication administration in large hospitals. Hospitals with 100–299 beds were more likely to report using pharmacists to review and approve nonemergency orders prior to dispensing; and, 69.4 percent of all hospitals used data analysis to drive patient safety quality improvement efforts.

Nurses' education and training. Educational strategies aimed to improve medication safety and avert unnecessary medication errors. One randomized controlled study used an interactive CD-ROM education program to improve the use of safe medication practices and decrease the rate of MAEs.[118] Direct observation of medication administration was used to assess the impact. After the training, nurses' use of safe administration practices increased, but preparation errors did not decrease. There were too few actual medication errors to analyze pre-post differences. Another approach used an 11 module Web-based educational strategy to improve drug safety with a small sample of nurses.[119] Direct observation of medication administration was used to determine the outcome. After using these modules, rates of nonintravenous MAEs decreased from 6.1 percent to 4.1 percent. Rates of errors in intravenous drug administration did not decline as expected. Dennison[120] reported the results of a medication safety training program for nurses. Knowledge scores improved in this pre-post test study, but there was no significant change in safety climate scores, labeling of intravenous infusion setups, or the number of self-reported errors.

Attempts to improve basic and continuing education in medication safety have been reported, but they have not assessed the impact on actual error rates. In a small pilot study, a problem-

based learning approach was found to enable students to use findings from topic-specific research to develop and apply solutions for clinical problems. Papastrat and Wallace[121] proposed using problem-based learning and a systems approach to teach students how to prevent medication errors and suggested content, but their approach was not compared to other teaching methods. Another proposed educational strategy for practicing nurses was to use simulation of medication administration and errors in a controlled setting to improve medication safety, "duplicate the complexity of the nurse-patient interaction and related cognitive thought"[122] (p. 249). Simulations could be used to prepare nurses to recognize and manage medication errors when and if they occur.

System change. Several attempts to change the system have been tested. Some of the strategies addressed the thoroughness of error reporting, some the processes and events surrounding medication administration, and some focused directly on reducing errors. Using a hospitalwide performance improvement project that emphasized system factors, not individual blame, error reporting increased from a rate of 14.3 percent to 72.5 percent.[123] To address intravenous infusion problems, a medication safety education program and medication calculation worksheets were introduced, followed by ongoing Plan-Do-Study-Act cycles.[124] Multiple system changes were also used to improve safety of intravenous drug infusion. These included removing 90 to 95 percent of potassium chloride ampoules from the bedside; developing preprinted labels for five common drug infusions; removing four-channel infusion pumps the unit and replacing them with double-channel infusion pumps with a simple interface design; standardizing administration of drugs given by bolus dose using a syringe pump; decreasing missed doses of immunosupression drugs for transplant patients from 25 percent to 9 percent by incorporating them into the main drug chart; implementing standardized prefilter and heparin-lock central venous catheters and heparin infusions into ICU protocol; redesigning drug infusion administration practices throughout the hospital; eliminating burettes for IV drug infusion; preparing standardized drug infusions for 36 drugs; and providing Intranet-based up-to-date drug information.

A time study and focus groups were used to compare nurse efficiency during medication administration using either medication carts with unit doses or a locked wall-mounted cupboard in each patient room.[125] After 12 weeks, the wall-mounted units were found to have decreased medication administration time for nurses an average 23 minutes per 12-hour shift. Time saved by not having to search for missing medications saved 0.38 full-time equivalent (FTE) annually. Pharmacists spent an additional 0.05 FTE in stocking room cupboards. Nurses reported more contact time with patients when using room cupboards and fewer interruptions by colleagues during medication preparation and administration. Two small experimental studies attempted to reduce distractions that frequently interrupt nurses during medication administration and thereby introduce the potential for error.[126, 127] In both studies a standardized protocol for safe administration of medications was introduced to the nursing staff in the experimental group and signage was used to remind others (physicians, patients, other staff) to not interrupt. The signage in the first study was a vest that the nurse administering medication wore; in the second it was a sign above the preparation area. Direct observation of the number and types of distractions provided the outcome measures in the first study; a questionnaire completed by each nurse administering medications provided the measure of distractions for the second. In both studies, the number of distractions was significantly reduced. Medication error rates were not captured.

One randomized controlled trial compared the use of a dedicated nurse for medication administration to nurses providing comprehensive care, including administering medications, to

their patients in two hospitals.[128] MAEs were then assessed using direct observation. The investigators found the error rates to be 15.7 percent at the intervention hospital and 14.9 percent in the control hospital. The rate of MAEs was not significantly different between control and experimental groups.

Involving patients in the administration of medications while in the hospital is another system strategy that has been assessed. With this intervention, hospitalized patients have the responsibility for administering their own medication under the supervision of nursing staff. A literature review reported on 12 studies that described and evaluated a patient self-administration program.[129] This review found that the patients' knowledge about their medications and the prescribed dosing increased, but knowledge about the potential side effects of their medications did not. Given the body of the reviewed literature, it appeared as though patients and families make as many or more MAEs than do health care providers.

System change with technology. Another rapid-cycle implementation project over 6 months used continuous quality improvement data before and after implementing a modular, computerized, integrated infusion system.[130] Most infusion error warnings occurred between 3 p.m. and 9 p.m., peaking at 6 p.m. Nurses responded to 12 percent of the infusion error warnings by altering the setting and averting errors. The nature of the 88 percent of warnings not responded to was not discussed. Risk scores associated with heparin infusion rates decreased almost fourfold. Almost all nurses used the new software correctly.

Two studies focused on documentation of medication administration. One study introduced a charting system with decision support and used a quasi-experimental design to determine the effects.[131] Researchers collected medication charting data for 8 weeks in both the control and study units. Staff in the study unit received an educational intervention about error avoidance through real-time bedside charting, followed by 12 weeks of monitoring and performance feedback. After the 12 weeks, medication charting rates increased from 59 percent to 72 percent in the intervention group. The second study used a computer-based "unreported meds followup" to remind nurse staff about scheduled medications omitted or not documented.[132] After charts were prospectively reviewed, a mandatory medication error prevention seminar was given to nurses, and a medication review report was created for nurses. Reported medication errors and documentation of medication administration were reviewed, medication administration policies were developed, and focus changed to the potential causes of errors. Documentation errors decreased over the 3 years of the study, and reported error rates increased by 0.5 percent each year.

Bar-coded medication administration (BCMA) is promoted as the most effective way to reduce administration errors and is being implemented widely. Conceptually this technology should catch nearly all errors, but rigorous evaluation of the impact of technology on error rates has lagged behind implementation. The biggest challenge to determining the effectiveness of BCMA or other interventions is the lack of valid measures of MAEs. Data from voluntary self-reported medication errors are known to capture only a small portion (5 percent to 50 percent) of actual errors, and the BCMA system itself greatly alters nurses' awareness of errors, thereby systematically affecting reported error rates. Many studies reporting analysis of the impact of BCMA have used data collected by the system only after implementation.[133–136] From these we learn the types of errors intercepted by the system. Three other studies of the impact of BCMA on administration errors reported very large reductions: 59–70 percent decrease,[137] 71 percent and 79 percent drops.[138] However, the sources of the data for determining these decreases are not known.

Direct observation of medication administration, a resource- and time-intensive approach to data collection, is the only way to gather unbiased data to evaluate the impact of BCMA on medication administration errors. Three studies have used direct observation; however, each evaluated the implementation of a different set of technology. Franklin and colleagues[139] reported a decline in MAE rates from 8.6 percent to 4.4 percent when a new system was implemented in a teaching hospital in England. The system included BCMA, computerized order entry, automated dispensing, and electronic medication administration record. Prescription errors also declined from 3.8 to 2 percent. It is noteworthy that the rate of both administration and prescribing errors by direct observation was much lower than other direct observation studies have reported. Paoletti and colleagues[140] used direct observation to determine the impact of BCMA and an electronic medication record in a hospital in the United States. They reported that the rate of MAEs declined from 13.5 percent to 3 percent. Finally, the implementation of only the electronic medication administration record led to a decline in MAEs from 10.5 percent to 6.1 percent using direct observation.[141] Health-related technology designed to increase medication safety has great promise, but more study using valid outcome measures and controlled interventions needs to be done to demonstrate the potential benefits.

Evidence Table 3. Strategies To Reduce Medication Administration Errors

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Anderson 2004[137]	Bar-coded technology	Quality improvement project		One hospital	Bar-coded point-of-care medication administration	59%–70% reduction in MAEs. Positive effect on nurses' satisfaction.
Bennett 2006[125]	Dispensing mechanisms to improve medication administration	Quality improvement project	Time study and focus groups to compare nurse efficiency using medication carts or a unit dose to locked wall-mounted cupboards in each patient room	Nurses in 2 units and pharmacists in one hospital	Wall-mounted cupboards in patient rooms	Wall-mounted units decreased medication administration time for nurses an average 23 minutes per 12-hour shift. Time saved not searching for missing medications saved 0.38 FTE annually. Pharmacist spent an additional 0.05 FTE in stocking room cupboards. Nurses reported more contact time with patients when using room cupboards. Nurses reported fewer interruptions during medication preparation and administration.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Burdeu 2006[124]	Improving safety of intravenous medication administration	Quality improvement project	Plan, do, study, act (PSDA) cycle was used to assess deviations in safe practice of drug infusions, using regular audits by ICU nursing management.	Began with 1 25-bed ICU, then applied lessons learned throughout one acute care teaching hospital in Melbourne, Australia	Provided a medication safety education program and medication calculation worksheets, followed by ongoing PDSA cycles.	Improved drug infusion labeling practices. 90 to 95% of potassium chloride ampoules were removed from the bedside. Preprinted labels were developed for the 5 drug infusions most commonly used. 4-channel infusion pumps were removed from the unit and replaced by double-channel infusion pumps with a simple interface design. Standardized administration of drugs given by bolus dose using a syringe pump. Decreased missed doses of immunosupression drugs for transplant patients from 25% to 9% by incorporating them into the main drug chart. Implemented standardized prefilter and heparin-lock central venous catheters. Eliminated burettes for IV drug infusion. Standardized drug infusion protocols for 36 drugs and provided Intranet-based up-to-date drug information.
Coyle 2005[133]	BCMA	Quality improvement project	Assessed process	161 medical centers in the Veterans Health System	Systemwide change to BCMA and electronic documentation	Acceptance of nurses and “marked decrease” in errors (data for this decrease not described).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dennison 2007[120]	Medication safety education program	Pre-post test Evaluation study of education program	Technology-enhanced education program	One coronary care unit in one hospital	Two computer-based education modules on medication error reduction and intravenous infusion of high-alert meds.	Nurses knowledge increased from pre- to post-test. Safety climate scores did not change. Labeling of infusion did not change. Number of reported errors did not change.
Fields 2005[130]	Improving safety of intravenous medication administration	Quality improvement project	Rapid-cycle implementation over 6 months, using continuous quality improvement data before and after implementation	100 new systems in 1 hospital in Georgia	Implemented a modular, computerized, integrated infusion system	Most infusion error warnings occurred between 3 p.m. and 9 p.m., and peaked at 6 p.m. 12% of warnings led to changes in pump settings. Risk score associated with heparin infusion rates decreased almost fourfold. Almost all nurses used the new software correctly.
Force 2006[123]	Medication error reporting	Quality improvement project	Used focus groups to gather information on the medication process and process failures to improve error and near-error reporting by pharmacists and nurses	1 hospital in Illinois	Implemented a hospitalwide performance improvement project, emphasizing identifying system factors, not individual blame.	After 1 year of implementation, error reporting increased from a rate of 14.3% to 72.5%.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Franklin 2006[119]	Drug safety education Types of MAEs	Pretest and post-test study	Conducted a drug safety program for nurses and assessed possible improvements in drug safety. Medication administration processes were observed before and after the program.	19 nurses in one hospital ward (63% completed all educational modules).	Web-based drug safety program with 11 modules	The most common types of MAEs were omission, wrong dose, extra dose, and fast intravenous bolus. Rates of nonintravenous MAEs decreased from 6.1% to 4.1%. While nurses used the drug safety program and there was a decrease in nonintravenous MAEs after implementation, there was no significant difference in total MAEs after implementation of the drug safety program.
Franklin 2007[139]	Health technology implementation	Before-and-after study	Reviewed records for prescribing errors, direct observation of nurse med administration	Surgical ward in one hospital in UK	CPOE, BCMA, automated dispensing, electronic medication administration record	MAEs declined from 8.6% to 4.4%. Prescribing errors declined from 3.8% to 2%. Ward pharmacist time increased, prescription time increased, nursing time on medication tasks declined.
Greengold 2003[128]	Medication administration nurses	Randomized controlled trial	Compared using a dedicated nurse for medication administration to nurses administering medications to their patients	2 hospitals	Using a dedicated nurse for medication administration	Generally, there were no significant differences in MAEs between the 2 types of interventions, but MAEs were lower in surgical units and higher in mixed medical and surgical units that used dedicated nurse medication administers.
Larrabee 2003[136]	BCMA	Quality improvement	Descriptive—process and experiences	1 hospital	BCMA	Occurrence reports increased, analysis of systems data for prevented errors found prevalence of “not-due,” wrong-dose, and wrong-patient errors. No omitted and missed doses errors were captured.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Leape 2000[116]	Interventions for reducing adverse drug events	Quality improvement	15-month period of rapid-cycle changes.	36 hospitals participating in an Institute for Healthcare Improvement (IHI) collaborative on reducing adverse drug events.	Education on IHI's method for rapid-cycle change and evaluation	Successful change strategies included nonpunitive reporting; standardized prescribing to reduce illegible handwriting and eliminate leading or trailing zeros; heparin protocols; removal of concentrated potassium chloride from nursing units; improved documentation of allergy information; standardized medication administration time; standardized protocols for chemotherapy; and implementation of insulin-ordering protocols. Of these, removing concentrated potassium chloride from nursing units was 100% successful, and implementing nonpunitive reporting and insulin-ordering protocols were the least successful (50% and 43%, respectively). Success of change strategy was associated with the commitment of the collaborative team (i.e., leadership), effective processes, and appropriate choice of interventions. Failure was attributed to lack of leadership support; ineffective team leadership; unclear aims; poorly designed interventions; lack of focus on underlying system failures; unclear measures; too much focus on data collection; involvement from only some stakeholders; opposition from physicians and nurses; and conflicting time demands for team members.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mahoney 2007[134]	Integrated clinical information technology	Quality improvement—measures only after implementation	Examined medication errors, turnaround time, decision-support overrides.	Multihospital system	Included CPOE, electronic record, BCMA, decision support, and drug dispensing	System decreased prescribing errors, increased pharmacist interventions, improved monitoring. 73 administration errors for every 100,000 doses were intercepted after implementation.
Meadows 2002[138]	BCMA	Review of BCMA system and effects	Relates briefly the results of two system interventions	2 hospitals	BCMA	The two hospitals had reductions in medication error rates of 71% and 79%. Data used to measure these not described.
Nelson 2005[131]	Decision support to improve medication administration	Pretest and post-test	Collected medication charting data for 8 weeks in both the control and study units. Staff in the study unit received an educational intervention about error avoidance through real-time bedside charting, 12 weeks of monitoring, and performance feedback.	Two 40-bed surgical units in one hospital in Utah	Educational intervention followed up with real-time feedback on documentation.	Medication charting rate increased from 59% to 72% in the intervention group.
Paoletti 2007[140]	BCMA and electronic medication administration record (MAR)	Evaluation study—before and after	Used direct observation to determine MAEs.	3 units in one hospital: 1 control, 2 intervention	BCMA and electronic MAR	Accuracy rate 86.5% before and 97% after.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Paparella 2004[122]	Educational interventions	Quality improvement	Medication safety education, using the NLN Medication Proficiency examination, a medication calculation test, an ongoing continuing educational program on medication safety, and tested medication administration safety simulation models to supplement education.	235-bed community hospital in Pennsylvania	Required medication safety education and calculation testing of all new RNs and LPNs, ongoing medication safety education for current staff, using simulation models "What's Wrong With This Patient."	The educational component for new nurses was used prior to matching with a preceptor during medication administration. The simulation program engaged nursing staff in identifying unsafe medication administration practices.
Papastrat 2003[121]	Educational interventions	Changing practice project	Pilot testing of problem-based learning and systems analysis methods for medication administration to undergraduate nurses.	First-semester baccalaureate nursing students at Thomas Jefferson University	New teaching method	Problem-based learning enabled students to use findings from topic-specific research to develop solutions for clinical problems. Students applied knowledge to clinical settings.
Pape 2003[126]	Reducing distractions during medication administration	Quasi-experiment	Three groups: one control, one used protocol, one used protocol and signage. Outcomes measured by observing medication rounds for distractions.	One medical/surgical unit in one hospital, 24 nurses	Protocol for safe medication administration. Signage—nurse administering medications wore vest asking others not to interrupt.	Distractions were statistically significantly less in the intervention groups, particularly the intervention group using both protocol and signage.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Pape 2005[127]	Reducing distractions during medication administration	Process Improvement	Interventions introduced after observation of distractions. Measured distractions with self-report tool.	5 units in one hospital, 20 nurses	Protocol and checklist for safe medication administration introduced to all nurses. Signage "STOP do not disturb" placed above med prep area.	Self-report of distractions from before and after signage was placed showed decline in distractions from other nurses, other personnel, external conversation, and loud noises.
Rask 2007[117]	Medication safety practices	Cross-sectional study	Survey of hospitals about adoption of National Quality Forum's safe practices and culture of safety	148 hospitals in the United States	None	There was high adoption of standardized labeling and storage of medications (90.5%), identification of high-alert medications (81%), and use of unit doses (81%). For-profit hospitals were more likely than not-for-profit hospitals to have unit-dose medication distribution systems (93.1% vs. 78.2%) and policies on reading back verbal orders (83.1% vs. 58.4%). There were greater distractions affecting medication administration in large hospitals. Hospitals having 100–229 beds were more likely to report using pharmacists to review and approve nonemergency orders prior to dispensing. 69.4% of hospitals use data analysis to drive patient safety quality improvement efforts.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sakowski 2005[135]	BCMA system	Evaluation study	Effect of implementing BCMA using a retrospective audit of warning and error reports generated by the BCMA system	6 hospitals in a multihospital system.	BCMA	Of 7,120 alerts and warnings, 5,606 actionable warning identified. Users overrode 78%. 25% of items listed as preventable errors and 70% of those labeled as possible errors were noise. Most common types of errors were early doses, wrong dose, doses without order, doses after order discontinued.
Schaubhut2000[132]	Expanding error reporting system Concurrent chart review process	Quality improvement	Reviewed reported medication errors, documentation of medication administration, identified need for medication administration policies, and focus on potential causes of errors	1 hospital in a suburb of New Orleans, LA	A computer-based "unreported meds followup" was created to remind nursing staff about scheduled medications omitted or not documented. Charts were prospectively reviewed, a mandatory medication error prevention seminar was given to nurses, and a medication review report was created for nurses.	Reported error rates increased by 0.5% each year over 3 years. Documentation errors decreased over time.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Schneider2006[118]	Educational interventions	Randomized controlled trial	Nurses were randomly assigned to use an interactive educational tool on medication administration. Direct observation of medication administration before and after the educational tool.	30 nurses (10 at each site) with at least 1 year experience, working full-time for at least 6 months, at 3 community hospitals in the Midwest within a large nonprofit health system	Interactive medication administration program	Errors in administrative practices decreased at a statistically significant level, errors in preparation increased slightly, and there were too few adverse drug events to analyze.
van Gijssel-Wiersma 2005[141]	Computerized medication charts	Before-after study	Compared prescription errors by review and administration errors by direct observation before and after	1 internal medicine unit	Computerized medication chart, updated daily, compared to handwritten 5-day medication record	Prescribing errors increased, mostly omitted name and date. Administration errors decreased from 10.5% to 6.1%.
Wright 2006[129]	Inpatient self-administration	Literature review	12 studies that measured patient compliance with self-administration programs (SAPs)	Retrieved 455 citations that involved patient SAPs, predominately in hospitals.	None	Even though SAPs varied widely in their structure and content, some SAPs reported that the patients' knowledge of their drug regimen (including the names and dosing frequency of their drugs) improved, but the patients' knowledge of possible side effects of their medications did not increase.

Evidence-Based Practice Implications

Medication safety is a significant issue in hospitals and throughout health care. Great improvements are needed, and hospitals are engaged in many efforts to reduce errors and increase this aspect of patient safety. Unfortunately, there is little evidence on which to base interventions. Based on the research literature, we can have confidence in only two aspects of our knowledge. First, data from voluntary self-reports of medication errors is neither reliable nor valid. Yet, this is the evidence most available for evaluating quality improvement. Interventions to improve the quality of voluntary self-report data include changing the culture to focus on system issues rather than individual deficiencies and having explicit and visible quality management system responses to these data. Staff who do not fear the response to an error report and see that the reports are used to improve quality are much more likely to take the time to report.

The second area about which there is some consensus in the literature is the rate and types of medication administration errors that commonly occur. Using the more reliable and valid data from direct observation studies, we see that the proportion of doses in error is between 20 and 27 percent counting wrong-time errors and between 7 and 18 percent without the wrong-time errors. MAEs are most likely to be wrong time, omissions, and wrong dose (wrong or extra dose). Because the nurse is often the last health care provider in the medication-use process, no one, except the patient, is in a position to intercept those errors. Given the number of medication doses administered each day in U.S. hospitals, the probable number of errors is truly staggering. If hospital patients get 10 doses of medication each day, at least 1 and possibly 3 of those will be wrong.

While the research base for practice interventions is growing, it is still weak for most of the strategies currently recommended to improve medication safety. System-focused strategies include increasing nurse staffing levels, otherwise decreasing workloads, improving the safety climate, and instituting policy and procedures such as RN independent double-checks. There are few research studies describing nurses' perceptions of the impact of these system features and even fewer assessing the actual impact, and none that have implemented and rigorously evaluated the effects of system strategies. Instituting new technological systems is most highly recommended. Given the emphasis, there have been surprisingly few studies actually assessing the impact on error rates of bar-coded medication administration and other medication safety technologies.

Process-focused factors include minimizing distractions and interruptions during medication administration, using equipment correctly, and assessing and monitoring the patients' responses to the medications. Again, a few small, single-site studies have assessed the effects of implementing protocols addressing these issues; but overall, the evidence is weak.

The human factors of knowledge and skills (e.g., mathematical) have been studied for decades, and changes in basic education and nurses' orientation and continuing education have been instituted. Studies linking these strategies to outcomes such as the rate of medication errors have not been completed. The impact of fatigue on MAEs is currently of great interest. But with only one descriptive study available and no interventions tested, it is difficult to know how to approach this issue.

Based on this review of the literature, it is clear that medication errors are an immense problem. When implementing interventions to improve medication safety, use the most reliable

and valid data available, and share the results through publications to make the knowledge available to all.

Research Implications

The implications for research follow directly on the discussion of practice implications. Research in this area is constrained by the need to carry out these projects "in the field." Secondary analysis of existing data sets cannot be used for most of the pertinent questions in this area. Laboratory studies are equally impossible. The situations at the heart of medication safety are complex, multifaceted, and multidisciplinary; knowledge about them must be produced with studies conducted within that complex environment. This requires health care institutions to simultaneously attempt to implement changes that will reduce the problem and evaluate the impact. Essentially, this is quality improvement (QI) work.

The question is, should the results of QI projects be considered evidence and used as part of the knowledge foundation for future evidence-based practice projects?[142] QI is a set of activities intended to improve some aspect of health care processes,[143] a dynamic and changing package of interventions,[144] and identification of ways to implement effective change.[145] For the most part, definitions of QI do not include assessing the effectiveness of these activities or producing knowledge. And yet, reports of QI projects are increasingly used as evidence for practice and organizational change.

Health care institutions are responding to the crisis in quality and safety with frenetic activities designed to bring about improvement. They desperately want evidence that will assist them in knowing which of these activities to focus on. Massive amounts of money are being invested in organizational changes to improve quality and safety with mostly expert advice and hunches to go on. There is little doubt that these projects are well intentioned; many of them suggest changes that are intuitive or reflect common sense. To move beyond the current state of multiple projects targeting similar changes, the industry needs evidence of the effects of specific changes: the direct and indirect effects, the intended and unintended effects, and the cost effectiveness.

By their nature, QI efforts are local, attempt to minimize disruption to the organization, and try to constrain costs of implementation. To justify the organization's investment in the project, there is a desire to show that the project had the intended effect. Further, the directors of the project often want to capitalize on the QI activities by reporting the results publicly, preferably through respected journals or presentations at professional meetings. As a result of these multiple goals, the project usually has only low-cost, superficial evaluation efforts that are then reported as evidence with an emphasis on outcomes supporting the intervention and omission of those that did not. Many current QI studies have significant bias and can cause harm by disseminating results that lead health care institutions to invest in activities that may not improve quality, while ignoring others that could.[146] But, there is no consensus on standards that can be applied to improve this situation. As Mosser and Kane[147] asked recently, What level of proof should we require to conclude that improvement has been achieved? What level of proof is there that the intervention was the cause of improvement?

The problem of bias inherent in local efforts to improve quality is crucial. When organizations make decisions to invest large amounts of money in a QI project, there is understandable reluctance to hear, let alone share, results that show no systematic effects on the outcomes of care. Yet, to produce the science required for future QI efforts, reports of activities

that were ineffective and those that resulted in unintended and disruptive side effects must also be shared with others. Most QI activities cannot be tested with rigorous and controlled research, and we therefore need to develop a QI science to enhance the internal and external validity of the results. We cannot accept poorly conducted studies of efforts to improve quality and safety—it is too crucial to the future of health care. At the same time, we must recognize that the complexity of projects taking place in the real world cannot be simplified and that analytic methods must substitute for experimental controls in this work.[148] Both the practitioners' distrust of research and its accompanying statistics and the researchers' disdain of the messiness of QI activities must be tempered with a better understanding.

Despite concerns about the rigor of QI, it is crucial that these activities be reported to promote learning about implementation methods that worked and those that did not, and the types of projects that produced desired results and those that did not. To maximize learning, these reports must be thorough and include both the intended and unintended outcomes, descriptions of the intervention and implementation must be candid, the robustness of the measures must be clear, and the description of the organizational context must be adequate. Recent guidelines for the publication of QI projects may assist in achieving this thoroughness and transparency.[149] Collaboration between the principals involved in the QI project and health systems researchers would maximize the potential for producing evidence from these field studies. It is unlikely that science will ever develop methods to study implementation and evaluation of QI projects in their natural setting with a level of rigor similar to experiments or clinical trials, and that makes the results of QI projects even more valuable. It is crucial that we learn which QI activities work in which settings and which outcomes can most likely be improved with organizational changes.

The specific issues most in need of research (QI activities) at this time are as follows:

- Bar-coding and other medication safety technology—widely recommended but little or no valid research using before-and-after designs.
- Independent RN double-checks—logical and widely recommended, but no research has been done describing, let alone testing, the effects of this policy.
- Relationship between nurse staffing and medication errors—a few descriptive studies and studies asking RN perceptions of the problem suggest that staffing and workload are major factors, but there are no research studies using valid and reliable data.
- Techniques to reduce distractions, interruptions, other risk factors for medication error need to be tested.
- Methods of effective education in medication safety for nurses and all providers.
- Effectiveness of implementing new checklists, policies, and procedures.
- Understanding work-arounds.
- Methods and techniques for successful implementation of system and process change.

Despite the national emphasis on patient safety and quality care, very little is known about effective medication safety strategies for nurses. The recent IOM report on medication safety [2] identified several areas needing future research, including the following:

- What are the most effective mechanisms to improve communication between patients and clinicians regarding the safe use of medications?
- What are the most effective mechanisms to improve patient education about the safe use of medications?
- Which self-management support strategies are effective in improving patient outcomes?

- How can information about specific medications be effectively used by patients? What is the impact of that information on patients' adherence and communication with clinicians?
- How can patient-centered approaches to medication safety decrease errors associated with medications and improve patient outcomes?
- How can medication-related competencies become a core competency among the current workforce?
- What is the impact of free samples on patient adherence and health outcomes?

Conclusion

There is a large and growing body of research addressing medication safety in health care. This literature covers the extent of the problem of medication errors and adverse drug events, the phases of the medication-use process vulnerable to error, and the threats all of this poses for patients. As this body of literature is evaluated, the fact that there are crucial areas about which we know little becomes apparent. Nurses are most involved at the medication administration phase, although they provide a vital function in detecting and preventing errors that occurred in the prescribing, transcribing, and dispensing stages. Administration errors comprise a significant proportion of all errors and yet, beyond that fact, there isn't much known about the causes or about the effectiveness of proposed solutions. Research addressing the complex process of medication use in hospitals is badly needed and requires a new approach to produce valid knowledge from studies done in the field with few controls of confounding factors.

Search Strategy

A search of the literature was conducted using PubMed® and CINAL®. The key words employed in the search included "adverse drug events," "drug administration," "medication administration," "medication administration errors," "medication error reporting," "medication safety," "nursing," "patient safety," and "work(ing) conditions." This resulted in 1,400 abstracts, which were narrowed as follows. Literature that addressed topics covered in this book on health information technology, specifically computerized provider order entry with clinical decision-support systems (for nurses and/or physicians) and bar-code medication administration systems, children, and medication reconciliation were excluded from this review, as were studies with only physicians and pharmacists as study subjects, those in home health care settings, and those related only to prescribing medications or patient compliance. Additional exclusion criteria included research not differentiating the nursing role in medication administration, administration of medications to reverse adverse drug reactions (e.g., naloxone for opioid overdose), prescribing and dispensing process of medications, and unique specifications regarding specific medications. Reviewed articles were searched for references that we did not already have, and PubMed® links were checked as additional articles were found. The final review also excluded editorials, newsletters, single-case studies, medication safety outside institutional settings (if dealing with patient self-management or adherence), and studies with critically flawed methodology and inadequate reporting. The literature was then also limited to reports written in English and research published in 1997 or later. A total of 70 articles were identified as having met the inclusion criteria as evidence and were discussed in this chapter.

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Chapter 38. Medication Reconciliation

Jane H. Barnsteiner

Background

According to the Institute of Medicine's *Preventing Medication Errors* report,[1] the average hospitalized patient is subject to at least one medication error per day. This confirms previous research findings that medication errors represent the most common patient safety error.[2] More than 40 percent of medication errors are believed to result from inadequate reconciliation in handoffs during admission, transfer, and discharge of patients.[3] Of these errors, about 20 percent are believed to result in harm.[3, 4] Many of these errors would be averted if medication reconciliation processes were in place.

Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient record or medication orders. According to the Joint Commission[5] (p. 1),

> Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner, or level of care. This process comprises five steps: (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare the medications on the two lists; (4) make clinical decisions based on the comparison; and (5) communicate the new list to appropriate caregivers and to the patient.

Recognizing vulnerabilities for medication errors, numerous efforts are underway to encourage all health care providers and organizations to perform a medication reconciliation process at various patient care transitions. The intent is to avoid errors of omission, duplication, incorrect doses or timing, and adverse drug-drug or drug-disease interactions. The Joint Commission added medication reconciliation across the care continuum as a National Patient Safety Goal in 2005.[6] The Institute for Healthcare Improvement (IHI) has medication reconciliation as part of its 100,000 Lives Campaign. This chapter reviews the evidence for medication reconciliation and makes recommendations for nursing practice.

Medication Reconciliation

A comprehensive list of medications should include all prescription medications, herbals, vitamins, nutritional supplements, over-the-counter drugs, vaccines, diagnostic and contrast agents, radioactive medications, parenteral nutrition, blood derivatives, and intravenous solutions (hereafter referred to collectively as medications).[6] Over-the-counter drugs and dietary supplements are not currently considered by many clinicians to be medications, and thus are often not included in the medication record. As interactions can occur between prescribed medication, over-the-counter medications, or dietary supplements, all medications and

supplements should be part of a patient's medication history and included in the reconciliation process.

The steps in medication reconciliation are seemingly straightforward.[7] For a newly hospitalized patient, the steps include obtaining and verifying the patient's medication history, documenting the patient's medication history, writing orders for the hospital medication regimen, and creating a medication administration record. At discharge, the steps include determining the postdischarge medication regimen, developing discharge instructions for the patient for home medications, educating the patient, and transmitting the medication list to the followup physician. For patients in ambulatory settings, the main steps include documenting a complete list of the current medications and then updating the list whenever medications are added or changed.

However, the process of gathering, organizing, and communicating medication information across the continuum of care is not straightforward. First, there is tremendous variation in the process for gathering a patient's medication history. Second, there are at least three disciplines generally involved in the process—medicine, pharmacy, and nursing—with little agreement on each profession's role and responsibility for the reconciliation process. Third, there is often duplication of data gathering with both nurses and physicians taking medication histories, documenting them in different places in the chart, and rarely comparing and resolving any discrepancies between the two histories.

Additionally, patient acuity may influence the process of reconciliation. For example, a patient admitted for trauma may result in cursory data gathering about the medication history. Alternatively, a patient with numerous comorbidities may stimulate gathering a more complete list of current medications. In general, there is no standardization of the process of medication reconciliation, which results in tremendous variation in the historical information gathered, sources of information used, comprehensiveness of medication orders, and how information is communicated to various providers across the continuum of care.[7]

Safety Vulnerabilities Necessitate Medication Reconciliation

A multitude of factors—such as patients' lack of knowledge of their medications, physician and nurse workflows, and lack of integration of patient health records across the continuum of care—all contribute to a lack of a complete medication reconciliation, which in turn creates the potential for error.

Physician and nurse workflows have not traditionally included making a regular inventory of all medications a patient is taking (including prescription medications, over-the-counter drugs, herbals, and other complementary drugs such as vitamins) or verifying these lists with the patient. There has been no standard regarding what constitutes a comprehensive medication history or where medication information is kept in the paper or electronic health record. A patient's medication history may be found in the nursing admission database, the medication administration record, the physician history, and/or the pharmacy profile. When health care information is not integrated across settings, organizations, and among clinicians, it is not easy to validate or fill in the gaps from patient-reported information. Patients and family members may not be good historians of a medication record, and due to limited access to pharmacy records, only an incomplete recording of current medications may be obtained. Lau and colleagues[8] compared community pharmacy drug lists with hospitalized patients and found 25 percent of prescription drugs in use at home were not recorded on the hospital admission record.

In inpatient facilities, there are several situations where medication reconciliation is needed. Generally, patients are admitted to the hospital for a specific procedure, such as surgery, or on an urgent basis. When specialty health care providers are focused on the one component of care related to the specific encounter and do not take a holistic view to other aspects of the patients' health care needs and practices, it is easy to overlook medications that may cause an adverse event when combined with new medications or different dosages. Some of the patient's daily medications may be discontinued during a hospital stay, and when there is a lack of a formal reconciliation process on discharge, the need to restart medications upon discharge may be overlooked. One example would be discontinuing an anticoagulant during a hospital stay and neglecting to restart it upon discharge. Another example is when orders from one unit of care (such as intensive care) are discontinued and new orders are written when the patient moves to another unit of care (such as a general care unit). The policy necessitating the rewriting of orders makes it easy for the prescriber to overlook medications that may need to be reordered when no formal medication reconciliation process is in place. These factors combine to create an unsafe medication environment in acute care settings.

Research Evidence

Medication reconciliation studies have focused on the accuracy of the medication history during various transitions: ambulatory to acute care inpatient setting, skilled nursing facility to acute care inpatient setting, inpatient acute care setting to skilled nursing facility, inpatient acute care setting to discharge, inpatient floor to the intensive care unit (ICU), and ICU to discharge. Little research has focused on outcomes related to the prevalence of errors resulting from a lack of or an incomplete patient medication list.

Reconciliation in the Ambulatory Setting

Medication discrepancies in outpatient records were addressed in three studies. Ernst and colleagues[9] found discrepancies in 26.3 percent of charts of patients requesting prescription renewal. Of the charts with discrepancies, 59 percent omitted medications from the electronic medical record medication list. Miller and colleagues,[10] upon examining patient records of an ambulatory family practice, found that while 76 percent of patients had prescribed medications, 87 percent of charts had incomplete or no documentation of those medications. Three years following institution of a reconciliation process, which included a form on the chart listing all medications ordered for a patient, 82 percent of charts had complete prescription medication documentation. Similar findings were noted in a study of cardiology and internal medicine practices[11] and in a group of patients receiving dialysis.[12] Whether patients used the prescribed medications as originally prescribed or if their medications were changed by another physician was not reported. The reconciliation process requires verification with the patient regarding their use of the prescribed medications.

Reconciliation in Acute Inpatient Settings

Nine studies examined medication reconciliation in acute inpatient settings. Bayley and colleagues[7] identified that the common discrepancies in medication history from ambulatory to inpatient care were omitted medication orders, altered doses, or incomplete allergy histories.

Vira and colleagues[13] found a 38 percent discrepancy rate in their study of newly hospitalized patients. Gleason and colleagues[4] found more than half of the patients they studied had discrepancies in medication histories or admission medication orders.

Among the most common medication discrepancies between what is in the patient's history and what is ordered upon admission to the hospital was omission of a medication that patients reported taking prior to admission.[13] These discrepancies result from incomplete documentation of the patient's medication history and a lack of time to search for the information. Nursing staff have been noted spending in excess of an hour per patient admission or transfer trying to accurately identify medications a patient has been receiving,[3] including getting a list of preadmission medications from the patient and filling in gaps through the pharmacy and primary care physician.

Chevalier and colleagues[14] examined nurses' perceptions of medication reconciliation practices. More than 60 percent of nurses reported that determining the medications a patient was taking at home, clarifying medication orders at transfer, and ensuring accurate discharge medication orders was a time-consuming process. Time requirements and staffing resources were identified as a barrier to completing the process. Although implementing a medication reconciliation process will likely consume more health care provider time initially, the process may become more efficient once in place. A standardized reconciliation process has been reported to reduce work and the rework associated with the management of medication orders. Rozich and colleagues[15] reported that implementing a systematic approach to reconciling medications was found to decrease nursing time at transfer from the coronary care unit by 20 minutes per patient, and pharmacy time at hospital discharge by more than 40 minutes. Stover and Somers[16] reported that case managers performing the reconciliation process spent 5 to 10 minutes per day completing the process with new admissions, and each case manager typically reviewed eight new admissions each day.

One challenge to having an accurate patient medication history is the lack of a standardized location in the patient chart where the information may be found. A nurse may need to check the nursing admission database, the medication administration record, the physician patient history and progress notes, and the pharmacy database. Rozich and Resar[15] found that prior to initiation of a reconciliation process, details of the current medications in the inpatient chart were nonexistent or incorrect 85 percent of the time. Similar findings were found in family practice.[17] Nickerson and colleagues[18] found that of the medication history discrepancies they identified, 83 percent had the potential for harm. Others reported that when a medication reconciliation process was instituted, it reduced discrepancies from 70 percent to 15 percent.[3, 19] Vira and colleagues[13] reported that a medication reconciliation process prevented the potential for harm in 75 percent of cases.

Transfers From Inpatient Floor to ICU and Discharge From the ICU

Two studies by Pronovost and colleagues[20, 21] examined medication reconciliation in the ICU. Examining discrepancies between medications a patient was receiving in the ICU and the discharge orders from the surgical ICU resulted in 94 percent of discharge orders needing to be changed. Following implementation of a paper-based medication tracking system, the error rate of discharge medication orders was reduced to zero.[20] Following implementation of a reconciliation process using an electronic form at discharge from a surgical ICU, only 21 percent of orders required changing.

Admissions Between Skilled Nursing Facilities and Hospitals

A study of medication changes during transfer from nursing home to hospital and hospital to nursing home found inaccurate and incomplete reconciliation of medication regimens.[22] The mean number of medication orders altered per patient on admission to the hospital from a nursing home was 3.1, and from the hospital to the nursing home was 1.4. Sixty-five percent of the medication changes were discontinuations, 19 percent were dose changes, and 10 percent were substitutions for medications with the same indications. The investigators estimated that 20 percent of the medication changes led to an adverse drug event.

Inpatient to Discharge

Four studies looked at the process of discharge from the hospital to home. Bayley and colleagues,[7] in a qualitative study including nurse, physician, and pharmacist informants, reported that reconciliation failures at discharge stemmed from not resuming medications held during the hospital stay, and insufficient patient education at discharge. These failures resulted from incomplete gathering of the home medication regimen at admission and rushed discharges.

Moore and colleagues[23] found that 42 percent of the patients they studied had one or more errors in the discharge medication orders. Most often medications that should have been restarted were not. The medications commonly involved were cardiovascular (36.4 percent), gastrointestinal (27.3 percent), and pulmonary (13.6 percent). Sullivan and colleagues[24] found that 59 percent of discrepancies not corrected at discharge could have resulted in patient harm.

The use of a multipart paper prescription form for discharge medications was found to improve accuracy. The form integrates admission medications, in-hospital changes, and discharge medications. One part of the form is used as the prescription, the second is placed in the chart, the third is given to the patient with instructions for home management, and the fourth is sent to the primary care physician. Accuracy of medication prescriptions with the use of a multipart form was 82 percent, as compared to 40 percent without the use of an integrated process.[25]

Medication History Accuracy With Electronic Health Records

The electronic health record is generally believed to contain more accurate information and facilitate easier retrieval of information than paper-based medical records. Studies of medication lists in electronic health records have found the data are only as accurate as what has been entered. Wagner and Hogan[26] found discrepancies between the number of medications patients reported taking (5.67) and that listed in the electronic record (4.69). Data entry errors accounted for 28 percent of the discrepancies, while 26 percent were related to failure of the clinician to enter medication changes into the electronic record.

DeCarolis and colleagues[27] found that a computerized medication profile was inaccurate in 71 percent of the patients they studied. They demonstrated that implementation of a standardized medication reconciliation process reduced the number of patients with unintended discrepancies by 43 percent, thereby significantly decreasing the potential for medication errors. However, developing and implementing an electronic reconciliation process requires technical support. Kramer and colleagues[28] reported needing grant funding with hospital matching funds for development and programming. Reprogramming is required anytime there are system upgrades.

Use of a computer order entry system can reduce errors at the time of discharge by generating a list of medications used before and during the hospital admission. The medication list with instructions can be printed and used for education and review with the patient.[7] The utility of such a system depends upon the prior implementation of an admission medication reconciliation system. Some electronic discharge medication ordering systems allow for direct transfer of the orders to the community pharmacy and to the primary care physician, as well as keeping a permanent record on the electronic health record.

Clearly there is a need for patients, families, health care providers, and pharmacies to have a single electronic medication record with everyone working from the same record and all medications being reconciled against this record. Electronic systems make it easier to access medication histories, but they need to be kept up to date, and information must be correlated with patients' actual medication use.

Electronic prescribing network systems are being developed that can instantaneously provide a patient's medication history to pharmacists, consumers, and health care providers, while protecting patient privacy. Additionally, electronic prescribing allows for key fields such as drug name, dose, route, and frequency. Electronic prescribing also allows for decision support such as checking for allergies, double prescribing, and counteracting medications.

Evidence-Based Practice Implications

There are numerous areas for nurse involvement in the area of medication reconciliation. The following are generally consensus recommendations; they have not been subjected to systematic study for effectiveness unless noted.

Define the Steps in the Reconciliation Process

A first step in having an accurate listing of medications is defining the steps in obtaining a complete medication history. IHI suggests three steps to the process: (1) verify by collecting the list of medications, vitamins, nutritional supplements, over-the-counter drugs, and vaccines; (2) clarify that the medications and dosages are appropriate; and (3) reconcile and document any changes.[29] Each health care setting needs to develop standards for who is responsible and how the process will be completed. Whittington and Cohen reported that the accuracy of medication lists went from 45 percent to 95 percent with the implementation of reconciliation standards.[30]

Clearly Identify Responsibilities for the Process

Health care professionals need to clearly identify team roles and responsibilities for medication reconciliation. This needs to include evaluating existing processes; identifying a standard location in the patient chart where the medication history is kept; and determining who will put the medication history onto the agreed upon place in the chart, the time frame for resolving variances, and how to document medication changes.[31] These processes would eliminate the duplication of history taking and documentation that currently exists in many settings.

Consider Use of a Standardized Form

Many settings have found the use of a standardized medication form facilitates an accurate list that is accessible and visible.[32] Numerous examples are available on the IHI and Joint Commission Web sites.

Have an Explicit Time Frame for Completion

Many organizations have a process in place that calls for reviewing the patients' medication list at every primary care visit and within 24 hours of an inpatient admission. High-risk medications such as antihypertensives, antiseizures, and antibiotics may need to be reconciled sooner, for example, within 4 hours of admission.

Design Education Programs for Health Care Professionals

Medication reconciliation is a complex process. Education programs need to include the research about medication reconciliation and the steps being put into place to make a safer system for patients.

Design and Implement a Monitoring Process

Implement a reconciliation review of open and/or closed patient records. Assess adherence to the process and identify the potential for and any actual harm associated with unreconciled medications. Auditing tools such as the Improvement Tracker on the IHI Web site may assist health care settings in tracking their findings over time. Share results with providers so they are able to note progress over time.

Educate Patients and Family Members To Serve as Advocates

Patient education needs to be a major focus in medication reconciliation. Patients may not be accurate historians.[32] Recognition that information is being gathered from laypeople needs to be acknowledged and assistance needs to be offered to make the information as accurate as possible. A number of approaches have been identified to assist patients and families—for example, reconcile the medication list at every ambulatory visit.[9] Establish a process where patients bring their medications, including all over-the-counter preparations, to every health care encounter.[9, 33] Use of a universal patient medication form has shown promise in North Carolina; the form can be found at www.scha.org. In addition, educating patients about their medications allows them to keep better track of the medications they are taking.

Challenges

There are many challenges associated with implementation of effective medication reconciliation programs across the continuum of care. First, developing and implementing effective programs is very complex considering the various sites of care, the need for standardization in the process, and the importance of including the patient in the process.

Garnering executive leadership and support, obtaining physician and nurse understanding of the need for medication reconciliation, and actively participating in the design and implementation of programs may be difficult in many organizations where providers already feel burdened. There is a time commitment in both obtaining the medication history and completing the reconciliation process.

Research Implications

Research is needed on all aspects of the medication reconciliation process to provide an evidence base for impacting the prevention of adverse drug events. The Institute of Medicine report *Preventing Medication Errors*[1] found that currently most of the studies reported in the literature have small sample sizes and are single-site quality improvement projects. Multisite studies across the continuum of care are needed to assess the scope of the problem. Intervention studies using a variety of approaches, both paper based and electronic, are needed to determine the accuracy, feasibility, and simplicity of maintaining accurate lists of a patient's medication history.

The medication reconciliation process takes time, initially an additional 30 to 60 minutes per admission.[15] If an inpatient unit has multiple discharges and admissions, this can translate to the need for additional full-time staff. If nurses are responsible for the process, nursing hours per patient day may need to increase. Study of how medication reconciliation processes change the workflow and time associated with it are needed.

Busy clinicians are resistant to changing their workflow. Designing and testing streamlined processes that will work across the continuum of care, from the ambulatory to the inpatient setting, and having all stakeholders involved in the design will facilitate the process.

Studies of the sustainability of medication reconciliation processes need to be carried out. What does it look like at 6, 12, and 24 months? Are improvements being maintained?

Patients need to be full partners and self-advocates in the medication reconciliation process. Studies on systematic, multifaceted education programs regarding how to best maintain a current and complete listing of all medications need to be undertaken, as recommended in *Preventing Medication Errors*.[1] Studies should also address what techniques (e.g., the use of a medication card) work best to maintain an accurate list of medications.

Conclusion

There is some evidence to demonstrate how a medication reconciliation process is effective at preventing adverse drug events. Few studies have been published demonstrating how to do the process effectively or outlining the costs associated with design and implementation of programs. Nonetheless, an effective medication reconciliation process across care settings—where medications a patient is taking are compared to what is being ordered—is believed to reduce errors. Comparing what is being taken in one setting with what is being prescribed in another will avoid errors of omission, drug-drug interactions, drug-disease interactions, and other discrepancies. Medication reconciliation is a major component of safe patient care in any environment.

Search Strategy

Searches were carried out using the terms "medication reconciliation," "medication verification," "medication safety" "medication systems," and "medication errors." OVID databases for CINAHL®, MEDLINE®, and Google databases were searched. English-language health care literature from 1965 through March 2007 was reviewed. Additional searches were carried out on numerous patient safety Web sites, such as the Institute for Safe Medication Practices, the National Patient Safety Foundation, the Joint Commission, and the Institute for Healthcare Improvement. Reference lists from articles on medication reconciliation were also used to identify additional publications.

Articles that describe various components of the reconciliation process were found. Studies tended to be about one of the steps in the handoff process, such as admission from home to an acute care facility. No studies were identified that described the reconciliation process along the entire continuum of care from admission to an acute care facility, transfer from one level of care to another (such as critical care to general care), and discharge back to the community to the primary care practitioner or skilled care facility. The majority of articles were descriptive, and published studies were primarily quality improvement projects with small sample sizes limited to single clinical sites.

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Evidence Table. Medication Reconciliation

Study	Aim	Design & Sample	Site	Outcome
Bates 1999[34]	Assess strength of patient risk factors for adverse drug events (ADEs)	Nested case control 4,108 admissions	11 medical and surgical units in 2 tertiary care hospitals	Adverse drug events more frequent in sicker patients with longer hospital stay. Few risk factors emerged when controlling for level of care and pre-event length of stay. Prevention strategies should focus on improving medications systems.
Bayley 2005[7]	Enhance understanding of how patient handoffs are related to risk of adverse medical events before and after implementation of an information technology solution	Informant interviews	One primary care practice and four inpatient facilities (one academic medical center and three community hospitals)	Based on thematic analysis of qualitative data, identified information barriers due to work processes, role definitions, and individual discretion which can assist in designing effective technology solutions.
Bedell 2000[11]	Examine frequency of discrepancy between medications prescribed and those taken and associated causal factors. Compare medication containers and reported use of medication with medical records	Descriptive design 312 medical records in ambulatory setting	5 cardiology and 3 internal medicine practices	545 discrepancies among 239 patients (76%) 278 (51%) taking meds not recorded in chart 158 (29%) not taking recorded meds 109 (20%) taking different dosage than in chart. Predictors of discrepancy: age of pt, number of meds and multiple physicians
Boockvar 2004[22]	Identify medication changes during transfer between hospital and nursing home and ADEs caused by these changes	Descriptive study of residents of 4 nursing homes admitted to 2 academic hospitals. Nursing home and hospital records reviewed to identify changes in medication regimens between sites. Medications matched and compared regarding dosage, route, and frequency of administration	4 nursing homes	During 122 admissions, the mean numbers of medications altered during transfer from nursing home to hospital and hospital to nursing home were 3.1 and 1.4, respectively (p<.001). Changes in drug use were discontinuations, dose changes and class substitutions. Of 71 bidirectional transfers, ADEs attributable to medication changes occurred during 14 (20%). Overall risk of ADE per drug alteration (n=320) was 4.4% Most medication changes (8/14) implicated in causing ADEs occurred in the hospital, most ADEs (12/14) occurred in the nursing home after nursing home readmission.

Study	Aim	Design & Sample	Site	Outcome
Chevalier 2006[14]	Measure nurses' perceptions of patient safety, medication safety and current medication reconciliation practice at transition points in a patient's hospital stay	Descriptive survey of 111 nursing staff	Three general medicine units	Inconsistent medication reconciliation completion due to insufficient time and lack of communication among heath care professionals.
DeCarolis 2005[27]	Compare usual process of obtaining medication history to systematic reconciliation process	Comparison of pharmacist obtained medication history to inpatient medical record and computerized outpatient medical profile.	1 VA medical center	71% of patients had inaccurate computerized profile. Unintended order discrepancies in 58% of patients. Medication reconciliation system reduced unintended order discrepancy to 43%
Ernst 2001[9]	Assess accuracy of data in the EMR and document frequency and types of discrepancies that occurred.	Compared prescription renewal requests with electronic medical record data. 950 prescription-renewal requests for 134 medications over 3 month period.	Family Medicine Outpatient Clinic	Medication discrepancies were noted for 250 (26.3%) requests. 58.8% of the discrepancies were for prescriptions patient was taking but that were not ordered in the EMR medication list.
Gleason 2004[4]	Identify type, frequency, and severity of medication discrepancies in admission orders. Assess whether pharmacist obtained admission med histories decreased number of med errors.	Convenience sample compared 204 pharmacist conducted medication histories from patients to medication and allergy history documented in patient charts	725 bed tertiary care academic medical center. Direct admissions to 12 adult medical-surgical units	Interviews took on average 13.4 minutes. Discrepancies in medication histories and admission medication orders identified in more than 50% of patients. 22% could have been harmful if no intervention.
Kramer 2007[28]	Establish feasibility of electronic system for pharmacist and RN admission and discharge medication reconciliation and assess effect on patient safety, cost, satisfaction among providers and nurses	Pre-post electronic reconciliation process	283 patients on general medicine unit, 147 in preimplementation phase and 136 in postimplementation phase.	Preimplementation RNs identified more incomplete medication orders and dosage changes Post implementation greater numbers of allergies were identified, pharmacists completed significantly more dosage changes and patients reported higher level of agreement re discharge medication instructions. Lack of MD participation, 25% did not complete electronic discharge report

Study	Aim	Design & Sample	Site	Outcome
Lau 2000[8]	Compare medication history in hospital medical record with community pharmacy records prior to admission	Prospective observational study of 304 patients	General medical units of 2 acute care hospitals	61% of patients had discrepancy from community pharmacy records to inpatient medication history. 26% of prescription medications in use prior to admission were not listed in hospital medical records.
Manley 2003[12]	Determine rate of drug record discrepancies in a hemodialysis population	Prospective observational study of 63 patients	Outpatient hemodialysis center	60% of patients had drug record discrepancies.
Miller 1992[10]	Improve family practice office chart documentation of prescribed medications through use of duplicate prescription forms	Descriptive study of implementation of duplicate prescription forms Baseline chart review – 67 charts Duplicate prescription form: 1 week = 50 charts; 40 months = 60 charts	Ambulatory family practice	Baseline: 51 patients (76%) had prescribed medications with 87% of charts with incomplete or no documentation 1 week: 83% of charts had complete prescription medication documentation 40 Months: 82% of charts had complete prescription medication documentation
Moore 2003[23]	Determine prevalence of medical errors from inpatient to outpatient setting	Descriptive study of 86 patients inpatient and ambulatory medical records	950 bed urban teaching hospital and affiliated primary care practice	42% of patients had at least 1 medication continuity error
Nickerson 2005[18]	Determine clinical impact on drug therapy problems (DTP) of pharmacist review of discharge medications at discharge	Randomized clinical trial with 6 month followup of 253 patients	2 inpatient family practice units	Pharmacist intervened in 481DTP with average per patient of 3.49. Control group retrospective chart review found 56% had DTP
Paquette-Lamontagne 2002[25]	Improve accuracy of patient profile information in community pharmacies with use of discharge prescription forms	Quasi experimental intervention with 89 patients	Medical units in 3 teaching hospitals	82% of medication profiles in experimental group were complete as compared to 40% in control group
Pronovost 2003[20]	Reduce medication errors with a reconciliation process using paper form at discharge fro surgical ICU	Intervention using paper medication discharge form for ICU discharges	Surgical ICU	At baseline 94% of discharge orders were changed due to discrepancies. At Week 24 discharge error rate was 0
Pronovost 2004[21]	Reduce medication errors with a reconciliation process using an electronic form at discharge from surgical ICU	Intervention using electronic medication discharge form for ICU discharges	1,455 patients in surgical ICU over 1 year period	21% of patients required medication order change. 6% due to allergy discrepancy

Study	Aim	Design & Sample	Site	Outcome
Rozich 2001[15] Rozich 2004[3]	Reduce medication discrepancies at health care transition points through the implementation of a medication reconciliation process on admission, during transfer and at discharge from the hospital	Descriptive study of implementation of medication reconciliation process	Acute care inpatient units Baseline 20 charts per week for 6 weeks the ongoing chart review	Baseline medication discrepancy rate 213 per 100 admissions. 7 month post introduction of reconciliation process rate was 42 per 100 admissions.
Vira 2006[13]	Describe potential impact of medication reconciliation process to identify and rectify errors at time of hospital admission and discharge	60 randomly selected patients. Compared admission medication orders with patient medication vials and interviews with patients, caregivers and outpatient health care providers. At discharge, pre-admission and in patient medications compared with discharge orders and written instructions.	Inpatient community hospital	60% of patients had minimum of 1 unintended variance with 18% having minimum of 1 clinically important variance. None were detected outside of reconciliation process
Wagner 1996[26]	Assess correspondence between medications the patient taking and documentation in EMR	Descriptive comparison of patient report and chart review study of 312 medical records	Outpatient geriatric center	Mean number of medications per patient: 5.67 Mean number of medications listed in EMR: 4.69 Missing medication recording attributed to patient misreport (36%) and MD/NP failure to note medication changes in EMR (26%)
Whittington 2004[30]	Reduce percentage of admission ADEs caused by errors in reconciliation through use of admission reconciliation form as hospital medication record and discharge prescription form	Descriptive study of implementation of medication reconciliation process Number of patients enrolled not reported	4 hospitals	Change from 45% to 95% accuracy of medication list on implementation of reconciliation process.
Winterstein 2006[35]	Evaluate medication safety infrastructure of critical-access hospitals in Florida	Qualitative assessments using self-administered survey and site visits of 7 hospitals.	7 critical access hospitals in Florida	Characteristics targeted for quality improvement included medication reconciliation. Admission medications infrequently reviewed, and readmissions were associated with higher prevalence of medication errors

Chapter 39. Personal Safety for Nurses

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Background

The safety of nurses from workplace-induced injuries and illnesses is important to nurses themselves as well as to the patients they serve. The presence of healthy and well-rested nurses is critical to providing vigilant monitoring, empathic patient care, and vigorous advocacy. Many workplace stressors that can produce diseases and injuries are present in nursing work environments. These stressors include factors related to the immediate work context, characteristics of the organization, and changes that are occurring external to the organization but throughout the health care industry.[1] Nurses experience significant physical and psychological demands during their day, as well as a work safety climate that can be adverse. Pressures within organizations to downsize, use nurses employed under alternative arrangements (pool and traveling staff), and the turnaround time for patient care (early discharge, higher patient loads) are examples of factors that are determined at an organizational level. The external context within which nurses practice includes lean managed care contracts, increasing use of complex technological innovations, an older nurse workforce, and increasing numbers of very sick elderly patients (aging population). Factors at each of these levels can produce threats to nurses' safety while on the job.

The hazards of nursing work can impair health both acutely and in the long term. These health outcomes include musculoskeletal injuries/disorders, other injuries, infections, changes in mental health, and in the longer term, cardiovascular, metabolic, and neoplastic diseases. In this chapter we will present major research findings that link common work stressors and hazards to selected health outcomes. These stressors include aspects of the way work is organized in nursing (e.g., shift work, long hours, and overtime) and psychological job demands, such as work pace. In addition, aspects of direct care work that influence nurse safety will be discussed, including the impact of physical job demands such as patient lifting and awkward postures, protective devices to prevent needlesticks, chemical occupational exposures, and potential for violence. Where possible, interventions that have demonstrated effectiveness to reduce the risk of illness and injury will be presented, as well as gaps in knowledge that can spur new lines of research inquiry.

Research Evidence

Shift Work and Long Work Hours

The relationship between work schedules and health and safety is complex and is influenced by characteristics of the work schedule (time of shift, direction and speed of rotation, pattern of days off, shift length, rest breaks), as well as characteristics of the job, the worker, and the work environment.[2] While the focus is on potential negative aspects, some workers experience benefits

from shift work and prefer it (e.g., incentive pay, reduced volume of activities and personnel when compared with day shift).

Researchers theorize that shift work exerts adverse effects by disturbing circadian rhythms, sleep, and family and social life.[2, 3] Disturbances in circadian rhythms may lead to reductions in the length and quality of sleep and may increase fatigue and sleepiness, as well as gastrointestinal, psychological, and cardiovascular symptoms. In addition, working at unusual times may make it difficult to interact with family and maintain other social contacts.[4] Similarly, long work hours may reduce the time available for sleep, leading to sleep deprivation or disturbed sleep and incomplete recovery from work.[5–7] This may adversely affect nervous, cardiovascular, metabolic, and immune functioning. Family and social contacts may also be reduced, which in turn may lead to physiological responses associated with stress. Long hours may also increase exposure times to workplace hazards such as chemicals; infectious agents; and physical, mental, and emotional demands. Long hours also may reduce time available for exercise or nutritious meals, and added job stress can increase smoking, alcohol consumption, and caffeine use.

Risks Associated With Shift Work

Sleep, sleepiness, performance, safety. Drake and coworkers[8] indicated that 32 percent of night workers (majority of shift hours between 9 p.m. and 8 a.m.) and 26 percent of rotating shift workers (shifts that change periodically from days to evenings or nights) experienced long-term insomnia and excessive sleepiness and were unable to adapt their sleep adequately on these shifts. Sleep loss makes people sleepier while awake, which may affect the shift worker's ability to perform activities safely and efficiently, both on and off the job. Increased sleepiness (or decreased alertness) in shift workers on the job has been demonstrated with subjective reports,[9] objective performance testing,[10] and EEG recordings showing brief, on-the-job sleep episodes.[11] Sleepiness is most apparent during the night shift, and poor daytime sleep appears to be a contributing factor.[12] A meta-analysis combining injury data from several studies indicated that injury risk increased by 18 percent during the afternoon/evening shift and 34 percent during the night shift compared to morning/day shift.[13] These results are consistent with worksite observations of increased subjective sleepiness and decreased reaction time during night shifts, and progressive decreases in total sleep time from early to late in the workweek.[14]

Social and familial disruptions. Because shift workers often work in the evening and sleep during the day, they frequently sacrifice participation in social and family activities. Furthermore, shift workers in continuously operating organizations such as hospitals are regularly required to work weekends and holidays, when much social and family interaction occurs.[15, 16] Consequently, too little time with family and friends is the most frequent and most negatively rated complaint among shift workers. The extent to which such disruptions occur depends both on the worker's schedule, type of family, gender, presence of children, and the degree of flexibility in the worker's social contacts and leisure pursuits.[15–17] For families, shift work often conflicts with school activities and the times when formal child care services are available, making arranging for the care of children more challenging,[17] affecting both the worker and the family's social adjustments.

Long-term effects and vulnerable groups. Although the specific contribution of shift work to other illnesses is not clear, several diseases have been associated with these work schedules. Gastrointestinal (GI) complaints are common in shift workers and could be due to changes in

circadian rhythms of GI function, sleep deprivation leading to stress response and changes in immune function, or the types of foods that are available during these shifts.[18, 19] Schernhammer and colleagues[20] reported an increased risk of colon cancer in nurses working 3 or more nights per month for 15 or more years.

Psychological complaints are frequently reported, including depression and other mood disturbances, personality changes, and relationship difficulties.[21] A review of 17 studies suggests that shift work increases risk for cardiovascular disease by 40 percent compared with day workers.[22] Possible mechanisms include decreased glucose tolerance, insulin resistance, elevated cortisol levels, and increased sympathetic activity. A systematic review of reproductive outcome studies concluded that shift work was associated with a modest increase in spontaneous abortion, preterm birth, and reduced fertility in women.[23] The effect on reproduction in men was not analyzed due to an inadequate number of studies. A meta-analysis of 13 studies examining night work and breast cancer reported that night work was associated with a moderately elevated risk among women.[24] The authors hypothesized that exposure to light at night reduces melatonin levels, increasing risks for cancer.

Shift work also may exacerbate preexisting chronic diseases, making it difficult to control symptoms and disease progression. Shift work interferes with treatment regimens that involve regular sleep times, avoiding sleep deprivation, controlling amounts and times of meals and exercise, or careful timing of medications that have circadian variations in effectiveness. Sood[25] suggests several conditions that may be exacerbated by shift work: unstable angina or history of myocardial infarction, hypertension, insulin-dependent diabetes, asthma, psychiatric illnesses, substance abuse, GI diseases, sleep disorders, and epilepsy requiring medication. Costa[26] adds to this list chronic renal impairment, thyroid and suprarenal pathologies, malignant tumors, and pregnancy. Aging is also associated with less tolerance of shift work, which may be due to age-related changes in sleep that may make it more difficult for older people to initiate and maintain sleep at different times of the day.[27] These sleep changes may begin as early as the 30s and 40s, so some workers who initially adapted well to shift work during their younger years may show more symptoms as they grow older.

Risks Associated With Long Work Hours

The number of studies examining long work hours is less extensive, but a growing number of findings suggest possible adverse effects. A meta-analysis by Sparks and colleagues[5] reports that overtime was associated with small but significant increases in adverse physical and psychological outcomes. A review by Spurgeon and colleagues[6] concluded that the adverse overtime effects were associated with greater than 50 hours of work per week, but little data are available about schedules with fewer than 50 hours. An integrative review by Caruso and colleagues[28] reported that overtime was associated with poorer perceived general health, increased injury rates, more illnesses, or increased mortality in 16 of 22 recently published studies. Dembe and colleagues,[29] examining data from the National Longitudinal Survey of Youth, found a dose-response relationship, such that as the number of work hours increased, injury rates increased correspondingly. Trinkoff and colleagues[30, 31] found that long work hours were related to the incidence of musculoskeletal injuries and needlesticks in nurses. Overall, these studies indicate that caution is needed in implementing schedules with extended work hours. Determining the number of work hours critically associated with risk for a specific job would require examining how extended hours interact with other factors contributing to fatigue,

such as work load, competing responsibilities, and opportunities for rest and recovery. Additional information on the effect of long work hours can be found elsewhere in this book.

Coping Strategies

Efforts to promote adaptation to (or ease the difficulties of coping with) shift work and long work hours include strategies for employers and strategies for workers. Most suggestions to date were written for shift work, but they may also be relevant for long work hours. A sampling of strategies suggested in the literature for shift work include designing new work schedules and rest breaks during work, altering circadian rhythms with bright light or blue light, optimally timing physical activity or other work demands, improving physical conditioning, using caffeine, planning dietary regimens, stress reduction, support groups, and family counseling.[32–39] Caldwell and Caldwell[36] suggest using behavioral and administrative strategies fully before considering pharmacologic aids since these stimulants and sedatives can be addictive and questions remain about the safety and effectiveness of long-term use. Taking naps during work is another intervention that has been associated with improvements in alertness[40, 41] and is an accepted practice in some Asian countries. More research is needed to determine the optimum length and timing of the nap and a practical environment at work to take a nap. Empirical evaluations and applications of the other techniques have begun and will be useful for some workers, but more research is needed to develop strategies that can be easily applied by workers in a wide range of demanding work schedule situations. Another type of strategy are work hour limits such as the recent Institute of Medicine recommendation[42] (p. 13) that work hours for nurses be limited to 60 hours per 7-day period and 12 hours per day.

Nurse Injury and Disease Outcomes

Musculoskeletal Injuries

Few industries in the United States have undergone more sweeping changes over the past decade than the health care industry. Changes in health care, including restructuring and redesign, have led to increasingly heavy demands on nurses and other health care workers. Extended schedules and increased work pace, along with increased physical and psychological demands, have been related to musculoskeletal injuries and disorders (MSD).[43] These demands have been found in laboratory and worker studies to increase the risk of musculoskeletal pain/disorders.[44–47]

Definitions for MSD vary, though most include pain in the affected body region (e.g., back or neck) for a specified duration or frequency,[48] along with other related symptoms such numbness and tingling.[49] Measurement of MSD also varies from study to study, with many studies relying on self-report and others requiring seeking care or obtaining testing or clarification/diagnosis by a clinician.[48] Researchers are careful to rule out nonwork-related MSD from their studies.

Health care workers are at extremely high risk of MSD, especially for back injuries. Health care workers are also overrepresented for upper extremity MSDs among workers' compensation (WC) claims.[50] In 2001, U.S. registered nurses (RNs) had 108,000 work-related MSDs involving lost work time, a rate similar to construction workers.[51] In 2003, the incidence rate for nonfatal

occupational injuries, many of which were MSDs, was 7.9 per 100 full time equivalents (FTEs) for hospital workers.[52]

Studies have shown that MSDs lead to sick days, disability, and turnover. In a survey of more than 43,000 nursing personnel in five countries, 17–39 percent planned to leave their job in the next year due to physical and psychological demands.[53] In previous research, the percentage of nurses reporting job change due to MSD ranged from 6 percent to 11 percent, depending on the body part injured (neck, shoulder, or back).[54] Staffing has also been related to MSD, with lower staffing complements related to increased injuries. Between 1990 and 1994, the Minnesota Nurses Association collected injury and illness data from 12 hospitals in the Minneapolis-St. Paul area. The researchers found that when RN positions in the hospitals decreased by 9.2 percent, the number of work-related injuries or illnesses among RNs increased by 65.2 percent. Lower staffing ratios for nurses and higher patient loads have both been shown to result in increased exposure to hazardous conditions and insufficient recovery time.[55] In a review of evidence, the Institute of Medicine indicated that there was strong relationship between nursing home staffing and back injuries.[56] In a recent study of the relationship of health care worker injuries to staffing in nursing homes, researchers indicated that staffing levels were significantly related to health care worker injury rates in nursing homes across three States.[57]

Physical/postural risk factors and MSD. Health care work is highly physically/posturally demanding,[54, 58, 59] and tasks requiring heavy lifting, bending and twisting, and other manual handling have been implicated in health care worker back injuries.[60] In one study, nurses were found to be at particular risk of back injury during patient transfers, which require sudden movements in nonneutral postures.[61, 62] Patient transfers also require flexion and rotation, increasing the injury risk due to a combination of compression, rotation, and shear forces.[63–65] Highly demanding physical work was associated with 9–12 times the odds of having a neck, shoulder, or back MSD among nurses.[54] Hoogendoorn and colleagues,[66] using video observations and questionnaires in a 3-year study of health care workers, found that extreme flexion and frequent heavy lifting had a strong impact on worker low-back pain. Other analyses found that physical/postural risk factors were related to impaired sleep, pain medication use, and absenteeism.[59]

Fewer studies have examined physical/postural risk factors in relation to health care worker neck and shoulder MSDs. Risk factors related to neck and shoulder pain include body placement in awkward postures that need to be maintained for long periods of time. Using direct observation, Kant and colleagues[58] found that surgeons had extensive static postures, along with operating room nurses who were required to maintain tension on instruments, leading to substantial musculoskeletal stress of the head, neck, and back. Lifting and stooping were significantly associated with health care worker arm and neck complaints,[67] whereas shoulder complaints were associated with pushing and pulling motions.[68, 69] Heavy lifting and actions with arms above shoulder height were associated with shoulder pain or injury in health care workers and in other occupational groups.[70–72] The evidence indicates that preventive interventions for MSD need to address physical/postural risk factors.

Work schedules and MSD. The work schedule can affect the sleep–wake cycle, and working extended hours, such as 12+ hour shifts, can lead to MSD due to extended exposure to physical/postural risk factors and insufficient recovery time.[73, 74] As physical/postural demands on the job increased for nurses, the likelihood of inadequate sleep also significantly increased.[59] Workers on schedules requiring frequent shift rotation and long hours may also be at higher risk for MSD.[75–78] In a survey of 1,428 RNs, more than one-third had extended work schedules, and

such schedules were associated with an increased likelihood of MSD.[79] A later study found that long work hours were related to incident musculoskeletal injuries in nurses.[30]

In workers with employment-related myalgia, symptoms increased with each successive workday, and remitted only by the second day off.[80] These workers had shorter periods of muscle rest, suggesting that continuous muscle tension was associated with musculoskeletal symptoms. In a British study of doctors-in-training, the fewer hours they slept and the more hours they worked, the more somatic symptoms, including MSD, they reported.[81]

Schedule components significantly related to MSD include long work hours, mandatory overtime, working while sick or on days off, and having fewer than 10 hours between shifts.[30] The new Institute of Medicine report, *Keeping Patients Safe*: *Transforming the Work Environment of Nurses*,[42] incorporated Wave 1 findings on nurse scheduling. More than one-third of staff nurses typically worked 12 or more hours per day. Among those working 12+ hours, 37 percent rotated shifts. On-call requirements were also very common (41 percent of the sample). Despite the long hours, few nurses took breaks; two-thirds typically took one or no breaks during their shift.

Mitigating MSD risks. Although two decades of research have demonstrated the work-relatedness of MSD, use of single-approach intervention methods to reduce MSD exposures (e.g., engineering controls, administrative changes, or worker training only) has shown inconsistent outcomes.[82] This is likely due to the combination of factors related to MSD and the need for broad organizational involvement to mitigate MSD problems.[83] Despite these concerns, important evidence-based successes have been demonstrated in reducing MSD, especially during patient lifting and transfer.[84, 85] Interventions incorporating participatory ergonomics have been found to improve upon previous approaches by allowing for extensive worker input into the design and adoption of preventive practices.[86, 87] In a participatory ergonomics approach, employees participate in the identification of ergonomic risk factors, brainstorm alternatives and solutions, handle implementation of controls, and assess control effectiveness along with symptom identification, ultimately becoming champions for ergonomics change.[86] Participatory ergonomics also has the potential for changing the culture of health care organizations, as employees begin to use ergonomic principles to improve jobs and the workplace. Because participatory interventions incorporate both management commitments to reducing injuries, along with workers who are involved in developing solutions, positive and effective workplace changes can occur.[88]

Interventions for MSD. Three common interventions used to prevent work-related musculoskeletal injuries associated with patient handling are (1) classes in body mechanics, (2) training in safe lifting techniques, and (3) back belts. Despite their wide spread use, these strategies are based on tradition rather than scientific evidence; there is in fact strong evidence these strategies are not effective.[85, 89] Recently there has been a major paradigm shift away from these approaches toward the following evidence-based practices: (1) patient handling equipment/devices, (2) no-lift policies, (3) training on proper use of patient handling equipment/devices, and (4) patient lift teams. Table 1 describes interventions and identifies challenges that have been associated with their implementation.

Table 1. Evidence-Based Interventions for Safe Patient Handling

Proposed Intervention	Description	Challenges to Implementation
Patient handling equipment and devices	Patient handling technologies include height-adjustable electric beds,[90–92] mobile mechanical patient lifts,[93–97] ceiling-mounted lifts,[98–100] friction-reducing devices/lateral transfer aids,[101–104] bed repositioning,[105–107] etc. More complete listings of patient handling equipment and devices are available.[108–110]	▪ Cost ▪ Assuring competency of all staff in its use ▪ Integrating multiple technologies ▪ Selecting the best technology to address the specific risks identified ▪ Technology often takes more time than performing the task manually
No-lift policies	Regardless of the title, these policies focus on minimizing manual patient handling.[84,111,112] No-lift policies have been developed through legislation or facility-based policies. National policies have been enacted in Europe and Canada. In the United States, State legislation related to manual patient lifting was recently passed in Texas and Washington. Facility-based policies are known as "no-lift policy," "zero lift," "minimal lift," "lift-free," or "safe patient handling and movement."	▪ Necessary equipment needs to be in place before the policy is implemented. ▪ Nonpunitive approach is necessary for success.
Training on proper use of equipment/ devices	While traditional classes in body mechanics and lifting techniques are not effective, evidence supports the need for ongoing training in use of equipment and devices.[84, 109, 113–115]	▪ Training all staff, across shifts ▪ Training on units with high staff turnover ▪ Need to reinforce training over time ▪ Need for "just-in-time" training when equipment is needed sporadically, such as bariatric device.
Patient lift teams	A lifting team is defined as "two physically fit people, competent in lifting techniques, working together to accomplish high-risk patient transfers."[116] This term is sometimes also referred to as "patient transfer team", "lift team" or a combination of these phrases.[116–125]	▪ Logistics of providing lift team services 24 hours a day/ seven days a week ▪ Cost ▪ Managing workload and logistics of "unscheduled lifts" that emerge during typical workday ▪ Addresses only patient lifts, ignoring other high-risk tasks such as repositioning, toileting, or bathing

Promising new interventions that are still being tested include use of unit-based peer leaders, clinical tools (algorithms and patient assessment protocols), and after-action reviews. Table 2 describes each intervention and identifies challenges associated with implementation.

Table 2. Interventions for Safe Patient Handling With Emerging Evidence

Proposed Intervention	Description	Challenges to Implementation
Peer leader education	Traditional education approaches (didactic classes in risk, body mechanics, and training in lifting techniques) have not been effective in sustaining changes over time. Newer approaches to education and training have emerged, demonstrating early success with a need to study these trends over time. One new model that shows promise is use of local peer leaders. A peer leader is a nurse designated on each unit (or shift) who receives special training to work on site with colleagues to make practice changes to improve safety. Their roles include ongoing hazard evaluation of the work environment, assure competency in use of patient handling equipment and devices, help sustain the unit-based ergonomic program over time.[109, 126] In the United States, peer safety leaders have been called Back Injury Resource Nurses (BIRNs),[109] and Ergo Rangers,[84] while in the Netherlands they are called Ergo Coaches.	▪ Selecting the "right" peer leader who is effective in coaching peers to change behaviors ▪ Incentives for peer leaders ▪ Support and timely response by management to issues raised by peer leader
Clinical tools (algorithms and patient assessment tools)	Unfortunately, nurses have become accustomed to using whatever limited lifting aids are available, if they are available, rather than carefully matching equipment to specific patient characteristics. Cognitive aids can assist clinicians to apply research to practice, thereby reducing unnecessary variation in practice. Use of patient assessment protocols and algorithms can provide a standardized way to assess patients and make appropriate decisions about how to safely perform high-risk tasks.[108, 109, 112, 127–129]	▪ Training all staff, across shifts ▪ Training on units with high staff turnover ▪ Need to reinforce training over time ▪ Integrating these clinical tools into routine processes, e.g., patient admission ▪ Timely and effective communication of the assessment and plan to all staff
After-action reviews (AAR)	After-action review is a way for nurses to learn not only from their own mistakes and near misses, but also from the mishaps experienced by their coworkers. It is not unusual for many nurses on a unit to identify a hazard and work around it, only to have another nurse fall prey to this risk in the environment. Immediately after an accident or near miss, staff will meet informally to evaluate what happened and how to prevent its reoccurrence on the unit. In AARs, staff should feel free to share knowledge without fear of embarrassment or recrimination. AAR is compatible with established mechanisms for dealing with errors and near misses such as incident reporting and root-cause analysis.[130, 131]	▪ Time constraints ▪ Support and timely response by management to issues raised by peer leader

Given the complexity of this high-risk, high-volume, high-cost problem, multifaceted programs are more likely to be effective than any single intervention, indicating the need to build a culture/climate of safety into the organization and employ more than one evidence-based approach. A culture of safety in terms of worker injury prevention is defined somewhat differently from patient safety culture, though there is some overlap between the terms. Safety culture is considered to be the product of multiple goal-directed actions to improve safety in an organization.[132] Nonetheless, empirical data supporting the impact of culture alone on reducing worker injuries are limited.

Needlesticks

Health care workers continue to be exposed to the serious and sometimes life-threatening risk of blood-borne infections in a wide variety of occupations and health care settings. An estimated 600,000 to 800,000 needlestick injuries occur annually,[133, 134] about half of which go unreported.[133, 135] It is estimated that each year more than 1,000 health care workers will contract a serious infection, such as hepatitis B or C virus or HIV, from a needlestick injury. An estimated 50 to 247 health care workers are infected with hepatitis C virus (HCV) each year from work-related needlesticks.[136] At an average hospital, workers incur approximately 30 needlestick injuries per 100 beds per year.[133] Nursing staff incur most needlesticks—54 percent of reported needlestick and sharp object injuries involve nurses.[137]

After a needlestick injury, the risk of developing occupationally acquired hepatitis B virus (HBV) infection for the nonimmune health care worker ranges from 6 percent to 30 percent, depending on the hepatitis B antigen status of the source patient. The risk of transmission from a positive source for hepatitis C is between 0.4 percent and 1.8 percent, and the average risk of transmission of HIV is 0.3 percent.[138] Risk of transmission increases if one is injured by a device visibly contaminated with blood, if the device is used to puncture the vascular system, or if the stick causes a deep injury. Health care workers, laundry workers, and housekeeping workers are often engaged in duties that expose them to high-risk needlestick injuries.

The number of occupationally acquired HIV infections is underestimated by the national case surveillance system. This is related to the Centers for Disease Control and Prevention's (CDC's) strict definition of a documented HIV seroconversion temporally associated with an occupational HIV exposure and the fact that these are voluntary reports. CDC U.S. surveillance data over 20 years include 57 health care workers with documented occupationally acquired HIV infection.[139] A total of 88 percent of these infections resulted from percutaneous injuries. Of these infections, 41 percent occurred after the procedure, 35 percent during a procedure, and 20 percent during disposal.[139] Recent State-based surveillance programs in California and Massachusetts will provide more complete estimates of the incidents, devices involved, and circumstances surrounding sharp exposures.[140]

Despite the promulgation of the original bloodborne pathogen (BBP) standard in 1991 by the Occupational Safety and Health Administration (OSHA), percutaneous injuries continue to occur in unacceptably high numbers in health care workers. The requirement under the BBP standard that HBV vaccine be made available free of charge to health care workers has greatly reduced the consequences of exposure to this pathogen. Advances in the treatment of HIV infection with prophylaxis has improved the prognosis for those health care workers infected with HIV-contaminated blood. Tragically, there is no vaccine or treatment for HCV, so nurses and other health care workers exposed to HCV-contaminated blood suffer from the potential of contracting a life-threatening illness. As such, it is imperative that all health care workers, not only those working in the acute care setting or those who traditionally handle needles on a regular basis, receive every available protection from occupational exposure to blood and body fluids.

The passage of the Federal Needlestick Safety and Prevention Act in 2000 has begun to afford health care workers better protection from this unnecessary and deadly hazard. Not only does the act amend the 1991 BBP standard to require that safer needles be made available, it also requires employers to solicit the input of front-line health care workers when making safe needle purchasing decisions.

Use of conventional needles in health care today has been compared with the use of unguarded machinery decades ago in the industrial workplace. Safer needle devices have integrated safety features designed into the product to prevent needlestick injuries. The term "safer needle device" is broad and includes many different devices, from those with a protective shield over the needle to those that are completely needle-free. Safer devices are categorized from passive to active, with passive devices offering the greatest protection because the safety feature is automatically triggered after use, without the need for health care workers to take any additional steps. An example of a passive device is a spring-loaded retractable syringe or self-blunting blood collection device. An example of an active safety mechanism is a sheathing needle that requires the worker to manually engage the safety sheath, frequently using their second hand and potentially resulting in more injuries.

A comparison of 1993 and 2001 percutaneous injury rates for nurses documented a 51 percent reduction in needlestick injuries, supporting the use of new technology in reducing percutaneous injury risk.[141] More recently, results from a number of intervention studies have found the use of safer needles systems reduced injury.[142–146] A study of safety needles at a tertiary-care hospital in Manhattan found a statistically significant reduction in the mean annual incidence of percutaneous injuries from 34.08 to14.25 per 1,000 FTE pre- versus postintervention. The reductions were observed across occupations, activities, times of injury, and devices.[146] Other factors related to working conditions also may need to be addressed to prevent and reduce needlesticks.[31]

While there has been widespread conversion to safer phlebotomy needles and intravenous catheters, for other devices such as laboratory equipment and surgical instruments, relatively small numbers of safer devices are in use.

Chemical Occupational Exposures

There are thousands of chemicals and other toxic substances to which nurses are exposed in practice. Hazardous chemical exposures can occur in a variety of forms—including aerosols, gases, and skin contaminants—from medications used in practice. Exposures can occur on an acute basis, up to chronic long-term exposures, depending upon practice sites and compounds administered; primary exposure routes are pulmonary and dermal.[147] Substances commonly used in the health care setting can cause asthma or trigger asthma attacks, according to a recent report.[148] The report explores the scientific evidence linking 11 substances to asthma, including cleaners and disinfectants, sterilants, latex, pesticides, volatile organic compounds (including formaldehyde), and pharmaceuticals. An important criterion for the selection of the substances in the report was the presence of safer alternative products or processes. The evidence is derived from an array of peer-reviewed sources of scientific information, such as the National Academy of Science Institute of Medicine. In this section, we will discuss some of the hazardous substances currently in use and provide references to obtain evidence on others, as well as for identifying safer alternatives.

Volatile organic compounds. Volatile organic compounds (VOCs) are chemicals that readily evaporate at room temperature, thus allowing the chemicals to be easily inhaled. Formaldehyde and artificial fragrances are two such sources that have a ubiquitous presence in hospitals. A study of occupational exposure to artificial fragrances found that health care workers had the highest rate of allergic sensitivity.[149] The fragrances are typically contained in devices that either aerosolize the chemicals into rooms or evaporate the fragrances from a solid form,

thus producing VOCs. Although the Food and Drug Administration is responsible for regulating fragrances and other chemicals in personal care products, the majority of these compounds have not been tested for potential toxic human health effects.[150] Strong odors, fumes, and perfumes are also potent triggers of asthma.[151] Formaldehyde, a known carcinogen,[152] is used in pathology and lab settings and is contained in bedding, drapes, carpets, acoustic ceiling tiles, and fabricated furniture. Artificial fragrances are used to address unpleasant odors. Purchasing low- and no-VOC products, which are readily available (e.g., no-VOC paint), is a key to addressing this problem. Also ensuring adequate indoor air circulation, which can decrease the concentration of VOCs in the air, effectively decreases the "dose" of the chemicals being inhaled.

Sterilants. As an example, ethylene oxide (EtO) and glutaraldehyde are commonly used in medical settings for sterilization. Nurses and other medical staff are exposed while cleaning equipment and work surfaces. Although both of these chemicals are powerful and effective, they are associated with serious human health risks. Glutaraldehyde is associated with respiratory irritation including asthma, skin irritation and dermatitis, and eye irritation and conjunctivitis.[153] In fact, in a review of health effects of glutaraldehyde exposure, almost all case reports of occupational asthma were of endoscopy nurses.[154]

The National Institute for Environmental Health Sciences[152] produces a report on carcinogens that summarizes the latest scientific evidence on the cancer-causing properties of many chemicals, including EtO,[155] formaldehyde, and others that are present in health care. In this report, EtO is also listed as a known human carcinogen. EtO has been associated with increased incidence of certain types of cancer in workers with long-term exposures.[156] Additionally, EtO is an eye and skin irritant and also may damage the central nervous system, liver, and kidneys.[157]

Medications. Many medications and compounds in use in personal care products have known toxic effects. These have been comprehensively reviewed with a detailed summary of the evidence of environmental and personal hazards associated with these compounds by Daughton and Ternes.[149] Although many medications can be hazardous to workers, those most commonly identified as hazardous to health care workers include antineoplastics and anesthesia. Anesthetic gases have been identified as particularly problematic, as gases escape into the air and can be inhaled by workers. Methods of induction have been studied in terms of worker exposure,[158] with findings indicating that such exposures (measured by urinary metabolites) frequently exceed National Institute for Occupational Safety and Health (NIOSH) recommended limits.[159] Hasei and colleagues[160] found that intravenous induction posed a far lower risk of exposure to health care workers.

There are also data to support the deleterious effects of exposure to antineoplastic drugs, especially an increased risk of spontaneous abortions among health care workers.[161] Cytotoxicity, genotoxicity, terotogenicity, and carcinogenicity are associated with such exposures.[152] For the past few decades, awareness of the risk of antineoplastic agents has been available, including guidelines for handling them published by the Occupational Safety and Health Administration.[162] Nursing functions of particular risk, according to NIOSH, include medication administration, handling contaminated linens, exposure to human wastes, handling drug containers, cleaning drug preparation areas, being involved with special procedures, and disposal of containers and other wastes.[163] Other research indicates that antineoplastics and cytostatics have been found in locations beyond the confines of the designated handling areas such as air vents, desks, countertops, and floors.[164, 165]

Pesticides. Pesticide use, both inside and outside of hospitals and health facilities, is another cause for concern. Because of the special vulnerabilities of children and pregnant women to pesticide exposures, control of pesticide use in health care settings is particularly important. In a survey conducted by Health Care Without Harm, all hospitals surveyed reported some regular applications of pesticides inside the hospital building, outside on the grounds, or both.[166] This report, *Healthy Hospitals: Controlling Pests Without Harmful Pesticides,* offers guidance on reducing pesticides and implementing safer integrated pest management techniques. Integrated pest management is a comprehensive approach to pest management that employs nontoxic and least-toxic products and processes to control pests. Beyond Pesticides, a 25-year-old organization that has been working with Health Care Without Harm on pesticide issues in the United States, is currently orchestrating several hospital-based pilot programs in Maryland.[167] They are working with hospital environmental services to implement an integrated pest management approach that will work for hospitals. These collaborations will result in a set of best practices for a range of facility types—small community hospitals, inner-city university health centers, and others.

Latex exposure. Latex allergy due to exposure to natural proteins in rubber latex is also a serious problem in health care workers. Diepgen[168] estimated that the annual incidence rate among all workers is 0.5 to 1.9 cases per 1,000 full-time workers per year. Symptoms may start with contact dermatitis located in the glove area, and symptoms can become more severe, such as asthma or anaphylaxis. The course of latex allergy as described by Amr and Bollinger[169] involves progressive impairment of nurses from continued exposure to latex, leading to an inability to continue working as nurses. In fact, the hazard from aerosolizing of latex particles attached to powder in latex gloves or from latex balloons bursting is of great concern, as these exposures can lead to occupational asthma.[170] The American Nurses Association has issued a position statement to suggest actions to protect patients and nurses from latex allergy in all health care settings. These include use of low-allergen powder-free gloves and removal of latex-containing products from the worksite throughout the facility to reduce the exposure at that institution.[171] Hospital environments that have gone latex-free need to ensure that they are not allowing balloons into the facility. As balloons break they can contribute latex into the air that remains for up to 5 hours.[172]

Summary of Key Issues Regarding Harmful Exposures

An awareness of the repercussions of exposure to chemicals and toxins has prompted action to reduce such exposures in health care settings. Promotion of the availability of safer alternatives has gained momentum as a means to reduce exposures. There are resources available to assist advocates and decisionmakers. The *Green Guide for Health Care* is an extensive toolkit providing recommendations for design, construction, renovation, operations, and management of sustainable (causing reduced occupational and environmental effects) and healthier buildings.[173] Also, a clearinghouse of nontoxic alternatives to various medical and health care products is available from the Sustainable Hospitals Project.[174] *Green Link,* a recently inaugurated newsletter, promotes healthier buildings and sustainable hospitals for patients and health care workers.[175] In addition, the American Hospital Association and the Environmental Protection Agency have partnered, forming Hospitals for a Healthy Environment, promoting purchasing of environmentally preferable products.[176] The focus on reducing chemical exposures will be increasingly important over the next decade, especially as the benefits for patient and worker health continue to be recognized.

Mental Health Effects of Nursing Work

Working in nursing increases the risk of experiencing both minor and major psychiatric morbidity[177, 178] with job strain contributing to this outcome.[179–183] Minor psychiatric morbidities include feelings of tension, anger, anxiety, depressed mood, mental fatigue, and sleep disturbance;[184] these are classified variously as burnout, subthreshold depression, or adjustment disorders. Mental disorders such as major depression, anxiety disorders, and psychotic disorders are less common, but they can be induced or exacerbated by work stress.[184] A variety of exposure types are associated with psychiatric morbidity. These fall into two categories: the overall allostatic load demanded by the work, and the organization of the work, including schedule and such job demands as the emotional toll when caring for patients.

Allostatic load is a theoretical concept whereby excessive demands and a persistent sympathetic (adrenergic) load on the body produce changes in neuronal, immune, and cardiovascular system structure and function, thus having a detrimental impact on bodily processes.[183, 185–188] Changes in neuronal function are associated with anxiety and depression.[185] Several types of psychosocial risk factors can contribute to this overall allostatic burden. High physical demands, fast-paced work, adverse work schedules, role stressors, career insecurity, difficult interpersonal relationships, nonstimulating jobs, and lack of autonomy have been associated with symptoms of anxiety and depression, several psychoses, and with substance use disorders.[183, 189, 190] Some studies have even provided longitudinal evidence linking job demands, lack of autonomy, and monotony at work to affective and substance use disorders.[183, 191, 193] Mental disorders in the workplace—depression in particular—have important consequences for quality of life, the costs and utilization of health care, safety, and productivity.[190, 194]

Extended work schedules have been associated with a variety of mental health indicators in nursing and in other occupations where these schedules are common. Proctor and colleagues[195] found that both the number of overtime hours and the number of cumulative days worked by automotive workers were associated with changes in mood States such as depression and tension. Hospital interns reported subjective deterioration in mood after long shifts.[196] Japanese managers reported decreased quality of life (validated by comparison to a measure of psychiatric distress) when working more than 10 hours per day consistently.[197] French customs workers used antidepressants at a higher rate when assigned to shift schedules with rapid rotation.[198] Shift work has been associated with more mental stress[199] and higher levels of burnout[200] among health care workers. Depression and anxiety have also been shown to vary with the level of work pace, variety, control, social support, and conflicting demands made on workers.[191, 201] Thus with both unfavorable work conditions and extended work hours, the effect on mental health may be multiplied. Fatigue is thought to be a central nervous system stressor.[195]

Nursing is emotionally demanding, with both emotional labor and the need to witness and bear with suffering taking its toll. Emotional labor is necessary to display socially appropriate emotions that are congruent with the job requirements in face-to-face interactions with patients. The more frequent and intense the interpersonal interactions are with others (staff, visitors, patients), requiring the nurse to expend emotional effort, the more likely the nurse will experience symptoms of burnout, including depersonalization and emotional exhaustion.[202, 203] Witnessing the suffering of others occurs in a variety of nursing care settings, but is common when end-of-life suffering is unrelieved.[205] Intense feelings of emotional pain can result and, if unresolved, can affect both physical health and family life.[204, 205]

Interventions to reduce work-related mental changes have focused on either changing the organization of work to reduce the stressors, or changing the workers' ability to cope with stress by providing cognitive-behavioral interventions, relaxation techniques of various types, or multimodal strategies.[184, 206] Although several nationwide initiatives on the prevention of mental disorders have emphasized the importance of addressing work organization factors,[190, 194] only a small number of studies have evaluated this approach, and results have not shown an overall strong relationship.[185] In nursing, Mimura and Griffiths[206] conducted a systematic review of interventions for nurses to reduce their work stress. Two of the reviewed studies used organizational interventions (changing to individualized nursing care and primary nursing), and only one of the two was deemed "potentially effective." Seven studies of strategies to help nurses manage their stress were presented; music, relaxation, exercise, humor, role-playing assertiveness, social support education, and cognitive techniques were among the stress-reducing strategies studied. The authors stated that no recommendations on the most effective approach were possible due to the small number of studies. In a larger meta-analysis of both nurses and other workers,[183] a moderate effect for cognitive-behavioral interventions and multimodal interventions was found, along with a small but significant overall effect for relaxation techniques. Organizational interventions were not significant; however, the authors posit that combining individual-level skills (e.g., cognitive-behavioral) with organizational changes may be a fruitful area for future research.

Violence

From 1993 to1999, 1.7 million incidents of workplace violence occurred annually in the United States, with 12 percent of all victims reporting physical injuries.[207] Six percent of the workplace crimes resulted in injury that required medical treatment. Yet, only about half (46 percent) of all incidents were reported to the police. The health care sector leads all other industries, with 45 percent of all nonfatal assaults against workers resulting in lost workdays in the United States, according to the U.S. Bureau of Labor Statistics (BLS).[208] The BLS rate of nonfatal assaults to workers in "nursing and personal care facilities" was 31.1 per 10,000, vs. only 2.8 per 10,000 in the private sector as a whole.[208] In two Washington State psychiatric forensic facilities, 73 percent of staff surveyed had reported at least a minor injury related to an assault by a patient during the previous year; only 43 percent of those reporting moderate, severe, or disabling injuries related to such assaults had filed for WC. In these two facilities, the survey found an assault incidence rate of 415 per 100 employees per year, compared to hospital incident report rates of only 35 per 100.[219]

Environmental and organizational factors have been associated with patient and family assaults on health care workers, including understaffing (especially during times of increased activity such as meal times), poor workplace security, unrestricted movement by the public around the facility, and transporting patients. The presence of security personnel reduces the rate of assaults, while increased risk is associated with the perception that administrators consider assaults to be part of the job, receiving assault prevention training, a high patient/personnel ratio, working primarily with mental health patients, and working with patients who have long hospital stays.

Emergency department personnel also face a significant risk of injuries from assaults by patients or their families. Those carrying weapons in emergency departments create the opportunity for severe or fatal injuries. California and Washington State have enacted standards

requiring safeguards for emergency department workers. Although mental health and emergency departments have been the focus of attention and research on the subject, no department within a health care setting is immune from workplace violence. Consequently, violence prevention programs would be useful for all departments.

The first report to the Nation on workplace violence underscores the lack of systematic national data collection on workplace assaults, the paucity of data evaluating violence prevention strategies, and the methodological flaws in published intervention research to date.[210] As background to this report, Runyan and colleagues[211] reviewed the violence prevention intervention literature and found five studies that evaluated violence prevention training interventions,[212–216] two that examined postincident psychological debriefing programs,[217, 218] and two that evaluated administrative controls to prevent violence.[220-221] Findings from the studies were mixed, with six reporting a positive impact and three reporting no or a negative impact. All were quasi-experimental and without a formal control group. Runyan and colleagues criticized the design of published violence prevention interventions to date because of their lack of systematic rigor in the evaluation. She calls for greater reliance on conceptual and theoretical models to guide research as well as stronger evaluation designs. She further suggests that studies must evaluate "process, impact and outcome measures."[211]

Since Runyan's review paper, Arnetz and Arnetz[219] reported on a randomized controlled trial of 47 health care workplaces examining a violence prevention intervention involving "continuous registration" of violent events for 1 year with "structured feedback" from supervisors. This study found that the intervention hospitals reported significantly more violence incidents than the control hospitals. The authors attributed this finding to increased awareness of the violence and improved supervisory support at the intervention facilities.

There is no Federal standard that requires workplace violence protections. California and Washington State both have legislation addressing workplace violence in health care settings. In 1996, OSHA published *Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers*.[222] The 1996 Federal guidelines provide a framework for addressing the problem of workplace violence and include the basic elements of any proactive health and safety program: management commitment and employee involvement, worksite analysis, hazard prevention and control, and training and education. The OSHA guidelines provide an outline for developing a violence prevention program, but since they are "performance based," the challenge of developing a specific process for implementing the guidelines in a manner that will yield results is left to the employer.

Between 2000 and 2004, Lipscomb and colleagues[223] conducted an intervention effectiveness study to describe a comprehensive process for implementing the OSHA Violence Prevention Guidelines and evaluate its impact in the mental health setting. Program impact was evaluated by a combination of quantitative and qualitative assessments. A comparison of pre- and postintervention survey data indicated an improvement in staff perception of the quality of the facility's violence prevention program as defined by the OSHA elements in both intervention and comparison facilities over the course of the project. Results of the comparison of the change in staff-reported physical assaults were equivocal.

Many psychiatric settings now require that all patient care providers receive annual training in the management of aggressive patients, but few studies have examined the effectiveness of such training. Those investigators that have done so have generally found improvement in nurses' knowledge, confidence, and safety after taking an aggressive behavior management program. However, implementation of comprehensive violence prevention programs that go

beyond staff training will improve safety of the health care workplace for all workers. These advanced programs include the use of currently available engineering and administrative controls such as security alarm systems, adequate staffing, and training.

Research Implications

Challenges in Measuring Nursing Working Conditions and Nurse Safety Outcomes

While there is increasing evidence linking nursing work environments to nurse health, much more effort has focused on understanding how work influences satisfaction and performance. Improving data and measures will allow better comparisons across studies and build evidence of which relationships are most important. Varied approaches are used to compile data about the nursing work environment. Measures of work characteristics have varied considerably and are most often related to the particular discipline and study objectives. In occupational health, the traditional assessments of exposure have expanded from obvious physical and chemical exposures to include psychosocial demands, physical demands, and leadership quality.[224] These measures are used in individual studies or translated to a job exposure matrix where estimated levels of exposure to an agent or stressor are assigned to an occupation or group of occupations.[225, 226] These approaches are more fully developed and utilized in Scandinavia and Europe, although the O*NET database describes job requirements, worker attributes, and the context of work (www.onetcenter.org).

A self-administered paper-and-pencil or electronic questionnaire is probably the most common approach to gathering information from nurses. The advantages over observation or interviews are obvious: they are generally less costly, can be administered over a broader population, are more uniform and standardized, and confidentiality and anonymity can be more efficiently assured. Yet, these same advantages can also be disadvantages: nurses have varying motivations to respond, leading to response bias; questionnaires are often developed by researchers based on particular study goals, limiting comparison across studies; and there is no opportunity to clarify questions or solicit rich detail. The level of the data may also be unclear. Some items may explicitly reflect the work group or organization, while others may reflect both. Clarity is needed about how many respondents is optimum to represent a particular level of analysis. Where multiple nurses' perceptions are solicited, all responses may be used to form an index or an average score.

Nurse Health Outcomes

Worker outcome data may be solicited from an individual through self-report interviews or questionnaires. These data are subject to the same limitations noted above, although nurse reports are more likely to yield detailed information about potential factors contributing to their health. Measuring nurse health outcomes also is challenging. No matter how data are collected, there can be some measurement error in assessing adverse health outcomes—and attributing them to the work environment. Many of these issues have been discussed in the sections on adverse health outcomes. For example, musculoskeletal injuries become chronic conditions and may not be attributed to the work. Likewise, mental health and substance abuse may be considered in isolation from the individual's work experience.

Another source that is rarely used is administrative data (e.g., incident reports, OSHA logs, WC data).[227] The Occupational Safety and Health Act (1970) requires employers to maintain records of serious workplace injuries and illnesses (29 USC section 657 c[2]). Unfortunately, these statistics may not reflect minor injuries requiring only first aid or injuries that can be episodic and remitting, such as back injuries, majors concerns for nurses. Data sources include logs maintained at the organizational level (OSHA Form 300), first reports of injury (FROI) documenting details of the injury (OSHA Form 301), and WC claims, when filed. The FROI may be used as the baseline data for entry into a WC system, although the two reports may be distinct. The FROIs serve as a more complete source of potentially claimable injuries to health care workers than WC data[228] as they represent all reported injuries, even those that do not lead to lost work time or a medical claim. Relying on WC claims data without using FROI data may introduce systematic selection biases because studies have shown that WC claims are more likely to be filed by workers who are unionized, working for a company too small to be self-insured, or who are more severely injured.[229] FROI data have been used to study injury in a population of home health workers[230] and to find that staffing was related to injuries in nursing home staff.[57] Yet FROI data are often unavailable to researchers or may contain injuries of limited severity.

Somewhat distinct from the OSHA reporting requirements, employers are required to comply with State WC regulations. WC is concerned with compensating injured or ill workers, while the OSHA Occupational Injury and Illness Recording and Reporting Requirements Act is designed to develop a database that can improve understanding of injury and illness, with the intent to prevent them. Thus, certain injuries and illnesses may be reportable under both systems, while others will be reportable under State WC law or under the OSHA recordkeeping rule. State WC benefit requirements also vary, with some States not requiring lost time, but requiring that the employee sought medical care. Other States require a certain number of days of lost time before filing a FROI. Unfortunately, ascertainment of nursing health outcomes varies across these data. Even when analyzing WC claims or FROI data with presumably broader inclusion, some injuries will be missed. For example, injured workers may seek care from their regular health provider and fail to mention the work-relatedness of the injury. In a cross-sectional study of unionized autoworkers diagnosed with work-related MSDs, only 25 percent filed WC claims.[231] In a population-based telephone survey, only 10.6 percent of workers reporting work-related MSDs had filed a WC claim.[232]

The need for standardization in data collection and measuring both work environment and worker outcomes is not new. As noted by NIOSH,[233] insufficient job data to link work factors to health outcomes is a barrier to research. An international conference on linked employer-employee data was held in 1998 to address issues of confidentiality, levels of analysis, and the need for coordination across Federal and State agencies.[234] The work in Europe and Scandinavia builds upon international work and could become a model across many countries. Unfortunately, data policy changes at the Federal and local levels are often slow to occur, as modifications to existing systems require long and arduous lobbying, legislation, and procedure and policy development before implementation. Moreover, the WC regulations are primarily State driven, and this is unlikely to change.

Researchers are encouraged to use established instruments and items, with established reliability and validity. If they are developing their own instruments, psychometric testing is essential. Findings benchmarked with other similar populations are useful to determine variation and explore sources of measurement error. When assessing work environments, the level of

analysis for the measure must be explicit (e.g., work group, organization, or system). Analytical strategies should be used to account for the multilevel nature of the data.

Administrative data for worker injuries can be very useful. Many health care organizations are implementing programs that are likely to affect both patient and worker safety, yet it may be difficult to efficiently evaluate the effectiveness of these programs. Ohio, for example, has used the claims data to support issuance and evaluation of safety grants used in lifting and other mechanical equipment purchases to reduce employee injuries.[235]

Conclusion

In this chapter, we have focused on the major injury and safety issues for working nurses. Some of these issues have been thoroughly researched, with extensive evidence-based findings available for epidemiology and prevention, whereas others remain to be studied and explained. As indicated, there is great potential for preventing nurse injury, even though many risk factors have yet to be addressed. The benefits of improvements to nurse safety are great, both for retaining nurses and attracting new nurses into the profession. For example, work hours that are excessive adversely affect nurses' health and thus can in turn adversely impact patient care. As many facilities are making important financial investments and system-level improvements to promote patient safety, it is important to leverage these efforts to improve worker safety as well. In the long run, these improvements will also benefit patients, as measures that are taken to improve safety for nurses should lead to a healthier and more effective workforce.

Search Strategy

Relevant papers for this review were identified from Pubmed,® CINHAL,® as well as from cited literature, and from NIOSH publications up through 2007. Searches were also performed examining journals such as the *American Journal of Industrial Medicine, American Journal of Public Health,* and *Scandinavian Journal of Work and Environmental Health.* As our chapter encompassed multiple outcomes, search terms varied depending on the category, and included but were not limited to, e.g., occupational health, organization of work, shiftwork, back injuries, musculoskeletal disorders, chemical exposures, mental health, work stress, and workplace violence.

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Evidence Table

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Shift work and long work hours						
Caldwell 2005[36]	Shift work, long work hours	Review	Fatigue		Medications	Provides a short overview of hypnotics such as temazepam, zolpidem, or zaleplon and alertness-enhancing compounds such as caffeine, modafinil, or dextroamphetaminethese compounds as well as factors to be considered before choosing one or more to help manage fatigue.
Caruso 2004[28]	Long work hours	Review	Health disorders, safety, health behaviors			In 16 of 22 studies, overtime was associated with poorer perceived general health, increased injury rates, more illnesses, or increased mortality. One meta-analysis of long work hours suggested a possible weak relationship with preterm birth. Overtime was associated with unhealthy weight gain in two studies, increased alcohol use in two of three studies, increased smoking in one of two studies, and poorer neuropsychological test performance in one study.
Costa 2003[26]	Shift work	Review	Health disorders			Organization of shift schedules according to ergonomic criteria and on specific medical surveillance are required to mitigate the adverse effects and ensure that the worker can cope satisfactorily. Consider very carefully psycho-physiological, pathological, and social factors that can influence tolerance and/or maladaptation.
Folkard 2005[13]	Shift work, long shifts	Review	Safety			Three main trends in risk are discussed: (i) risk is higher on the night shift, and to a lesser extent the afternoon shift, than on the morning shift; (ii) risk increases over a span of shifts, especially so if they are night shifts; and (iii) risk increases with increasing shift length over 8 hours.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Knauth 2003[34]	Shift work	Review	Health, safety		Prevention, compensatory measures	Discusses measures that can be taken to optimize the well-being of shift workers and to identify ill-health at an early stage: the design of shift systems, taking account of variation in the views and circumstances of employees, and strategies to combat sleepiness at work and elsewhere.
Knutsson 2003[18]	Shift work	Review	Health disorders			The strongest evidence exists for an association of shift work with peptic ulcer disease, coronary heart disease, and compromised pregnancy outcome.
Megdal 2005[24]	Night work	Meta-analysis	Breast cancer	13 studies		Studies on night shift work and breast cancer risk collectively show a modest increased breast cancer risk among women (aggregate estimate 1.48, 95% CI = 1.36–1.61).
Revell 2005[35]	Shift work, long work hours	Review	Circadian adaptation		Light treatment	Reviews studies in which bright light and melatonin were administered to try to counteract jet lag or to produce circadian adaptation to night work. Demonstrates how jet lag could be prevented entirely if rhythms are shifted before the flight using their preflight plan and discusses the combination of interventions that they now recommend for night shift workers.
MSD epidemiology						
Ariens 2002[44]	Work-related neck musculoskeletal problems	Longitudinal cohort study	Frequency of sickness absence due to neck pain x3 days or more	758 workers		Found “work-related neck flexion, neck rotation, low decision authority, and medium discretion over work activities” as measured by the Job Content Questionnaire to be significant risk factors for absence from work due to neck pain.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Fredriksson 2002[236]	Work environment	Population-based case control study	Persons seeking health care for neck or shoulder pain	17,000 men and women ages 20–59, living in Norrtalje district, central Sweden		There were associations between seeking care and the physical and psychosocial factors in the work environment. In women, "long term perceived high workload, long term exposure to frequent hand or finger work, and frequent bending and twisting and hindrance at work was associated with seeking care for neck or shoulder pain," whereas, in men long-term exposure to vibrating tools was found. For women, high perceived workload and hindrance (risk of injury, risk to work quality or of extra work) combined to increase risk of seeking care.
Maul 2003[237]	Course of work-related low-back pain over up to 8 years of followup	Longitudinal study	Low-back pain occurring in the past 12 months. 1–7 days = mild 8+ days = mod/severe pain	Nurses working at a university hospital in Switzerland		The prevalence of low-back pain was 73–76% over the 8-year period. Over the 8-year period, about half reported the same number of days of back pain at followup, with about half of those remaining experiencing more days of back pain, and rest fewer days with back pain.
Bernard 1997[48]	Work activities related to musculoskeletal problems	An extensive review of over 600 epidemiologic studies	Neck, shoulder, upper extremity (wrist, arm, hand) and back MSDs	Variety of occupations		Summarized evidence for work relatedness of MSD. Findings include strong causal evidence for awkward and static work postures related to back MSD and posture related to neck MSD. Tendinitis, hand, elbow/wrist MSD strongly related to repetition, force, and posture combined. There is evidence for a causal relationship between highly repetitive work and neck and neck/shoulder MSDs, and for forceful exertion and repetition in relation to shoulder MSD.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Punnett and Wegman 2004 [238]	Work-related MSDs	Review of studies with 94 article citations	MSDs	Variety of occupations		Despite numerous studies on the relationship between MSD and occupation, there continues to be debate. From a review of the epidemiologic literature, the authors, along with the Institute of Medicine and others internationally, conclude there are adequate data to support the impact of physical work demands on MSD. Risk factors for MSD with sufficient evidentiary support include repetitive motion, forceful exertions, nonneutral postures, and vibration. Nursing is noted as one of the "high-risk sectors" for MSDs "with rates up to 3–4 times higher than the overall frequency."
Rogers 2005[239]	Work-related injuries	Literature review Best practices Focus groups with hospital nurses Observation of hospital ergonomic hazards	Nurse MSD	Hospital nurses in North Carolina		Evidence on MSD epidemiology and prevention summarized, along with best practices for addressing many ergonomic hazards that lead to nurse MSD. Preventive interventions proposed and recommendations provided.
Trinkoff 2006[30]	Work schedule including work hours, mandatory overtime and on-call	Three-wave longitudinal study	Reported neck, shoulder, and back MSD cases Nordic questionnaire	2,617 registered nurses working in nursing in the past year		Hours/days per week were significantly related to increased MSD; working 13+ hours/day, on days off/vacation days, mandatory overtime, on-call, with <10 hrs between shifts all significantly related to increased MSD. This was largely due to exposure to physical demands of the work.
Needlesticks and sharps						
Dement 2004[240]	Sharps exposure	Surveillance	Blood and body fluids	24,000 health care workers employed in a university-based tertiary care hospital		2,730 BBF exposures between 1998 and 2002, resulting in an overall annual rate of 5.5 events/100 FTEs and a rate of 3.9 for percutaneous exposures. Much higher rates were observed for house staff, nurse anesthetists, inpatient nurses, phlebotomists, and surgical/operating room technicians. Rates of percutaneous exposures from hollow needles were found to decrease over the study period; however, exposure rates from suture needles appear to be increasing.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Sohn 2004[145, 146]	Sharps exposure	Research report	Percutaneous injuries	New York City tertiary care hospital	Safer needle system composed of various safety-engineered devices	A statistically significant reduction in the mean annual number of percutaneous injuries from 34.08 to 14.25 per 1,000 FTE pre- verses postintervention.
Trinkoff 2007[31]	Needlestick injuries and consequences, sharps exposure by positions specialty and work setting, work schedule	Three-wave longitudinal study	Reported prevalent (past year) and incident needlesticks (measured longitudinally)	2,273 registered nurses working in nursing in the past year		Specialties with highest percentage of past year needlesticks: emergency, critical care, OR, and cath lab/diagnostics (≥ 21%). Working increased hours/day, weekends/month, and nonday shifts significantly increased the risk of needlesticks.
Vaughn 2004[241]	Sharps exposure	Research report	Adherence to safe needle precautions	Non-Federal general hospitals in Iowa		Survey of infection control professionals and health care workers found that positive predictors of consistent adherence included infection control hours/FTE (OR = 1.03), frequency of standard precaution education (OR = 1.11), providing personal protective equipment (OR = 1.82), use of needleless IV systems (OR = 1.42), and management support for safety (OR = 1.05).
Mental health						
Van der Klink 2001[184]	Stress-related psychological problems; intervention studies		Outcomes include quality of worklife, psychologic resources, physiologic responses, complaints, absenteeism	48 experimental studies	Cognitive-behavioral interventions, multimodal interventions, relaxation techniques, organization-focused interventions	Moderate effect for cognitive-behavioral and multimodal interventions. Small effect for relaxation techniques. No significant effect for organization-focused intervention.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Violence						
Duhart 2001[207]	Violence	Survey report	Workplace violent crime	National survey		Department of Justice, National Crime Victimization Survey, a population-based survey assessing the incidents of criminal acts of workplace violence, reported 1.7 million incidents per year. Rates are reported by occupation, demographic variables, as well as the relationship of victim to perpetrator.
Gerberich 2004[242]	Violence in health care	Nested case-control study	Assault	MN RNs		Incidence of physical assault was 13.2 per 100 persons per year. Among 310 cases and 946 control subjects, odds ratios for assault were increased in nursing homes or long-term care facilities (2.6; 95% confidence interval [CI] = 1.9–3.6), emergency departments (4.2; 95% CI = 1.3–12.8), and psychiatric departments (2.0; 95% CI = 1.1–3.7); in environments not "bright as daylight" (2.2; 95% CI = 1.6–2.8); and for each additional hour of shift duration (1.05; 95% CI = 0.99–1.11). Risks were decreased when carrying cellular telephones or personal alarms (0.3; 95% CI = 0.2–0.7).
Runyan, 2000 [211]	Violence	Review	Workplace assault			Literature search and review of workplace violence intervention studies yielded 137 articles including the term intervention, while only 9 studies involving the evaluation of interventions. Results of intervention studies were equivocal. Research employing rigorous methods studying interventions to prevent workplace violence are needed
Chemical exposures						
Buckley 2002[149]	Fragrance exposures	Physiological assessment	Allergic reactions	Multiple occupations		Health care workers had the highest prevalence of allergic sensitivity to fragrances.
Daughton 1999[150]	Exposure to pharmaceuticals and personal care products	Review	Adverse effects			Review of toxic pharmaceuticals and personal care products in the environment. This includes various drugs, disinfectants, fragrances, sun screen, nutritional supplements, etc.

Author, year	Safety issue	Design type	Outcome measure	Setting population	Intervention	Findings reported by authors
Dranitsaris 2005[161]	Cytotoxic drug exposure	Meta-analysis	Adverse health effects Spontaneous abortion, congenital malformations, stillbirths	Health care workers		Risk of spontaneous abortions for workers handling cytotoxic drugs was elevated.
Sattler 2007[243]	Hospital environment	Literature review	Adverse health effects, compromise of the environment	Patients, health care workers, and the community		Review of products used in the hospital setting and their adverse health effects. Explores alternative product selection.
Takigawa 2006[154]	Exposure to glutaraldehyde	Review	Adverse health effects	Multiple occupations		Review of toxicity of glutaraldehyde and workplace exposure. Includes case series for asthma and skin reactions that incorporate many findings from exposed nurses.

Chapter 40. The Effects of Fatigue and Sleepiness on Nurse Performance and Patient Safety

Ann E. Rogers

Background

Although the words “fatigue” and “sleepiness” are often used interchangeably, they are distinct phenomena. Sleepiness refers to a tendency to fall asleep, whereas fatigue refers to an overwhelming sense of tiredness, lack of energy, and a feeling of exhaustion associated with impaired physical and/or cognitive functioning.[1] Sleepiness and fatigue often coexist as a consequence of sleep deprivation.

Even though fatigue can be due to a variety of causes (e.g., illness, a vigorous workout, or a period of prolonged concentration), this chapter will focus on the effects of fatigue associated with insufficient sleep (see Key Terms and Definitions). The impact of extended work shifts and the relationship of these work schedules to nurse and patient safety will also be explored. Several practices that show demonstrable potential for reducing the adverse effects of fatigue on patient safety will be reviewed at the end of the chapter.

Insufficient Sleep

Studies suggest that average sleep durations have decreased from 9 hours in 1910 to as little as 6.9 hours on workdays in 2002.[2–6] Objective measurements, however, suggest that mean sleep times may actually be somewhat lower than are typically reported in surveys. For example, 273 randomly selected middle-aged residents of San Diego (40 to 64 years) reported sleeping approximately 7 hours, an amount that appeared to correspond to their time in bed. Mean sleep times obtained from wrist actigraphy, however, revealed that participants slept on average 6.22 hours, approximately 43 minutes less than their subjective reports.[7]

Sleeping longer on weekends and nonworkdays is also common,[4, 6] suggesting that individuals are obtaining insufficient sleep on workdays, then attempting to “catch up” on weekends. Americans slept on average 36 minutes more on weekends in 2002,[4] which is somewhat longer than the 23 minutes reported by British adults.[6] American nurses who participated in a recent survey, however, obtained on average 84 minutes more sleep on nonworkdays than work days (8.2 hours on nonworkdays compared to 6.8 hours on workdays),[8] which is more than triple the amount reported by British adults and more than double that of other Americans.

Individuals working nights and rotating shifts rarely obtain optimal amounts of sleep. In fact, an early objective study showed that night shift workers obtain 1 to 4 hours less sleep than normal when they were working nights.[9] Sleep loss is cumulative and by the end of the workweek, the sleep debt (sleep loss) may be significant enough to impair decisionmaking, initiative, integration of information, planning and plan execution, and vigilance.[10, 11] The effects of sleep loss are insidious and until severe, are not usually recognized by the sleep-deprived individual.[12, 13]

Finally, it is not uncommon for nurses and other shift workers to acknowledge falling asleep when working nights.[8, 14, 15] Almost one-fifth of the nurses working permanent night shifts reported struggling to stay awake while taking care of a patient at least once during the previous month.[15] Another survey found that the occurrence of falling asleep during the night shift occurred at least once a week among 35.3 percent of the nurses who rotated shifts, 32.4 percent of the nurses who worked nights, and 20.7 percent of the day/evening shift nurses who worked occasional nights.[16] Objective recordings using ambulatory polysomnographic recorders and actigraphy have verified that nurses, air traffic controllers, and even commercial truck drivers regularly fall asleep for brief periods during the night shift.[17–19]

Effects of Insufficient Sleep

Although the exact amount of sleep needed by healthy adults has not been determined, the effects of insufficient sleep have been well documented. A review of the relevant literature over the past 15 years reveals that insufficient sleep (or partial sleep deprivation) has a variety of adverse effects. Despite the wide range of research methodologies (e.g., qualitative studies, surveys and clinical trials, instruments) and settings (e.g., field studies, and time-isolation laboratories, and sample sizes), the results are quite similar: insufficient sleep has been associated with cognitive problems, mood alterations, reduced job performance, reduced motivation, increased safety risks, and physiological changes. Results from laboratory studies of total sleep deprivation (one or more nights without sleep) were not included in this review, since the focus of this section is on insufficient sleep (partial sleep deprivation) and not on total sleep deprivation.

It is important to note that none of the several hundred studies reviewed for this paper showed *any* positive effects from sleep restriction in healthy adults. While it is true that one night of sleep deprivation can temporarily elevate mood in depressed patients,[20, 21] it has adverse effects on mood in healthy individuals of all ages,[22, 23] including nurses.[24] Depression increases,[25, 26] irritability increases,[27, 28] and people report feeling more stressed when sleep is restricted.[24] Extended sleep times, however, are not associated with improved mood or health and may be associated with poor health. Mortality rates were highest among subjects ages 30 to 100 years who slept 8 or more hours, and lowest among those who slept 7 hours sleep,[29] findings that were identical to those obtained a year later from a prospective study of 82,975 registered nurses (Nurses Health Study).[30]

Contrary to what one might expect, partially sleep-deprived older women (55 to 65 years) in one study suffered fewer ill effects when compared to younger women (20 to 30 years),[31] and sleep-deprived older drivers (52 to 63 years) of both genders performed better than sleep-deprived younger drivers (20 to 25 years).[32] An earlier study, however, reported that younger male drivers were more resistant to the adverse effects of sleep deprivation than older male drivers.[33]

Although some people are less impaired by insufficient sleep than others,[34] several studies have shown that failure to obtain adequate sleep is an important contributor to medical error.[25, 35–37] Although most studies have focused on measuring the effects of sleep deprivation on the performance of interns and resident physicians, sleep deprivation also has adverse effects on the performance of hospital staff nurses.[8] Using data from the first sample of nurses (n = 393) who participated in the Staff Nurse Fatigue and Patient Safety Study, Dawson and his colleagues (Dawson, personal communication, 2005) found a significant relationship between sleep in the prior 24 hours and the risk of making an error. Nurses who reported an error or near miss

obtained significantly less sleep than nurses who did not report an error or near miss (6.3 ± 1.9 hours versus 6.8 ± 1.7 hours). Using techniques described in one of their papers,[38] researchers determined that there was a 3.4 percent chance of an error when nurses obtained 6 or fewer hours of sleep in the prior 24 hours and 12 or fewer hours of sleep in the prior 48 hours (Dawson, personal communication, 2005). Although a 3.4 percent risk of an error or near miss sounds insignificant, it would translate to a probability of 34 events per day in an average teaching hospital with 1,000 nursing shifts per day.

In addition to jeopardizing patient safety, nurses who fail to obtain adequate amounts of sleep are also risking their own health and safety. According to the National Center for Sleep Disorders Research and the National Highway Transportation Safety Administration Expert Panel on Driver Fatigue and Sleepiness,[39] sleep loss is the leading cause of drowsy driving and sleep-related vehicle crashes. Drowsy drivers have slower reaction times,[40] reduced vigilance,[41, 42] and information processing deficits,[40] which make it difficult to detect hazards and respond quickly and appropriately.[39] Laboratory studies have shown that moderate levels of prolonged wakefulness can produce performance impairments equivalent to or greater than levels of intoxication deemed unacceptable for driving, working, and/or operating dangerous equipment.[43, 44] Dawson and his colleagues[43, 44] were the first to report that prolonged periods of wakefulness (i.e., 20 to 25 hours without sleep) can produce performance decrements equivalent to a blood alcohol concentration of 0.01 percent, and numerous other studies have confirmed that prolonged wakefulness significantly impairs speed and accuracy, hand-eye coordination, decisionmaking, and memory.[45–49] Although numerous studies have shown that night shift workers report very high rates of drowsy driving and motor vehicle accidents when driving home after work,[50–52] the majority of research on drowsy driving among health care providers has focused on the dangers of resident physicians driving home after a night of being on-call.

There is also a growing body of evidence that sleep duration is (1) linked to metabolism and the regulation of appetite, and (2) decreased sleep times may be a contributing factor to the growing epidemic of obesity in this country. Several large-scale studies have shown dose-dependent relationships between sleep duration and obesity, with greater sleep deprivation associated with a higher risk of obesity.[53, 54] Glucose tolerance is altered by short-term sleep restriction,[55] and habitually short sleep durations have been shown to significantly increase the risk of developing diabetes in women.[56] Tightly controlled laboratory studies have also shown that short sleep durations, e.g., 4 hours per night, can result in alterations of hormones involved in the regulation of appetite (e.g., leptin, cortisol, and thyrotropin).[57]

Sleep is also believed to play a role in regulating immune function. Both human and animal studies have shown that immunological challenges such as vaccinations and both experimentally induced and spontaneous infections tend to increase sleep duration, often increasing the duration and intensity of slow-wave sleep (deep sleep) and decreasing REM sleep (rapid eye movement sleep or dream sleep).[58, 59] Even though studies evaluating the effects of sleep deprivation on immunity have shown a variety of effects,[60–65] no study has been able to link these changes in immune function with increased rates of infection or other adverse effects on health.

Extended Work Hours

Although the hazards associated with the prolonged hours worked by resident physicians and interns have been documented in numerous studies,[25, 65–68] limited attention has been paid to the hours worked by nurses or the effects of these hours on patient safety. Early studies tended to focus on nurse satisfaction with the new 12-hour shift schedule, only minimally addressing the

increased risk of errors.[35] More recent studies, however, have shown that the 12-hour shifts favored by many nurses and frequent overtime are associated with difficulties staying awake on duty, reduced sleep times, and nearly triple the risk of making an error.[14, 69, 70]

Although the majority of hospital staff nurses (75 percent) now work 12-hour shifts, some nurses report being scheduled to work for periods as long as 20 consecutive hours.[14, 69] Data collected on 11,387 shifts revealed that nurses left work at the end of their scheduled shift less than once every six shifts (15.7 percent), and worked on average 49 to 55 minutes extra each shift they worked.[14, 69] Working overtime, whether at the end of a regularly scheduled shift (even an 8-hour shift) or working more than 40 hours in a week, was associated with a statistically significant increase in the risk of making an error.[14, 69] The most significant elevations in the risk of making an error occurred when nurses worked 12.5 hours or longer; the risk was unaffected by whether the nurse was scheduled to work 12.5 hours or more, volunteered to work longer than scheduled, or was mandated to work overtime.[14, 69]

A little over two-thirds of the nurses participating in the Staff Nurse Fatigue and Patient Safety Study reported struggling to stay awake on duty, and 20 percent reported actually falling asleep on duty.[14, 71] In fact, critical care nurses reported struggling to stay awake almost once every five shifts they worked. Not all of the difficulties remaining alert occurred at night (24:00–06:00); 479 episodes of drowsiness (40 percent) occurred between 6 a.m. and midnight, and 40 episodes (23 percent) of actually falling asleep on duty were reported between 6 a.m. and midnight.[14] Nurses working 12.5 hours or longer were significantly more likely to report difficulties remaining alert than nurses working fewer hours per day,[14] and they obtained on average 30 minutes less sleep.

Although the participants (n = 35) in Urgrovics and Wright's 1990 study[72] reported fewer difficulties driving home after switching to 12 hour shifts, at least two recent studies contradict their findings. All but two of the nurses (n = 45) who worked 12-hour night shifts in an intensive care unit of a large tertiary care center reported having at least one motor vehicle accident or near accident during the previous 12 months driving to or from work.[73] More recently, over half of the participants in the Staff Nurse Fatigue and Patient Safety Study (54 percent) reported struggling to stay awake driving home from work during the 28-day data-gathering period.[74] While difficulties remaining alert driving home were common (drowsy driving was reported approximately once every five shifts), critical care nurses reported difficulties remaining awake driving home after working 12.5 consecutive hours or more approximately once out every three shifts they worked. In fact, critical care nurses who worked 12-hour shifts had a 1.87 percent greater risk of fighting sleep on their drive home from work than nurses working traditional 8-hour shifts (95 percent confidence interval [CI] = 1.43–2.45, $P < 0.0001$).[74]

According to a recent report of the National Institute of Occupational Safety and Health (NIOSH),[75] working more than 40 hours per week (overtime), working extended shifts (more than 8 hours), and working both extended shifts and overtime can have adverse effects on worker health. Extended shifts have been associated with increased musculoskeletal injuries,[76] more cardiovascular symptoms,[77–79] the development of hypertension,[80] and higher risks for injury.[81–83] Working overtime has also been associated with poorer perceived health,[84, 85] increased neck and musculoskeletal discomfort,[76, 86, 87] increased risk for preterm birth,[88] diabetes,[89, 90] and cardiovascular disease,[91–93] as well as increased morbidity and mortality[94] and higher rates of accidents.[95, 96] Not all studies, however, suggest that overtime is associated with poorer perceived health,[97] increased risk of developing diabetes mellitus, or cardiovascular disease.[98]

Studies have shown that accident rates increase during extended periods of work,[96] with accident rates rising after 9 hours, doubling after 12 consecutive hours,[81, 83] and tripling by 16 consecutive hours of work.[82] Data from the National Transportation Safety Board aircraft accident investigations also show higher rates of error after 12 hours.[99] Other studies show no change in accident frequency or severity of accidents,[100, 101] while one study showed that workers on a 12-hour shift schedule had lower rates of injuries at work, but higher rates of more significant injuries away from work.[82] The combination of extended shifts and overtime, while rarely studied, has been associated with high rates of motor vehicle accidents or near misses in the prior year,[73] more musculoskeletal pain, and cardiovascular symptoms.[77]

Consecutive Shifts

Fatigue can be exacerbated with increased numbers of shifts worked without a day off,[102, 103] and working more than four consecutive 12-hour shifts is associated with excessive fatigue and longer recovery times.[104] Folkard and Tucker[83] also suggested that the accumulation of fatigue over successive work shifts might explain the rise in accident rates observed in their meta-analysis. On average, risk of an accident was approximately 2 percent higher on the second morning/day shift; 7 percent higher on the third morning/day shift, and 17 percent higher on the fourth morning/day shift than on the first shift. Accident risks also increased over successive night shifts (e.g., on average risk was 6 percent higher on the second night, 17 percent higher on the third night, and 36 percent higher on the fourth night) and were significantly higher than on day/morning shifts, a finding similar to that reported by Hanecke and colleagues several years earlier.[81]

Fatigue Countermeasures and Other Recommended Safety Practices

Fatigue-related problems are believed to cost the United States an estimated $18 billion dollars per year in lost productivity and accidents.[105] More than 1,500 fatalities, 100,000 crashes, and 76,000 injuries annually are attributed to fatigue-related drowsiness on the highway.[105] On-the-job performance also deteriorates: railroad signal and meter reading errors increase at night, minor errors occur more often in hospitals, and switchboard operators take longer to respond to phone calls.[106] Two significant nuclear power plant accidents (Three Mile Island and Chernobyl) and the environmentally disastrous grounding of an oil tanker (Exxon Valdez) occurred at night, during early morning hours when vigilance is at its lowest. In the case of the Exxon Valdez grounding, sleep deprivation was identified as one of the major causal factors of the grounding (the third mate had been awake 18 hours and the ship's master had not slept in the 36 hours prior to the accident).[107] According to a supplemental report,[108] sleep deprivation was a contributory, if not causal, factor in the poor decisions made the night before the launch of the Space Shuttle Challenger.

A variety of industries and professions have developed programs to reduce sleepiness-based errors under the aegis of "fatigue management."[109–111] These programs usually include an educational component [112–116] and sometimes include schedule alterations.[114, 117] Employees are usually given information about circadian rhythms, sleep hygiene measures, shift work and its adverse effects, and a variety of strategies that can be used to reduce fatigue (e.g., judicious use of caffeine and napping during night shifts).[118, 119] Managers may be urged to consider altering

the starting times of shifts whenever possible to make schedules more compatible with circadian rhythms; to avoid scheduling employees to work more than two or three consecutive night shifts; and to provide adequate recovery time between shifts, especially when an employee is rotating off night shift. Hours of service regulations, where applicable, are also considered in the development of a fatigue management program.[119]

Only limited information about the efficacy of these programs is available to the public. Although several specialized fatigue countermeasures programs have been developed and tested by the U.S Coast Guard, the Crew Endurance Management System,[113] and the Commercial Mariner Endurance Management System,[112] information about the efficacy of these programs has not been disseminated. Private companies implementing Fatigue Countermeasures Programs consider their use to be proprietary information. In fact, the only paper describing the efficacy of a fatigue countermeasures program reported only equivocal results.[116]

Other Recommended Safety Practices

Rest breaks, napping, exercise, bright lights, and pharmacologic measures may be used to provide temporary relief from the symptoms of fatigue during the work shift. Although frequent short rests breaks are usually recommended for the prevention of fatigue, anecdotal information, collective bargaining agreements, and even research studies suggest that nurses are regularly sacrificing their breaks and meal periods to provide patient care.[120–126] In fact, a recent study revealed that hospital staff nurses were completely free of patient care responsibilities during a break or meal period less than half the shifts they worked (2,429 out of 5,221 shifts). There were 334 shifts (10 percent) in which nurses reported having no opportunity to sit down for a break or meal period. The rest of the time (2,249 out of 5,211 shifts) nurses reported having the time for a break or meal, but that they were not relieved of patient responsibilities during that time.[126] On average nurses reported having only 25.7 minutes break during their entire shift. Nurses working the longest hours were least likely to receive appropriate breaks (e.g., 10 minutes every 2 hours and a 30-minute meal period free of patient care responsibilities).

Studies have shown that short breaks not only improve performance and reduce subjective fatigue,[127–130] they are effective in controlling the accumulation of risk associated with prolonged task performance (e.g., 2 hours sustained work)[131, 132] and sleepiness.[129] Other studies however, have shown that rest breaks and tea breaks can decrease fatigue but not necessarily accident risk or errors.[126, 133]

Napping. Even though napping during breaks or meal periods is often prohibited, both laboratory and field studies suggest that naps (15 minutes to 3 hours) are quite effective in increasing alertness during extended work periods or at night.[134–139] Since few operational settings allow for long naps (e.g., 3 hours), most naps studied in operational settings are short. For example, 20-minute single naps during the first night shift improved the speed of responses on a vigilance task at the end of the shift,[134] and 26-minute in-seat naps have been shown to increase physiological alertness and psychomotor performance of airline pilots.[140] When pilots were allowed a nap during night flights, their performance improved by 34 percent, and physiologic alertness improved 54 percent compared to the no-nap condition.[140]

The alerting effects of naps are varied, with most studies suggesting that improvements in subjective alertness and performance are sustained for up to an hour or more postnap.[138, 139, 141] Longer naps tend to produce longer periods of alertness and improved performance.[142] Although some studies report sleep inertia, or a period of decreased alertness and performance immediately following a nap,[138, 139, 141] this effect was not seen in Driskell's meta-analysis.[142]

Stimulants. Caffeine is probably the most commonly used fatigue countermeasure.[143] Its effects have been studied alone,[144] as well as in combination with rest breaks, naps, and other stimulant medications.[145–147] Generally, caffeine's onset of action occurs approximately 15–30 minutes after ingestion and its effects last 3–4 hours. Although tolerance can develop, significant increases in alertness and performance can be obtained with 200 mg of caffeine (approximately the amount of caffeine in one to two cups of coffee), with positive effects occurring with doses ranging from 100 mg to 600 mg.[143, 145] Although caffeine alone improved alertness and performance during a laboratory study, the combination of napping and caffeine was more efficacious than just napping or just caffeine alone in a field study of evening and night shift workers.[146] Six hundred milligrams of caffeine was also as effective as 20 mg d-amphetamine and 400 mg modafinil in producing short-term performance and alertness during prolonged sleep loss.[148] Modafinil has also been shown to be effective in increasing alertness on laboratory measures of performance among workers diagnosed with shift work sleep disorder (see Table 1 for a description of the disorder),[149–151] but produced mixed results when evaluated during a randomized, double-blind cross-over study of sleep-deprived emergency room physicians. Even though modafinil improved some aspects of cognitive functioning and perceived alertness, participants had difficulties falling asleep when given an opportunity.[152] Although other compounds have been recommended (e.g., melatonin), their efficacy has not been established.[153, 154]

Bright light. Although a number of studies have shown that bright lighting in control rooms, work areas, and laboratory environments can increase alertness at night and facilitate entrainment to night shift work,[154–157] this strategy may not help nurses as much as other types of workers. Protocols typically involve exposure to bright lights (approximately 2,500 lux) or normal lighting (approximately 150 lux) while working at a desk for periods of 2 to 6 hours. No one has evaluated the efficacy of intermittent exposure to bright lights or the effects of alternating exposure to bright lights with the dim lighting typically found in patient rooms at night.

Exercise. Exercise typically produces increased subjective alertness and improved cognitive performance in both sleep-deprived and nonsleep-deprived subjects.[158, 159] Exercising for 10 minutes, however, produces only transient (30–50 minutes) increases in subjective alertness. In one study there were no effects on performance after exercise, but within 50 minutes there were signs of increased drowsiness on electroencephalogram (EEG) recordings.[160] As a result of this finding, the authors of the study caution that people who use exercise as an intervention for maintaining alertness during a period of sleep loss may end up sleepier than if they had not exercised.

Research Evidence

There is a very large, strong body of evidence showing that insufficient sleep has adverse effects on cognition, performance, and mood. These effects have been documented by at least two meta-analyses[22, 150] and several clinical trials,[32, 161, 162] as well as by studies using somewhat less robust designs including time series, cross-sectional, before-and-after designs, and noncomparative descriptive studies.[11, 30, 37, 163–167] The adverse effects of insufficient sleep have also been documented in a variety of settings ranging from tightly controlled laboratories[11, 32, 162, 163, 166] to field studies,[30, 37, 164–167] and in a variety of occupational groups.

The studies demonstrating a relationship between adverse effects on health and obtaining less than 7 hours sleep per night tend to use less robust designs (e.g., cross-sectional designs, time series designs, comparative and noncomparative descriptive designs), but they often include large numbers of participants. Although survey and cross-sectional designs may not be as rigorous as controlled clinical trials, the number of recent studies suggesting similar relationships between insufficient sleep, altered glucose metabolism,[56, 168] and increased risks of developing diabetes mellitus[54, 169] and obesity[53, 54] is powerful and convincing evidence that a relationship exists between these variables. Longer sleep durations (e.g., more than 8 to 9 hours per night) were also associated with greater risks of dying or developing a chronic illness such as DM or cardiovascular disease,[29, 56, 168] leading researchers to speculate that individuals who routinely obtain higher than normal amounts of sleep may have preexisting health problems.[29]

The evidence regarding shift duration, however, is less clear-cut. Although some studies suggest that reductions in the work hours of resident physicians and interns is associated with fewer errors,[35] other studies suggest that the implementation of work hour limitations has not decreased the number of adverse events.[169,170] Although there are numerous literature reviews,[171–173] descriptive and other comparative studies,[14, 25, 26, 69, 174–176] there are no meta-analyses and only one systematic review[177] focusing on the impact of work hours on medical errors or work performance. The strongest study, involving 20 critical care residents and interns and direct observation of errors, found that traditional schedules were associated with 35 percent more serious errors, and shortened workdays (16 hours) were associated with both fewer order-writing errors and diagnostic errors.[35] Unfortunately, this study has not been replicated outside of the critical care setting or at any other institution.

The evidence demonstrating a relationship between working long hours and adverse effects on health is stronger. Not only are there several large-scale studies documenting higher injury rates when people worked overtime or extended shifts,[82, 178, 179] there are several literature reviews[83, 170] and three meta-analyses examining the effects on worker health.[78, 79, 83]

Clinical trials that would provide more definitive answers to questions regarding shift duration and adverse health effects have not been done, nor are they likely to be done because of ethical issues.

Although more than 170,000 employees from a variety of industries (including aviation, rail, trucking, maritime, health care, petrochemical, nuclear energy, and law enforcement) have been exposed to fatigue countermeasures programs,[115] there is very limited information about their efficacy. Typical reports indicate that some aspects of a particular program were successful (e.g., employees slept longer at night,[180] napping improved alertness on duty,[129] and that participants used most of the suggested strategies),[116] but the reports rarely assess the efficacy of the program as a whole for improving alertness on the job and reducing errors. The only published study describing the outcomes of a fatigue countermeasures program for resident physicians involved a very small sample (n = 6) and produced mixed results.[116] Although participants reported increased subjective alertness after using the suggested strategies for a month, there were no improvements in their performance, mood, or the amount of sleep obtained when working the night shift.

There is strong evidence that short naps can improve alertness during night shifts and prolonged periods of wakefulness. Data obtained from several small clinical trials,[134, 138, 140, 146] and a meta-analysis[142] all support the use of this strategy for improving alertness at night. In addition, there are several small clinical trials that suggest a short daytime nap can improve alertness during the afternoon.[181–184]

The effects of rest breaks were more variable. Study designs evaluating the efficacy of rest breaks on performance and alertness also tended to be weaker, involving quasi-experimental designs[128, 130, 131, 133, 185] rather than randomized clinical trials[129] or meta-analyses. Given that almost all of the aforementioned studies were field studies conducted at actual worksites during regular workhours, the choice of somewhat less rigorous designs is understandable.

There is strong evidence that use of caffeine, either alone or in combination with a nap, can increase alertness. Although there are no meta-analyses evaluating the efficacy of caffeine, the utility of caffeine for increasing alertness has been demonstrated through numerous clinical trials,[144, 145, 147] and its widespread use by adults. (Mean caffeine consumption in the United States is estimated at 238 mg or slightly more than two cups of coffee per day per person.)[186] Other measures to increase alertness, such as bright lighting and exercise, either lack sufficient evidence or may not be practical for nurses.

Evidence-Based Practice Implications

Although studies have not always been able to document that the cognitive deficits associated with insufficient sleep lead to medical mishaps, there is enough evidence to suggest that insufficient sleep can have adverse effects on patient safety and the health of nurses. The effects, summarized in Table 1, provide the basis for the two recommendations in Table 2.

Table 1. Adverse Effects of Restricted Sleep on Patient Safety and the Health of Nurses

Sleep Duration in 24 Hour Period	Adverse Effects on Patient Safety	Adverse Effects on Health
< 7 hours	More likely to report struggling to stay awake during work shift[14]	Increased risk of developing cardiovascular disease and DM among nurses[187] Increased risk of becoming obese over a 10-year period[53]
≤ 6 hours	Risk of making an error is 3.4% during a work shift among nurses who slept ≤ 6 hours in 24 hours prior to shift (Dawson, personal communication)	Increased prevalence of DM and altered glucose metabolism[56, 168] Risk of obesity is 23% greater than subjects sleeping 7–9 hours[53]
< 5 hours	Increased subjective and objective sleepiness, and reduced performance on cognitive tasks[22, 161]	Increased risk of developing DM demonstrated in nurses[187] Risk of obesity is 50% greater than among subjects sleeping 7–9 hours[53]
≤ 4 hours		Altered levels of appetite-regulating hormones (leptin, cortisol, and thyrotropin)[57] Risk of obesity is 73% greater than among subjects sleeping 7–9 hours[53]

Table 2. Evidenced-Based Recommendations for Practice Related to Sleep Duration[32]

Recommendation	Practice Implication
Nurses need to obtain 7–8 hours sleep per night to protect both the health of their patients and their own health	Get 7 to 8 hours of sleep each day (24-hour period) before you go to work.
Younger nurses (e.g., those 20–30 years old) need to be particularly careful about obtaining sufficient sleep, since their mood and performance may be more adversely affected by insufficient sleep.	If you are younger than 30 years of age, adequate sleep is especially important for providing safe and high-quality patient care.

To implement these recommendations, many nurses will have to be willing to make substantial changes in their behavior. Despite their more sophisticated knowledge about health and illness, the sleep habits of nurses mirror those of other Americans. Only a little more than one-fourth of the participants in the Staff Nurse Fatigue and Patient Safety Study (27.2 percent) obtained at least 6 hours sleep prior to every shift they worked during the 28-day study period; more than one-quarter of the 11,387 shifts studied (29.1 percent) were worked by nurses who obtained less than 6 hours sleep, an amount that has been associated with higher risks of errors (Dawson, personal communication, 2005). Although few nurses would consider coming to work if they were legally drunk, the data suggest that many nurses are unaware of or disregard the equally serious risks associated with insufficient sleep.

Although it might be argued that family responsibilities prevented hospitals staff nurses from obtaining sufficient sleep, regression analysis has shown that this is not the case. Neither childcare nor elder care responsibilities were associated with reduced sleep times on workdays. Instead, longer work shifts, longer commutes, higher caffeine intakes, complaints of poor sleep, and older age (of the nurse) were associated with shorter sleep durations.[188] Childcare responsibilities, however, were associated with shorter sleep times on nonworkdays.

Several authorities have recommended that work shifts be limited to 12 hours in a 24-hour period and employees limited to working no more than 48 to 60 hours per week.[171, 173, 189, 190] Although 12-hour shifts are quite popular among nurses, most authorities do not recommend the use of 12-hour shifts unless there are sufficient rest breaks, there are adequate arrangements for coverage of absentees, overtime will not be added, and shift systems are designed to minimize the accumulation of fatigue.[173, 190, 191] Rosa[173] also recommends that 12-hour shifts not be adopted if there are staffing shortages, citing the dangers associated with an already fatigued worker covering part or all of a vacant shift.

In fact, legislation pending in the Massachusetts State legislature would (1) prohibit resident physicians from working more than 10 consecutive hours in all high-intensity settings, (e.g., emergency departments, intensive care units, etc.); (2) limit resident physician workhours to 18 consecutive hours in all other areas; (3) mandate 16 consecutive hours off after an 18-hour shift and require 10 consecutive hours off between all other work shifts; and (4) require all physicians, not just trainees, to notify patients before providing care if the physician has been awake 22 hours out of the prior 24 hours.[192] Although the workhours of most nurses will not be altered by this legislation, limiting the duration of nursing shifts and mandating sufficient rest periods between shifts would also be of benefit for nurses and the patients they care for.

Table 3. Evidenced-Based Practice Recommendations Related to Shift Duration and Number of Workhours During a Week

Recommendation	Practice Implication
Schedules that involve working 48 or 60 hours per week,[193] or working 7 consecutive 12-hour shifts in one week in order to have 7 consecutive days off the next week[194] are unacceptably risky,[83] and should be prohibited.	Do not work any more than 48 hours in a 7-day period.
The continued use of 12-hour shifts cannot be recommended given the current working conditions, including the almost daily need for nurses to stay beyond the end of their scheduled shift, the frequent absence of breaks during the workday, and the higher risk of errors associated with 12-hour shifts.[14, 69, 126]	Nurse managers should not schedule nurses for 12-hour shifts and nurses should not request 12-hours shifts.
If nurses insist on continuing to work 12-hour shifts, several measures should be taken to reduce the risks to patients and nurses. These steps include reducing the number of consecutive shifts to no more than three,[83, 104] providing adequate meal and rest breaks,[120, 195] revising schedules to ensure that nurses have at least 10–12 hours off between work shifts so that they have adequate time for sleep, commuting, and completing their domestic responsibilities, and requiring that nurses use their off-duty time to get sufficient sleep.	If you are scheduled to work a 12-hour shift, (1) do not work more than three shifts without a day off; (2) insist that provisions are made for sufficient staffing to ensure that you are able to be free of patient care responsibilities for 10 minutes every 2 hours and for 30 minutes to eat a meal; and (3) insist that you have at least 10–12 hours off between shifts so that you can obtain sufficient sleep.

The emphasis on maximizing opportunities for sleep is intentional. Because long workhours are often associated with insufficient sleep,[25, 36, 196] some authorities believe that fatigue on the job is more likely to be associated with a lack of sleep than the number of hours spent working.[191, 197] Workers who report high workloads, stressful workweeks, or who score higher on burnout indexes have shorter sleep times,[198, 199] as well as more arousals, greater sleep fragmentation, more wake time after sleep onset, lighter sleep, and less deep sleep.[200, 201] Fatigue and daytime sleepiness associated with stressful working conditions and burnout is believed to be a result of insufficient sleep, rather than a direct result of stressful working conditions or burnout.

Although employer support will be required to implement schedule changes, there are several strategies that nurses can adopt to improve their ability to remain alert throughout their entire shift. Even though the following three fatigue countermeasures were developed mainly for night shift workers, the first two recommendations are also appropriate for nurses working other shifts.

Practice Recommendations for Use of Caffeine

1. Caffeine should be used therapeutically. Caffeine should not be consumed on a regular basis or when alert. Instead, caffeine consumption should occur only at the beginning of a shift or about an hour before an anticipated decrease in alertness (e.g., between 3 a.m. and 5 a.m.). To reduce the possibility of insomnia, caffeine consumption should stop at least 3 hours before a planned bedtime.[202]

2. Nurses should be allowed to nap during their break and meal periods. Naps should be short, e.g., less than 45 minutes, to reduce the likelihood of awakening from deep sleep and

experiencing sleep inertia.[143] Some nurses may prefer to take a shorter nap, and have a 15-minute wake up period before they resume patient care.

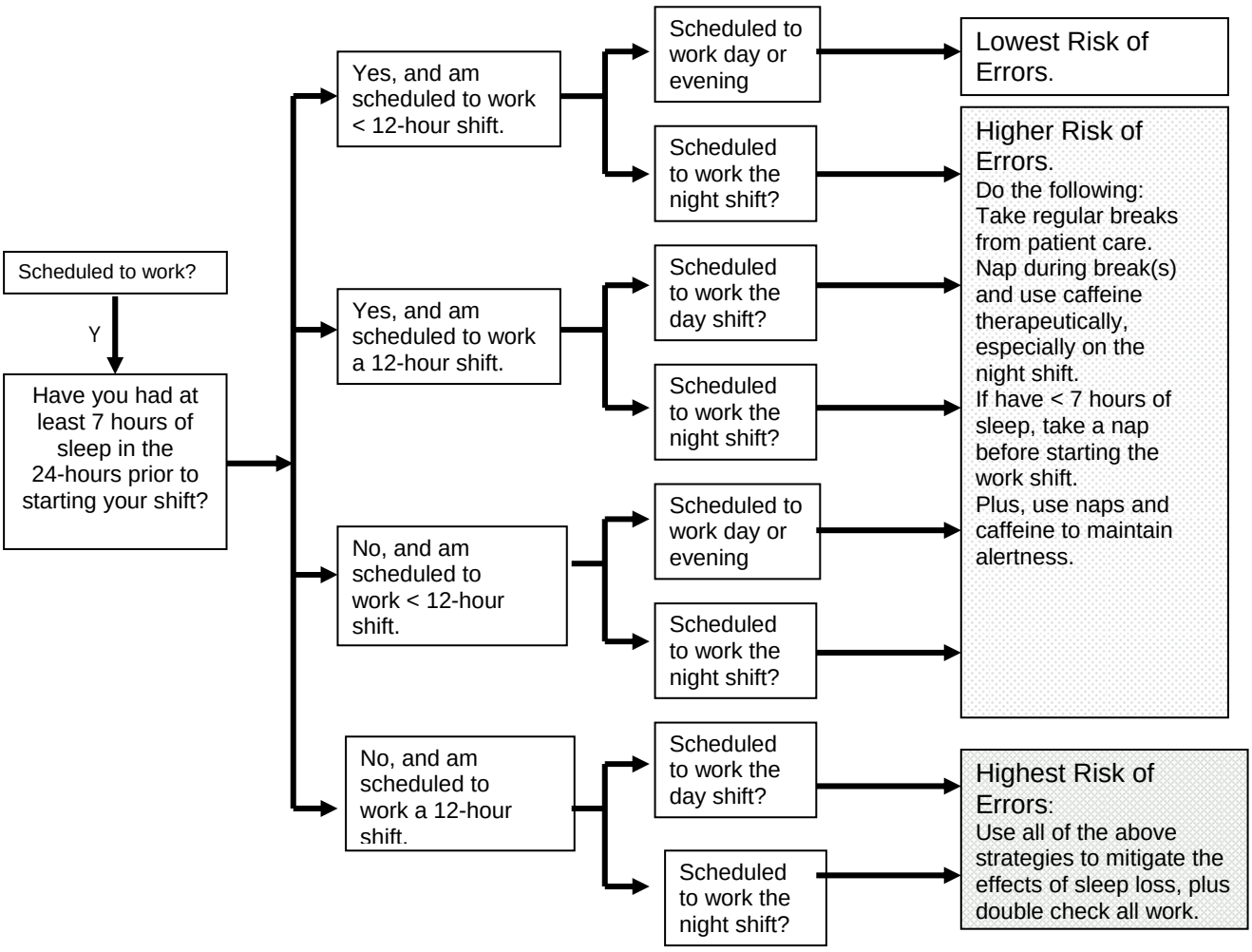
3. Nurses, particularly those who start their shift at 11 p.m. or midnight, should consider napping prior to starting their shift. Not only are nurses who work at night required to be awake and vigilant when their body temperature is lowest and their sleep tendency is greatest, they are typically awake longer before the beginning of their shift than workers on other shifts.[203]

Table 4. Evidenced-Based Recommendations for Practice Related to Improving Alertness on the Job

Recommendation	Practice Implication
Caffeine should be used therapeutically. Caffeine should not be consumed on a regular basis or when alert. Instead, caffeine consumption should occur only at the beginning of a shift or about an hour before an anticipated decrease in alertness e.g., between 3 a.m. and 5 a.m. To reduce the possibility of insomnia, caffeine consumption should stop at least 3 hours before a planned bedtime	Do not consume caffeine outside of workhours. Consume caffeinated beverages only at the beginning of the shift or about an hour before an anticipated decrease in alertness, e.g., between 3 a.m. and 5 a.m. Avoid consuming caffeinated beverages at least 3 hours before bedtime.
Nurses should be allowed to nap during their break and meal periods. Naps should be short, e.g., less than 45 minutes, to reduce the likelihood of awakening from deep sleep and experiencing sleep inertia. Some nurses may prefer to take a shorter nap and have a 15-minute wake up period before they resume patient care	Use breaks and meal periods for a short nap, particularly during the night shift. Naps should be less than 45 minutes in duration. If you are somewhat sluggish when you first awaken, take a shorter nap so that you have at least a 15-minute wake up period before resuming patient care.
Nurses, particularly those who start their shift at 11 p.m. or midnight, should consider napping prior to starting their shift. Not only are nurses who work at night required to be awake and vigilant when their body temperature is lowest and their sleep tendency is greatest, they are typically awake longer before the beginning of their shift than workers on other shifts	If you work nights, especially if you start working at 11 p.m. or midnight, take a nap prior to starting your shift to help you remain alert during the early morning hours. Although it may be more difficult to schedule, taking a short nap before working a 12-hr night shift, would also help improve your alertness during the early morning hours.

Finally, nurses should realize that most people are not accurate judges of how impaired they are by fatigue or sleep loss.[204, 205] Few adults can perform at high levels for more than 12 consecutive hours or function adequately with less than 6 hours sleep. Figure 1 illustrates the risks associated with combining insufficient sleep with extended shifts and outlines strategies to reduce fatigue-related errors.

Figure 1. Risks Associated With Various Combinations of Sleep Duration, Shift Duration, and Shift Time, and Strategies To Mitigate the Effects of Insufficient Sleep and Extended Work Shifts



Research Implications

More research is needed to understand the effects of fatigue on patient safety. Controlled trials are needed to determine optimal work schedules in hospital settings and test fatigue countermeasures. Since night shifts cannot be eliminated, the efficacy of fatigue countermeasures, naps during break periods, therapeutic use of caffeine, and other measures should be tested in hospital environments. Since the use of naps and caffeine have been shown to increased alertness during prolonged sleep deprivation and during night shift work, these measures should also be evaluated to determine if they would be effective for increasing alertness on day and evening shifts.

Finally, there is no information about the sleep of nurses working outside of hospital environments, and only limited information about the workhours of nurses in nursing homes and extended-care facilities. Nor is there any information about the sleep and performance of nurses who work 24-hour shifts (e.g., nurse-midwives and some advanced practice nurses) or who are

required to take call. These issues and others need to be examined to improve both the safety of patients and the nurses who care for them.

Although many questions remain unanswered, "We do know enough," according to L. G. Olson and A. Ambrogetti, "to end the worse abuses of the human sleep-wake cycle, and we need to see a shift by both hospital employers and the medical [nursing][*] profession towards addressing this issue"[206] (p. 416). The service regulations written during the first two decades of the 20th century recognized that people cannot work for long periods of time each day without adequate time to sleep. Eighty years later, at the beginning of the 21st century, it is perhaps time to acknowledge that nurses cannot provide safe care when they are fatigued, have worked for more than 12 consecutive hours, and/or have not had at least 12 to 16 hours off between shifts.

[*] Material in brackets added by author.

Table 5. Critical Research Questions

Research Question	Research Goal	Possible Study Methods
What is the optimal schedule for minimizing fatigue among hospital staff nurses? For nurses working in long-term care facilities?	To evaluate different types of schedules to determine which is the most effective for minimizing fatigue among hospital staff nurses and nurses working in long-term care facilities.	Controlled clinical trials of schedules involving different shift durations, number of consecutive days off, and types of shifts, e.g., night versus day shift.
Will the risk of making an error decrease if shifts are shortened to ≤ 10 hours and/or nurses get at least 7 hours sleep?	To determine if shorter work durations and obtaining adequate amounts of sleep reduce the risk of making an error.	Clinical trial, with one group assigned to shorter shifts, the second group assigned to obtain at least 7 hours sleep, and the third group assigned to work shorter shifts and obtain at least 7 hours sleep.
Since most nurses and managers favor 12-hour shifts despite their well-recognized hazards, how can the culture of individual nursing units be changed to discourage their use?	To determine what factors favor the continued use of 12-hour shifts and how to alter those factors to make shorter shifts more acceptable to staff nurses and nurse managers.	Qualitative approaches, in combination with rating scales to assess unit culture and institutional commitment to improving patient safety.
What differentiates those nurses who always obtain at least 6 hours sleep prior to working from those who fail to get at least 6 hours sleep prior to working?	To identify the characteristics of nurses who are most likely to obtain the minimum amount of sleep necessary to provide care safely.	Correlation studies and regression models.
Will fatigue countermeasures, e.g., naps during break periods and therapeutic use of caffeine, increase the alertness of nurses working at night? Decrease the risk of making an error?	To evaluate the efficacy of fatigue countermeasures for increasing the alertness and decreasing the risk of errors when nurses work at night.	Clinical trial comparing the alertness and risk of errors in night shift nurses assigned to fatigue countermeasures group to those who are not assigned to the intervention group.
Will fatigue countermeasures, e.g., naps during break periods and therapeutic use of caffeine, increase the alertness of nurses working 12-hour shifts? Decrease the risk of making an error?	To evaluate the efficacy of fatigue countermeasures for increasing the alertness and decreasing the risk of errors when nurses work 12-hour shifts	Clinical trial comparing the alertness and risk of errors of nurses working 12-hours shifts assigned to fatigue countermeasures group to those who are not assigned to the intervention group.
Should nurse midwives and other advanced practice nurses be allowed to work 24-hour shifts?	To determine if 24-hour shifts worked by nurse midwives and other advanced practice nurses are safe.	Observational study using methodology similar to that used to evaluate the safety of 24-hr shifts worked by critical care residents.

Conclusion

The evidence is overwhelming that nurses who work longer than 12 consecutive hours or work when they have not obtained sufficient sleep are putting their patients' health at risk; risk damaging their own health; and if they drive home when they are drowsy, also put the health of the general public at risk. Nurses, nurse managers, nursing administrators, and policymakers need to work together to change the culture that not only allows, but often encourages nurses to work long hours without obtaining sufficient sleep.

Key Terms and Definitions

Table 6. Key Definitions

Term	Definition
Insufficient sleep	A condition that results from sleeping less than needed. Healthy adults who obtain enough sleep do not require an alarm clock to awaken them in the morning, do not have difficulties with remaining alert after lunch or during a boring lecture, and do not sleep in on weekends.
Wrist actigraphy	Wristwatch-sized instrument used to record frequency and amplitude of wrist movements. Used to distinguish sleep from waking states.
Sleep debt	The difference between the amount of sleep you need and the amount you obtained. The larger the sleep debt, the more likely you are to fall asleep during the daytime.
Polysomnographic recorders	Recording equipment used to record sleep. Equipment records electroencephalograms (EEG), electro-oculograms (EOG), and electro-myograms (EMG) needed for staging sleep.
Shift work sleep disorder	A sleep disorder effecting individuals who work at night. Individuals with this disorder have difficulty remaining awake during their work shift and have trouble sleeping after working at night, yet have no trouble sleeping at night or staying awake during the day on their days off.

Search Strategy

Relevant papers for this review were identified from three databases (MEDLINE,® CINHAL,® and PsychLit) using the period 1990–2006. Several older, classical works were also cited. Hand searches were also performed examining journals such as the *Journal of Sleep Research and Sleep.* Only those papers that focused on the effects of chronic partial or total sleep deprivation for a single night, extended work shifts, and strategies to reduce fatigue-related errors and accidents were included in this review. Search terms included "caffeine," "chronic partial sleep deprivation," "fatigue," "fatigue countermeasures," "extended work shifts," "napping," "overtime," "performance," "resident physicians," "registered nurses," "rest breaks," "sleep loss," "sleep restriction," "staff nurses," "total sleep deprivation," and "vigilance."

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Evidence Table 1. Effects of Insufficient Sleep on Patient Safety and Health of Individuals

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Belenky 2003[161]	Chronic sleep restriction	Randomized controlled trial (2)	Randomized controlled trial (2) Vigilance, objective and subjective sleepiness (3)	69 healthy volunteers (16 women, 50 men) ages 24–62	Subjects' sleep restricted to 3 hr, 5 hr, 7 hr, or 9 hr/night for 7 nights	With mild to moderate sleep restriction (5–7 hr), performance initially declined then stabilized at levels below their baseline levels. With severe sleep restriction, performance continued to decline throughout the study period. There were no improvements in performance associated with increased sleep time (9 hr).
Harrison 1997[162]	One night's sleep loss	Randomized controlled trial (2)	Cross-over design (2), Verbal communication (3)	9 healthy college students		There was a significant reduction in word fluency, and subjects tended to become fixated within a particular semantic category. Speech was also more monotonic or flattened without appropriate intonation
Pilcher 1996[22]	Sleep loss	Meta-analysis (1)	Meta-analysis (1) Effects of sleep loss on cognition, motor performance, and mood (3)	19 studies and 1,932 participants		Sleep deprivation had more profound negative effects on mood than it did on cognition or motor performance. The effect sizes for partial sleep deprivation (≤ 5 hours sleep/night) on mood and cognitive function were larger than for long-term sleep deprivation 45 hours/week).

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Philibert 2005[150]	Sleep loss and cognitive function, memory and vigilance	Meta-analysis (1)	Meta-analysis (1) Effects of sleep loss among physicians on cognitive function, memory and vigilance (3)	60 studies published between 1971 and 2004 involving 959 physicians and 1,028 nonphysicians		Cognitive performance in physicians is affected by sleep deprivation. Smaller effect sizes in studies of physicians likely related to difficulty in controlling the exact number of hours sleep in field studies or the chronic sleep deprivation experienced by the "rested cohorts."
Phillip 2004[32]	One night's sleep loss	Randomized trial (2)	Cross-over design (2) Reaction time, subjective sleepiness and performance ratings (3)	10 younger (20–25 years) and 10 older (52–63 years) drivers		Reaction times were slower in older subjects without sleep deprivation; however, after sleep deprivation, the reaction times of older subjects remained unaffected, while the reaction times of younger subjects were significantly increased. Sleepiness and perception of performance were equally affected in both groups of subjects.
Ayas 2003 (a)[56]	Insufficient sleep	Time series (7)	Longitudinal study (3), self-reported sleep duration and risk of DM (1)	70,260 women ages 45–65 years who were enrolled in the Nurses Health Study		There was an elevated risk of developing DM among nurses who obtained less than 5 hours sleep/day or more than 9 hours sleep/day.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Gangwisch 2005[53]	Sleep restriction	Time series study (7)	Cross-sectional and longitudinal examination (4) of sleep duration and weight gain over a 10-year period (2)	Participants in the NHANES I study, 9,588 participants in the cross-sectional study and 6,981 participants in the longitudinal study		Subjects with sleep durations less than 7 hours at baseline (1982) were more likely to be obese 10 years later than subjects who obtained at least 7 hours sleep. Sleep durations greater than 7 hours were not consistently associated with either an increased or decreased risk of obesity.
Gottlieb 2005[168]	Chronic sleep restriction	Cross-sectional study (4)	Cross-sectional study (5) Usual sleep time, fasting glucose levels, blood glucose levels 2 hours glucose challenge (3)	Participants in the Sleep Heart Health Study (722 men and 764 women)		Sleep durations of ≤ 6 hours or > 9 hours were associated with increased prevalence of DM and impaired glucose tolerance
Kripke 2002[29]	Chronic sleep restriction	Cross-sectional study (4)	Survey (5) Participants were 30–100 years of age, sleep durations and morbidity and mortality rates over a 6-year period (1)	1.1 million participants from the American Cancer Society's Cancer Prevention II Study.		Mortality rates were highest among subjects who obtained ≥ 8-hr sleep or less than 3.5–4.5 hr. The lowest risks were found among those who obtained 7 hours sleep.
Singh 2005[54]	Sleep restriction	Cross-sectional study (4)	Survey (5), total sleep time in the 2 weeks prior to survey, and body mass index (BMI) (3)	3,158 randomly selected adults in the metropolitan area of Detroit, MI		Overall prevalence of obesity was 24.8% and significantly higher in those with lower amount s of sleep. After controlling for age, sex, loud snoring, hypertension, DM, arthritis, and alcohol intake, sleeping less than 6 hours greatly increased the risk of being obese.

Evidence Table 2. Extended Work Hours

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Arnedt 2005[174]	On-call schedules and performance	Nonrandomized trial (3)	Nonrandomized controlled trial (l3) 60-minute test battery consisting of sustained attention, vigilance, simulated driving performance, and self-reports of performance (3).	34 pediatric residents at a university hospital in the northeastern region of the U.S.	Residents tested in four conditions: (1) after a night of heavy call (on call every 4th to 5th night), (2) a night on a light call schedule (call is less frequent than heavy call), (3) after a night of light call and enough alcohol to obtain a blood alcohol level of 0.04–0.05, and (4) after a night of heavy call plus alcohol	Performance following a night of heavy call was quite similar to performance after drinking alcohol. Reaction times were slowed, errors of commission increased 40%, and lane variability and speed were significantly increased after a night of heavy call.
Fletcher 2004[169]	Number of hours worked	Systematic Review (11)	Literature review (6) Reviewed 7 studies between 1966 and 2004 related to reducing resident work hours. Outcomes included mortality, adverse events, and medication errors (1).			Research was not robust enough to reveal whether workhour limitations directly improve patient safety. None of studies involved clinical trials, and few used large databases or controlled for potential confounders.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Landrigan 2004[35]	Number of hours work	Nonrandomized trial (3)	Nonrandomized trial (3) Number of serious medical errors observed by trained observers in ICU (2), raters blinded to work schedules	20 critical care interns at large university teaching hospital	Traditional call scheduled with extended hours and every third night call, and a restricted schedule that reduced work shifts to 16 hours	Interns made 35.9% more serious medical errors during the traditional schedule than during the intervention schedule. Both the rate of serious medication errors and diagnostic errors were significantly increased during the traditional schedule compared to the intervention schedule.
Akerstedt 2002[178]	Number of hours worked, and overtime	Longitudinal, descriptive study (7)	Observational study with controls (4) Phone interviews, fatal occupational accidents (3)	47,860 Swedes interviewed over a 20-year period about issues related to work and health		There were 169 fatal occupational accidents. Predictors included male gender, difficulties sleeping in the past 2 weeks, and nonday work. Age, socio-economic status, overtime (>50 hr/week) or physically strenuous work did not increase the risk of a fatal occupational accident.
Dembe 2005[207]	Number of hours worked, overtime	Time series (7)	Survey (5), occurrence of injury (3)	10,793 Americans with a variety of occupations who participated in the National Longitudinal Survey of Youth between 1987 and 2000		Working a job with overtime was associated with a 61% higher injury rate compared to jobs without overtime. Working ≥12 hours per day was associated with a 37% increase in hazard rate, and 60 hr/week 23% increase in hazard rate. Injury rates increased in a dose-response fashion according to the number of hours per day (or week) that were worked. Injury rates were not affected by type of job or other factors such as gender.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Folkard 2003[83]	Work hours, shift work and safety	Meta-analysis (1)	Meta-analysis (1). Risks across different shifts, risks over successive shifts, risks over hours of duty, risk as a function of breaks (3)	26 studies		Risk of injury increases in a linear fashion across the shifts, with the lowest risk during the day shift and the highest risk at night. There was a slight increase in risk between 2 and 3 a.m., but effect was relatively small compared to substantial decrease in risk over most of night. Risks increased across successive shifts, e.g., risk was 6% higher on second night, 17% higher on 3rd night, and 36% higher on 4th night. Risks increased in exponential fashion after 8th hour of work, and during the 12th hour was double that during the first 8 hours. Risks of injury rose substantially between successive breaks, and that risk had doubled by the last 30-minute period before the next break. (This phenomenon occurred on all three shifts and during each 2-hour period between breaks.)
Sparks 2003[208]	Weekly workhours, ill health	Meta-analysis (1)	Meta-analysis (1) Weekly workhours, health problems (3)	21 studies		There was a mean correlation of 0.13 between weekly workhours and ill health.
Van der Hulst 2003[79]	Long work hours and health	Systematic literature review (1)	Systematic literature review (1) workhours, adverse health effects (3)	27 empirical studies		Long workhours were associated with adverse health effects (cardiovascular disease, DM, disability retirement, physiological changes, and health-related behavior).
Yang 2006[80]	Long workhours and hypertension	Cross-sectional study (4)	Survey (4), workhours/week and hypertension	24,205 working adults living in California		After controlling for age and other health and lifestyle factors, individuals working more than 50 hours/week had a 1.29 times the risk of developing hypertension than those working 15–39 hours.

Evidence Table 3. Fatigue Countermeasures

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Smith-Coggins 1997[116]	Maintenance of vigilance, fatigue countermeasures program	Nonrandomized controlled trial (3)	Nonrandomized controlled trial (3) Ambulatory polysomnography recordings during main sleep period, daily performance testing, and daily subjective ratings of sleep, mood, and intervention use (3) Tested on both day and night shifts.	6 emergency room physicians	Measures obtained at baseline, after a placebo intervention, and after the implementation of a fatigue countermeasures program	Increased subjective alertness reported after 1 month, but there were no improvements in performance, mood, or the amount of sleep obtained when working night shift.
Lilley 2002[133]	Fatigue, accidents and rest breaks	Noncomparative study (8)	Survey (5) Payment method, ethnicity, injury, fatigue, sleep duration, work duration, breaks and their duration (3)	367 logging and silviculture workers in New Zeeland		Presence or absence of breaks did not affect fatigue, but was associated with few injuries.
Neri 2002[129]	Maintenance of Vigilance, rest breaks	Randomized controlled trial (2)	Randomized controlled trial (2) Continuous recordings of EEG, subjective ratings of sleepiness, psychomotor vigilance testing (reaction time) (3)	28 pilots, flight simulator	Treatment group received 5 short breaks spaced hourly during flight, control group received 1 break in middle of simulated night flight	The short breaks reduced both objective and subjective sleepiness for at least 15 minutes postbreak and perhaps up to 25 minutes.
Rogers 2004[126]	Errors and rest breaks	Noncomparative study (8)	Survey (5) Daily reports of break duration, patient care responsibilities during break and meal periods, errors and near errors (3)	393 randomly selected full-time hospital staff nurses		No significant difference in number of errors reported by nurses who were relieved of patient care responsibilities during shift and those who were not. Mean duration of break and meal period during shift was 23.8 minutes. Shift duration did not effect duration of breaks and meal periods during the shift.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Tucker 2003[131]	Injuries and rest breaks	Noncomparative study (8)	Retospective analysis of accident data over a 3-year period (4), number of injuries in each 30-minute interval that preceded a break (every 2 hours) (3)	1,954 employees at an auto assembly plant in the UK		Risk of injury rose in each 30-minute period (n = 4) preceding each scheduled break, then decreased to baseline during the first 30-minute period after the break.
Driskell & Mullen, 2005[209]	Use of napping to improve performance and reduce fatigue	Meta-analysis (1)	Meta-analysis (1) Evaluated the effect of naps on performance, the effect of the nap duration, the effect of the postnap interval (3)	12 studies		Naps improved performance and reduced fatigue. There were no circadian effects on performance and fatigue.
Gillberg 1996[184]	Maintenance of vigilance, napping during work period	Randomized controlled trial (2)	Randomized controlled trial (2) Performance measures, reaction-time tests, and EEG/EOG recordings before, during, and after drive (3)	9 sleep-deprived truck drivers, driving simulator	Subjects assigned to one of three conditions: (1) day drive of 90 min, (2) night driving with 30-min rest period, and (3) night drive with 30-min nap	Effects on driving were small but significant, with a higher variability of sleep and lane positioning. Subjective and objective sleepiness were higher in the night driving conditions. Neither the nap nor the rest period affected performance or sleepiness.
Gillberg 1996[210]	Maintenance of vigilance, napping during daytime	Randomized controlled trial (2)	Randomized controlled trial (2) Cross-over repeated measures design. Karolinska Sleepiness Scale, visual performance task, and continuous EEG/EOG recordings (3)	8 healthy young males, laboratory setting	Sleep restricted to 4 hours at night, randomly assigned to either nap (20 min during mid-day) or no nap condition	Nap decreased subjective sleepiness, improved performance during test period 30 minutes after the nap.
Harma 1989[203]	Maintenance of vigilance, napping prior to shift	Noncomparative study (8)	Survey (5) Individual characteristics, short-term memory, alertness (3)	146 nurses and nursing assistants		Participants who took a nap prior to starting their night shift were less likely to report on-the-job fatigue.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Purnell 2002[134]	Maintenance of Vigilance, napping during night shift	Randomized controlled trial (2)	Randomized controlled trial (2), counterbalanced cross-over design, performance on neurobehavioral test battery, subjective fatigue, drowsiness driving home after a 12-hour night shift (3)	Worksite in New Zealand, 24 male aircraft maintenance engineers	During experimental week, subjects were given an opportunity to take a 20-minute nap at work between 1 and 3 a.m.; were not allowed opportunity to nap during control week.	20-minute nap significantly improved speed of response on vigilance test on first night shift, but not second night shift. Subjective fatigue ratings, level of sleepiness reported during drive home from work, or subsequent sleep duration and quality.
Rosekind 1994[140]	Maintenance of vigilance, napping during work shift	Randomized controlled trial (2)	Randomized controlled trial (2) vigilance performance testing, ambulatory physiological monitoring of sleepiness (3)	Regularly scheduled trans-Pacific airline flights	Intervention group allowed to take a 40-minute planned nap during cruise over water; control group not allowed a nap	Mean nap duration was 27 minutes. Fewer lapses in vigilance performance in nap group compared to no-nap group, fewer micro-sleep events (34 compared to 120 in the no-nap group), no micro-sleep events during last 30 minutes of flight or when landing compared to 27 micro-sleep events during the last 30 minutes of flight and landing from the no-nap group. Longer naps produced longer periods of alertness. Sleep inertia was not observed in the 1-hour period after the nap.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Sallinen 1998[138]	Maintenance of Vigilance, napping during night shift	Randomized controlled trial (2)	Randomized controlled trial (2), efficacy of naps during night shift evaluated using visual reaction times, subjective ratings of sleepiness, and physiological sleepiness (3)	14 experienced male shift workers, simulated work shift in laboratory	Subjects randomly assigned to take either a 30-minute or 50-minute nap at 1 a.m. or 4 a.m. Control condition was a shift without a nap.	Naps improved ability to respond to visual signals early in second half of night shift. Physiological sleepiness was improved by the nap at 1 a.m., but not the nap at 4 a.m. Subjective sleepiness somewhat decreased by the naps. Sleep inertia lasted approximately 10–15 minutes.
Bonnet 2005[211]	Maintenance of vigilance, sleep restriction, and use of stimulants	Systematic literature review (11)	High-quality systematic literature review (1) related to the safety and efficacy of five different stimulants	239 papers, most were double-blind clinical trials		Recommend caffeine as initial stimulant of choice due to its availability in multiple forms, widespread use, limited abuse potential, and little impact on sleep several hours later.
De Valck 2001[144]	Maintenance of vigilance, slow-release caffeine	Randomized controlled trial (2)	Randomized controlled trial (2) Cross-over design with sleep restricted subjects (4.5 hours of 7.5 hours time in bed) completed a 45-minute driving task, POMS, and Stanford Sleepiness Scale (3)	12 subjects ages 20–25 years, driving simulator	Subjects randomly assigned to take 300 mg sustained-release caffeine tablet or placebo after 4 hours sleep	Caffeine intake reduced lane drifting, speed deviations, and accident liability. Sleep loss produced significant impairments in driving ability.
De Valck 2003[147]	Maintenance of vigilance, slow-release caffeine, and a nap	Randomized controlled trial (2)	Randomized controlled trial (2) Cross-over design with sleep restricted subjects (4.5 hours of 7.5 hours time in bed) completed a 45-minute driving task, POMS, and Stanford Sleepiness Scale (3)	12 subjects ages 20–25 years, driving simulator	Subjects randomly assigned to take a 30-minute nap, 300 mg slow-release caffeine tablet, or placebo after 4 hours sleep	Both the 30-minute nap and caffeine were successful in counteracting driver sleepiness. Effect of slow-release caffeine lasted longer than the effects of the 30-min nap.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Gill 2006[152]	Maintenance of vigilance, modafinil	Randomized controlled trial (2)	Randomized controlled trial (2) Cognitive performance, subjective alertness on night shift (3)	25 emergency room physicians	Cross-over design used, all subjects randomly assigned to either modafinil or placebo group. After a 2-week washout period, received either placebo or modafinil.	Although modafinil improved subjective alertness and certain aspects of cognitive function, it made it more difficult fall asleep when arrived home.
Schweitzer 2006[146]	Maintenance of vigilance, napping, and caffeine	Randomized controlled trial (2)	Randomized controlled trial (2) tests the efficacy of napping, caffeine, and the combination of napping and caffeine in laboratory study. Cross-over design (2) for field portion of study. Outcomes included maintenance of wakefulness testing and psychomotor vigilance task (3)	Laboratory study 68 healthy individuals, field study, 53 shift workers (nights and evening shift)	Laboratory study included the following treatments: (1) an evening nap before the first 2 of 4 night shifts, plus placebo; (2) caffeine taken nightly; and (3) the combination of evening naps and caffeine. Field study tested subjects in both of the following conditions: (1) an evening nap prior to the first two of 4 night shifts, plus caffeine taken nightly; and (2) no placebo and no nap group.	Laboratory study—all interventions alone and in combination improved alertness and performance. The combination of napping and caffeine was more effective than individual interventions. Field study—napping plus caffeine improved alertness and performance.

Source	Safety Issued Related to Clinical Practice	Design Type	Study Design, Study Outcome Measures	Study Setting & Study Population	Study Intervention	Key Finding
Wesensten 2005[148]	Maintenance of vigilance, caffeine, dextroamphetamine and modafinil during prolonged sleep deprivation	Randomized trial (2)	Randomized trial (2) Performance testing, Stanford Sleepiness Scale, modified Maintenance of Wakefulness Test, and test of executive functioning	48 healthy young adults, laboratory	Subjects sleep deprived for 85 hour then given 600 mg caffeine, dextro-amphetamine 20 mg, modafinil 400 mg or placebo	Caffeine, dextroamphetamine, and modafinil were equally efficacious for restoring and maintaining cognitive function and alertness during 85 hours of sleep deprivation.
LeDuc 2000[160]	Maintenance of vigilance, exercise	Randomized trial (2)	Randomized trial (2), cognitive testing, subjective alertness, mood, performance testing, and maintenance of vigilance testing (3)	12 aviators	Subjects sleep deprived then assigned to the rest condition (10 minutes) or exercise condition	No beneficial effects from 10-minute rest. Exercise produced transient improvements in alertness (30–50 minutes), but after 50 minutes evidence of increased drowsiness on EEG.

Chapter 41. Preventing Health Care–Associated Infections

Amy S. Collins

Background

The occurrence and undesirable complications from health care–associated infections (HAIs) have been well recognized in the literature for the last several decades. The occurrence of HAIs continues to escalate at an alarming rate. HAIs originally referred to those infections associated with admission in an acute-care hospital (formerly called a nosocomial infection), but the term now applies to infections acquired in the continuum of settings where persons receive health care (e.g., long-term care, home care, ambulatory care). These unanticipated infections develop during the course of health care treatment and result in significant patient illnesses and deaths (morbidity and mortality); prolong the duration of hospital stays; and necessitate additional diagnostic and therapeutic interventions, which generate added costs to those already incurred by the patient's underlying disease. HAIs are considered an undesirable outcome, and as some are preventable, they are considered an indicator of the quality of patient care, an adverse event, and a patient safety issue.

Patient safety studies published in 1991 reveal the most frequent types of adverse events affecting hospitalized patients are adverse drug events, nosocomial infections, and surgical complications.[1, 2] From these and other studies, the Institute of Medicine reported that adverse events affect approximately 2 million patients each year in the United States, resulting in 90,000 deaths and an estimated $4.5–5.7 billion per year in additional costs for patient care.[3] Recent changes in medical management settings have shifted more medical treatment and services to outpatient settings; fewer patients are admitted to hospitals. The disturbing fact is that the average duration of inpatient admissions has decreased while the frequency of HAIs has increased.[4, 5] The true incidence of HAIs is likely to be underestimated as hospital stays may be shorter than the incubation period of the infecting microorganism (a developing infection), and symptoms may not manifest until days after patient discharge. For example, between 12 percent and 84 percent of surgical site infections are detected after patients are discharged from the hospital, and most become evident within 21 days after the surgical operation.[6, 7] Patients receiving followup care or routine care after a hospitalization may seek care in a nonacute care facility. The reporting systems are not as well networked as those in acute care facilities, and reporting mechanisms are not directly linked back to the acute care setting to document the suspected origin of some infections.

Since the early 1980s HAI surveillance has monitored ongoing trends of infection in health care facilities.[8] With the application of published evidence-based infection control strategies, a decreasing trend in certain intensive care unit (ICU) health care-associated infections has been reported through national infection control surveillance[9] over the last 10 years, although there has also been an alarming increase of microorganism isolates with antimicrobial resistance. These changing trends can be influenced by factors such as increasing inpatient acuity of illness, inadequate nurse-patient staffing ratios, unavailability of system resources, and other demands that have challenged health care providers to consistently apply evidence-based recommendations to maximize prevention efforts. Despite these demands on health care workers

and resources, reducing preventable HAIs remains an imperative mission and is a continuous opportunity to improve and maximize patient safety.

Another factor emerging to motivate health care facilities to maximize HAI prevention efforts is the growing public pressure on State legislators to enact laws requiring hospitals to disclose hospital-specific morbidity and mortality rates. A recent Institute of Medicine report identified HAIs as a patient safety concern and recommended immediate and strong mandatory reporting of other adverse health events, suggesting that public monitoring may hold health care facilities more accountable to improve the quality of medical care and to reduce the incidence of infections.[3] Since 2002, four States (Florida, Illinois, Missouri, and Pennsylvania) set legislation mandating health care organizations to publicly disclose HAIs.[10, 11] In 2006, the Association for Professionals in Infection Control and Epidemiology (APIC) reported that 14 States have mandatory public reporting, and 27 States have other related legislation under consideration.[12] Participation in public reporting has not been regulated by the Federal sector at this time. Some hospital reporting is intended for use solely by the State health department for generating confidential reports that are returned to each facility for their internal quality improvement efforts. Other intentions to utilize public reporting may be aimed at comparing rates of HAI and subsequent morbidity and mortality outcomes between different hospitals. This approach is problematic as there is currently a lack of scientifically validated methods for risk adjusting multiple variations (e.g., differences in severity of illnesses in each population being treated) in patients' intrinsic and extrinsic risks for HAIs.[13–15] Moreover, data on whether public reporting systems have an effective role in reducing HAIs are lacking.

To assist with generating meaningful data, process and outcome measures for patient safety practices have been proposed.[13, 14, 16] Monitoring both process and outcome measures and assessing their correlation is a model approach to establish that good processes lead to good health care outcomes. Process measures should reflect common practices, apply to a variety of health care settings, and have appropriate inclusion and exclusion criteria. Examples include insertion practices for central intravenous catheters, appropriate timing of antibiotic prophylaxis in surgical patients, and rates of influenza vaccination for health care workers and patients. Outcome measures should be chosen based on the frequency, severity, and preventability of the outcome events. Examples include intravascular catheter-related blood stream infection rates and surgical-site infections in selected operations. Although these occur at relatively low frequency, the severity is high—these infections are associated with substantial morbidity, mortality, and excess health care costs—and there are evidence-based prevention strategies available.[17, 18]

Definitions of Health Care-Associated Infections

The Centers for Disease Control and Prevention (CDC) developed baseline definitions for HAIs that were republished in 2004.[19] HAIs were defined as those that develop during hospitalization but are neither present nor incubating upon the patient's admission to the hospital; generally for those infections that occur more than 48 to 72 hours after admission and within 10 days after hospital discharge. Some hospitals use these definitions exactly as written; other hospitals may use some but not all of the CDC definitions; and other health care facilities may need to modify or develop their own definitions. Whatever definition is used, it should be consistent within the institution and be the same or similar to those developed by CDC or those used by other investigators. Having standard definitions is useful if the health care facility wants

to compare surveillance results or performance measures within its various medical/surgical specialties, against those of other health care institutions, or with national published data.

Patient Risk Factors for Health Care–Associated Infections

Transmission of infection within a health care setting requires three elements: a source of infecting microorganisms, a susceptible host, and a means of transmission for the microorganism to the host.

Source of Microorganisms

During the delivery of health care, patients can be exposed to a variety of exogenous microorganisms (bacteria, viruses, fungi, and protozoa) from other patients, health care personnel, or visitors. Other reservoirs include the patient's endogenous flora (e.g., residual bacteria residing on the patient's skin, mucous membranes, gastrointestinal tract, or respiratory tract) which may be difficult to suppress and inanimate environmental surfaces or objects that have become contaminated (e.g., patient room touch surfaces, equipment, medications). The most common sources of infectious agents causing HAI, described in a scientific review of 1,022 outbreak investigations,[20] are (listed in decreasing frequency) the individual patient, medical equipment or devices, the hospital environment, the health care personnel, contaminated drugs, contaminated food, and contaminated patient care equipment.

Host Susceptibility

Patients have varying susceptibility to develop an infection after exposure to a pathogenic organism. Some people have innate protective mechanisms and will never develop symptomatic disease because they can resist increasing microbial growth or have immunity to specific microbial virulence properties. Others exposed to the same microorganism may establish a commensal relationship and retain the organisms as an asymptomatic carrier (colonization) or develop an active disease process.

Intrinsic risk factors predispose patients to HAIs. The higher likelihood of infection is reflected in vulnerable patients who are immunocompromised because of age (neonate, elderly), underlying diseases, severity of illness, immunosuppressive medications, or medical/surgical treatments. Patients with alterations in cellular immune function, cellular phagocytosis, or humoral immune response are at increased risk of infection and the ability to combat infection. A person with a primary immunodeficiency (e.g., anemia or autoimmune disease) is likely to have frequently recurring infections or more severe infections, such as recurrent pneumonia.[21] Secondary immunodeficiencies (e.g., chemotherapy, corticosteroids, diabetes, leukemia) increase patient susceptibility to infection from common, less virulent pathogenic bacteria, opportunistic fungi, and viruses. Considering the severity of a patient's illness in combination with multiple risk factors, it is not unexpected that the highest infection rates are in ICU patients. HAI rates in adult and pediatric ICUs are approximately three times higher than elsewhere in hospitals.[22]

Extrinsic risk factors include surgical or other invasive procedures, diagnostic or therapeutic interventions (e.g., invasive devices, implanted foreign bodies, organ transplantations, immunosuppressive medications), and personnel exposures. According to one review article, at least 90 percent of infections were associated with invasive devices.[23] Invasive medical devices bypass the normal defense mechanism of the skin or mucous membranes and provide foci where

pathogens can flourish, internally shielded from the patient's immune defenses. In addition to providing a portal of entry for microbial colonization or infection, these devices also facilitate transfer of pathogens from one part of the patient's body to another, from health care worker to patient, or from patient to health care worker to patient. Infection risk associated with these extrinsic factors can be decreased with the knowledge and application of evidence-based infection control practices. These will be discussed in further detail in Chapter 42, "Targeting Health Care–Associated Infections: Evidence-Based Strategies."

Prolonged hospitalization, due to a higher acuity of illness, contributes to host susceptibility as there is more opportunity to utilize invasive devices and more time for exposure to exogenous microorganisms. These patients are also more susceptible to rapid microbial colonization as a consequence of the severity of the underlying disease, depending on the function of host defenses and the presence of risk factors (e.g., age, extrinsic devices, extended length of stay). Exposure to these colonizing microorganisms is from such sources as (1) endemic pathogens from an endogenous source, (2) hospital flora in the health care environment, and (3) hands of health care workers. A study related to length of hospitalization examining adverse events in medical care indicated that the likelihood of experiencing an adverse event increased approximately 6 percent for each day of hospital stay. The highest proportion of adverse events (29.3 percent) was not related to surgical procedures but linked instead to the subsequent monitoring and daily care lacking proper antisepsis steps.[24]

Means of Transmission

Among patients and health care personnel, microorganisms are spread to others through four common routes of transmission: contact (direct and indirect), respiratory droplets, airborne spread, and common vehicle. Vectorborne transmissions (from mosquitoes, fleas, and other vermin) are atypical routes in U.S. hospitals and will not be covered in this text.

Contact transmission. This is the most important and frequent mode of transmission in the health care setting. Organisms are transferred through direct contact between an infected or colonized patient and a susceptible health care worker or another person. Patient organisms can be transiently transferred to the intact skin of a health care worker (not causing infection) and then transferred to a susceptible patient who develops an infection from that organism—this demonstrates an indirect contact route of transmission from one patient to another. An infected patient touching and contaminating a doorknob, which is subsequently touched by a health care worker and carried to another patient, is another example of indirect contact. Microorganisms that can be spread by contact include those associated with impetigo, abscess, diarrheal diseases, scabies, and antibiotic-resistant organisms (e.g., methicillin-resistant *Staphylococcus aureus* [MRSA] and vancomycin-resistant enterococci [VRE]).

Respiratory droplets. Droplet-size body fluids containing microorganisms can be generated during coughing, sneezing, talking, suctioning, and bronchoscopy. They are propelled a short distance before settling quickly onto a surface. They can cause infection by being deposited directly onto a susceptible person's mucosal surface (e.g., conjunctivae, mouth, or nose) or onto nearby environmental surfaces, which can then be touched by a susceptible person who autoinoculates their own mucosal surface. Examples of diseases where microorganisms can be spread by droplet transmission are pharyngitis, meningitis, and pneumonia.

Airborne spread. When small-particle-size microorganisms (e.g., tubercle bacilli, varicella, and rubeola virus) remain suspended in the air for long periods of time, they can spread to other people. The CDC has described an approach to reduce transmission of microorganisms through

airborne spread in its *Guideline for Isolation Precautions in Hospitals.*[25] Proper use of personal protective equipment (e.g., gloves, masks, gowns), aseptic technique, hand hygiene, and environmental infection control measures are primary methods to protect the patient from transmission of microorganisms from another patient and from the health care worker. Personal protective equipment also protects the health care worker from exposure to microorganisms in the health care setting.

Common Vehicle. Common vehicle (common source) transmission applies when multiple people are exposed to and become ill from a common inanimate vehicle of contaminated food, water, medications, solutions, devices, or equipment. Bacteria can multiply in a common vehicle but viral replication can not occur. Examples include improperly processed food items that become contaminated with bacteria, waterborne shigellosis, bacteremia resulting from use of intravenous fluids contaminated with a gram-negative organism, contaminated multi-dose medication vials, or contaminated bronchoscopes. Common vehicle transmission is likely associated with a unique outbreak setting and will not be discussed further in this document.

Responsibility for Risk Reduction

Infection Control Department's Program Responsibilities

In 1985, the Study of the Efficacy of Nosocomial Infection Control (SENIC) project was published, validating the cost-benefit savings of infection control programs.[8] Infection control programs were proven to be effective as hospitals with certain practices reduced their infection rates by 32 percent, compared with an *increase* of 18 percent in hospitals without these components over a 5-year period.[8, 26] Essential components of effective infection control programs included conducting organized surveillance and control activities, a trained infection control physician, an infection control nurse for every 250 beds, and a process for feedback of infection rates to clinical care staff. These programmatic components have remained consistent over time and are adopted in the infection control standards of the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCAHO). The evolving responsibility for operating and maintaining a facility-wide effective infection control program lies within many domains. Both hospital administrators and health care workers are tasked to demonstrate effectiveness of infection control programs, assure adequate staff training in infection control, assure that surveillance results are linked to performance measurement improvements, evaluate changing priorities based on ongoing risk assessments, ensure adequate numbers of competent infection control practitioners, and perform program evaluations using quality improvement tools as indicated.

Infection Control Personnel

It has been demonstrated that infection control personnel play an important role in preventing patient and health care worker infections and preventing medical errors. An infection control practitioner[27] (ICP) is typically assigned to perform ongoing surveillance of infections for specific wards, calculate infection rates and report these data to essential personnel, perform staff education and training, respond to and implement outbreak control measures, and consult on employee health issues. This specialty practitioner gains expertise through education involving infection surveillance, infection control, and epidemiology from current scientific publications

and basic training courses offered by professional organizations or health care institutions.[28, 29] The Certification Board of Infection Control offers certification that an ICP has the standard core set of knowledge in infection control.[30, 31, 32]

Over time, the workload responsibilities of the ICP have significantly increased to encompass additional administrative functions and regulatory compliance reporting, sometimes covering prevention of infection activities in other facilities that belong to the health care system (e.g., long-term care, home care, and outpatient settings). The expanding scope of ICP responsibilities being performed with limited time and shrinking resources has created an imbalance in meeting all tasks, leading to regular completion of only essential functions and completing less essential functions when time permits. In a 2002 ICP survey examining resource allocations, the activity consuming the greatest amount of mean estimated time was surveillance, followed by education, prevention strategies to control transmission, infection control program communication, and outbreak control. In examining the tasks and the time allocations necessary to complete essential infection control responsibilities, a recent expert review panel recommended new and safer staffing allocations: 1 full-time ICP for every 100 occupied beds. Further staffing levels and recommendations are included for different types of health care facilities by bed size.[33] To maximize successful completion of current reporting requirements and strategies for the prevention of infection and other adverse events associated with the delivery of health care in the entire spectrum of health care settings, infection control personnel and departments must be expanded.[34]

Nursing Responsibilities

Clinical care staff and other health care workers are the frontline defense for applying daily infection control practices to prevent infections and transmission of organisms to other patients. Although training in preventing bloodborne pathogen exposures is required annually by the Occupational Safety and Health Administration, clinical nurses (registered nurses, licensed practical nurses, and certified nursing assistants) and other health care staff should receive additional infection control training and periodic evaluations of aseptic care as a planned patient safety activity. Nurses have the unique opportunity to directly reduce health care–associated infections through recognizing and applying evidence-based procedures to prevent HAIs among patients and protecting the health of the staff. Clinical care nurses directly prevent infections by performing, monitoring, and assuring compliance with aseptic work practices; providing knowledgeable collaborative oversight on environmental decontamination to prevent transmission of microorganisms from patient to patient; and serve as the primary resource to identify and refer ill visitors or staff.

Prevention Strategies

Multiple factors influence the development of HAIs, including patient variables (e.g., acuity of illness and overall health status), patient care variables (e.g., antibiotic use, invasive medical device use), administrative variables (e.g., ratio of nurses to patients, level of nurse education, permanent or temporary/float nurse), and variable use of aseptic techniques by health care staff. Although HAIs are commonly attributed to patient variables and provider care, researchers have also demonstrated that other institutional influences may contribute to adverse outcomes.[35, 36] To encompass overall prevention efforts, a list of strategies are reviewed that apply to the clinical

practice of an individual health care worker as well as institutional supportive measures. Adherence to these principles will demonstrate that you H.E.L.P. C.A.R.E. This acronym is used to introduce the following key concepts to reduce the incidence of health care–associated infections. It emphasizes the compassion and dedication of nurses where their efforts contribute to reduce morbidity and mortality from health care–associated infections.

Hand Hygiene

…so they shall wash their hands and their feet, that they die not:
and it shall be a statute for ever to them…
Exodus 30:21 Revised Standard Version

Overview. For the last 160 years, we have had the scientific knowledge of how to reduce hand contamination and thereby decrease patient infections from the seminal work on hand washing by the Hungarian obstetrician, Ignaz Semmelweis. Epidemiologic studies continue to demonstrate the favorable cost-benefit ratio and positive effects of simple hand washing for preventing transmission of pathogens in health care facilities.[37, 38] The use of antiseptic hand soaps (i.e., ones containing chlorhexidine) and alcohol-based hand rubs also effectively reduce bacterial counts on hands when used properly. Even though the clear benefits of hand washing have been proven in multiple settings, the lack of consistent hand-washing practices remains a worldwide issue. In a resource-poor area of Pakistan, a recent household hand-washing campaign demonstrated a 50 percent lower incidence of pneumonia in children younger than 5 years compared to households that did not practice hand washing. Children under 15 years in hand-washing households had a 53 percent lower incidence of diarrhea and a 34 percent lower incidence of impetigo. Hand washing with plain soap prevented the majority of illnesses causing the largest number of childhood deaths globally.[39] The World Alliance for Patient Safety, formed by the World Health Organization, has adopted infection reduction programs—in both developed and developing countries—as its first goal.[40, 41] The World Alliance for Patient Safety advocates a "clean care is safer care" program, in which health care leaders sign a pledge to take specific steps to reduce HAIs in their facilities. Hand hygiene is the first focus in this worldwide initiative.

Understaffing and hand hygiene. Hospitals with low nurse staffing levels and patient overcrowding leading to poor adherence to hand hygiene have been associated with higher adverse outcome rates and hospital outbreak investigations.[34, 42, 43] In an ICU setting,[44] it was demonstrated that understaffing of nurses can facilitate the spread of MRSA through relaxed attention to basic infection control measures (e.g., hand hygiene). In a neonatal ICU outbreak,[45] the daily census was above the maximum capacity (25 neonates in a unit designed for 15), and the number of assigned staff members was fewer than the number necessitated by the workload, which resulted in relaxed attention to basic infection-control measures (use of multidose vials and hand hygiene). During the highest workload demands, staff washed their hands before contacting devices only 25 percent of the time, but hand washing increased to 70 percent after the end of the understaffing and overcrowding period. Ongoing surveillance determined that being hospitalized during this period was associated with a fourfold increased risk of acquiring an HAI. These studies illustrate an association between staffing workload, infections, and microbial transmission from poor adherence to hand hygiene policies.

Time demands. A perceived obstacle is that time to complete patient care duties competes with time needed for hand washing, particularly in technically intense settings such as an ICU. Hospital observational studies demonstrate that the frequency of hand washing varies between

hospital wards and occurs an average of 5 to 30 times per shift, with more hand washing opportunities in an ICU.[46] With time limitations due to patient acuity demands or nurse-patient ratios and limited availability of sinks, the use of waterless, alcohol-based hand rubs has been shown to improve health care workers' compliance with hand hygiene practices in the ICU.[47]

Hand washing behaviors. Observational studies have found that on average, health care workers adhere to recommended hand hygiene procedures 40 percent of the time (with a range of 5 to 80 percent).[44] These studies implemented various interventions to improve hand washing, but summarized effects by measuring responses over a short time frame, without demonstrating long-lasting behavioral improvements. Two studies demonstrated the use of multidisciplinary interventions to change the organizational culture on frequency of hand washing that resulted in sustained improvements during a longer followup time period.[48, 49]

Behavioral theories that examine the relationship of multiple factors affecting behavioral choices have been applied to the complex issue of hand washing compliance. These theories illustrate the influence of the individual *intention* to perform hand washing and organizational influences that affect the outcome behavior. The Theory of Planned Behavior has been studied in this context, acknowledging that the intention to wash hands involves a person's (1) attitude whether or not the behavior is beneficial to themselves, (2) perception of pressure from peers, and (3) perceived control on the ease or difficulty in performing the behavior.[50–53] These perceptions are also influenced by the strength of the person's beliefs about the significance of the outcomes of the behavior; the normative beliefs, which involve the individual evaluation of peer expectations; and control beliefs, which are based on a person's perception of their ability to overcome obstacles that obstruct their completion of the behavior.

Monitoring compliance. Although standards for hand hygiene practices have been published with an evidence-based guideline[44] and professional collaborations have produced the *How-to-Guide: Improving Hand Hygiene,*[54] there is no standardized method or tool for measuring adherence to institutional policy. Varying quality improvement methodologies and a lack of consensus on how to measure hand hygiene compliance have made it difficult to determine the effectiveness of hand hygiene expectations within and across health care settings. The Joint Commission has instituted a partnership with major infection control leadership organizations in the United States and abroad to identify best approaches for measuring compliance with hand hygiene guidelines in health care organizations though its Consensus Measurement in Hand Hygiene (CMHH) project. The participating organizations include APIC, CDC, the Society for Healthcare Epidemiology of America, the World Health Organization World Alliance for Patient Safety, the Institute for Healthcare Improvement, and the National Foundation for Infectious Diseases. The final product of this project, due to be completed in early 2008, will be an educational monograph that recommends best practices for measuring hand hygiene compliance.[55]

Summary. Hand hygiene adherence and promotion involve multiple factors at the individual and system level to provide an institutional safety climate for patients and health care staff. Methods used to promote improved hand hygiene require multidisciplinary participation to identify individual beliefs, adherence factors, and perceived barriers. Program successes have been summarized and should be reviewed to establish improved hand hygiene as a priority program at your facility.[44, 56, 57]

Hand Hygiene: Key Points

- The practice of appropriate hand hygiene and glove usage is a major contributor to patient safety and reduction in HAIs. It is more cost effective than the treatment costs involved in a health care–associated infection.
- Joint Commission infection control standards include hand washing and HAI sentinel event review, which are applicable to ambulatory care, behavioral health care, home care, hospitals, laboratories, and long-term care organizations accredited by the Joint Commission.
- Hand hygiene is the responsibility of the individual practitioner and the institution. Developing a patient safety culture backed by administrative support to provide resources and incentives for hand washing is crucial to a successful outcome.
- Hand hygiene promotion should be an institutional priority.
- Select methods to promote and monitor improved hand hygiene. Monitor outcomes of adherence to hand hygiene in association with reduced incidence of HAI.
- Establish an evaluation model to recognize missed opportunities for appropriate hand hygiene.

Environmental Cleanliness

The health care environment surrounding a patient contains a diverse population of pathogenic microorganisms that arise from a patient's normal, intact skin or from infected wounds. Approximately 10^6 flat, keratinized, dead squamous epithelium cells containing microorganisms are shed daily from normal skin,[58] and patient gowns, bed linens, and bedside furniture can easily become contaminated with patient flora. Surfaces in the patient care setting can also be contaminated with pathogenic organisms (e.g., from a patient colonized or infected with MRSA, VRE, or *Clostridium difficile*) and can harbor viable organisms for several days. Contaminated surfaces, such as blood pressure cuffs, nursing uniforms, faucets, and computer keyboards,[59, 60] can serve as reservoirs of health care pathogens and vectors for cross-contamination to patients. Studies have demonstrated that health care workers acquire microorganisms on gloved hands without performing direct patient contact and when touching surfaces near a colonized patient.[59, 61] Another study determined that a health care worker's hand became contaminated after entering a regular patient's room (one who was not on contact precautions) and only touching common surfaces close to the patient (bed rails, bedside table), without direct patient contact. The same hand contact was done by other personnel in unoccupied rooms that had been terminally cleaned after patient discharge. Ungloved hands became contaminated with low levels of pathogenic microorganisms more than 50 percent of the time, even from surfaces in rooms that had been terminally cleaned after patient discharge.[62] It is important to consider this likelihood of hand contamination could occur (contamination would also apply to the external surface of gloves, if worn) and to perform routine hand hygiene to bare hands or ungloved hands to reduce hand contamination before touching clean**,** general-use surfaces (e.g., computer keyboard, telephone, med cart, medical record, cleaning supplies, etc.). Proper disinfection of common surfaces and proper hand hygiene procedures (after direct contact to surfaces or contact with glove usage) is also critically important to reduce direct or indirect routes of transmission.[63] Persistence of environmental contamination after room disinfection can occur and has been recently demonstrated to increase the risk of transmission to the next susceptible room occupants.[64–66]

Thus, patients with known colonization or diseases with multi-drug-resistant organisms or *Clostridium difficile* require Contact Precautions in addition to the Standard Precautions to reduce the risk of transmission from the patient and the contaminated environment to others.

Nurses can ensure clean medical equipment is used between patients and can work with environmental services personnel to maximize clean conditions in and around patient rooms. It is necessary to consistently perform hand hygiene after routine patient care or contact with environmental surfaces in the immediate vicinity of the patient. Infection control procedures are recommended to reduce cross-contamination under the following situations:[67]

1. Use EPA-registered chemical germicides for standard cleaning and disinfection of medical equipment that comes into contact with more than one patient.
2. If *Clostridium difficile* infection has been documented, use hypochlorite-based products for surface disinfection as no EPA-registered products are specific for inactivating the spore form of the organism.
3. Ensure compliance by housekeeping staff with cleaning and disinfection procedures, particularly high-touch surfaces in patient care areas (e.g., bed rails, carts, charts, bedside commodes, doorknobs, or faucet handles).
4. When contact precautions are indicated for patient care (e.g., MRSA, VRE, *C. difficile*, abscess, diarrheal disease), use disposable patient care items (e.g., blood pressure cuffs) wherever possible to minimize cross-contamination with multiple drug-resistant microorganisms.
5. Advise families, visitors, and patients regarding the importance of hand hygiene to minimize the spread of body substance contamination (e.g., respiratory secretions or fecal matter) to surfaces.

A patient safety goal could be to adopt a personal or an institutional pledge, similar to the following: I (or name of health care facility) am committed to ensuring that proper infection control and environmental disinfection procedures are performed to reduce cross-contamination and transmission so that a person admitted or visiting to this facility shall not become newly colonized or infected with a bacterium derived from another patient or health care worker's microbial flora.

Leadership

Health care workers dedicate enormous effort to providing care for complex medical needs of patients, to heal, to continuously follow science to improve the quality of care—all the while consciously performing to the best of their ability to *Primum non nocere* (First, do no harm). Though medical errors and adverse events do occur, many can be attributed to system problems that have impacted processes used by the health care worker, leading to an undesired outcome. Health care workers evaluate their professional impact based on outcomes that demonstrate that medical and nursing orders are completed properly, that a sentinel event did not occur, clinical judgment was properly utilized to improve patient care, and that most patients leave in stable or better health than when they arrived. With all the complicated patient care administered, if the patient did not acquire an infection during a hospitalization, is that an indication that all patient care interactions were practiced aseptically? Or could the lack of infection be attributed to some process interactions where the patient received a microbial exposure that was less than the threshold needed to acquire an infection or, fortuitously, the patient had enough natural immunity to ward off a potential infection? Although success is measured by an outcome with or without infection, we should consistently practice in such a manner to reduce patient exposure to exogenous microorganisms, which would consequently reduce the risk of infection.

Responsibility for risk reduction involves the institution administrators, directors, and individual practitioners. It is clear that leaders drive values, values drive behaviors, and

behaviors drive performance of an organization. The collective behaviors of an organization define its culture. The engagement of nursing leaders to collaborate with coworkers and hospital administrators in safety, teamwork, and communication strategies are critical requirements to improve safe and reliable care. Developed and applied concurrently, they weave a supporting framework for the effective implementation of new technologies and evidence-based practices.[68] If patients are not receiving all the evidence-based care that is indicated (regardless of a noninfectious outcome measure), then we have a professional obligation to demonstrate leadership to develop the methods to improve that care. The challenge is how to develop and sustain the change necessary to translate infection prevention knowledge into everyday clinical practice. As each person accepts his or her role in that responsibility, that leadership and role model example will influence a standard culture and expectation for all health care workers and support personnel to implement best practices.

Each institution must communicate the evidence-based practices to health care staff, have access to expertise about infection control practices, employ the necessary resources and incentives to implement change, and receive real-time feedback of national and comparative hospital-specific data.

> Health care institutions simply must expect more reliable performance of essential infection-control practices, such as hand hygiene and proper use of gloves. It is no longer acceptable for hospitals with substandard adherence to these basic interventions to excuse their performance as being no worse than the dismal results in published reports. Most institutions still tolerate defect or failure rates in hand hygiene of 40 percent or more—levels that would be considered shocking in any other industry[69] (p. 274).

Institution improvements should focus on process improvements that sustain best practices, using multifactorial approaches, and a commitment from the top administration through all levels of staff and employees to implement best practices.[70]

Proper Use of Personal Protective Equipment

Infection control practices to reduce HAI include the use of protective barriers (e.g., gloves, gowns, face mask, protective eyewear, face shield) to reduce occupational transmission of organisms from the patient to the health care worker and from the health care worker to the patient. Personal protective equipment (PPE) is used by health care workers to protect their skin and mucous membranes of the eyes, nose, and mouth from exposure to blood or other potentially infectious body fluids or materials and to avoid parenteral contact. The Occupational Safety and Health Administration's Bloodborne Pathogens Standard states that health care workers should receive education on the use of protective barriers to prevent occupational exposures, be able to identify work-related infection risks, and have access to PPE and vaccinations.[71]

Proper usage, wear, and removal of PPE are important to provide maximum protection to the health care worker. However, PPE may not be 100 percent protective, individual work practices may lead to exposure (e.g., needlestick injury), breaches in PPE might occur, and some breaches may go unrecognized. All PPE should be removed when leaving the patient care area.[25] Gloves prevent gross contamination of the hands when touching body fluids, reduce the likelihood that microorganisms present on the hands of personnel will be transmitted to patients during invasive or other patient care procedures, and reduce the likelihood that hands of personnel contaminated with microorganisms from a patient or a fomite can transmit these microorganisms to another

patient. Gloves may have small, unapparent defects or may be torn during use, and hands can become contaminated during removal of gloves,[72–75] thus hand hygiene is essential before donning another pair of gloves.

Various types of masks, goggles, and face shields are worn alone or in combination to provide barrier protection. A surgical mask protects a patient against microorganisms from the wearer and protects the health care worker from large-particle droplet spatter that may be created from a splash-generating procedure. When a mask becomes wet from exhaled moist air, the resistance to airflow through the mask increases. This causes more airflow to pass around edges of the mask. The mask should be changed between patients, and if at anytime the mask becomes wet, it should be changed as soon as possible. Gowns are worn to prevent contamination of clothing and to protect the skin of health care personnel from blood and body fluid exposures. Gowns specially treated to make them impermeable to liquids, leg coverings, boots, or shoe covers provide greater protection to the skin when splashes or large quantities of potentially infective material are present or anticipated. Gowns are also worn during the care of patients infected with epidemiologically important microorganisms to reduce the opportunity for transmission of pathogens from patients or items in their environment to other patients or environments. When gowns are worn, they must be removed before leaving the patient care area and hand hygiene must be performed.

Improper use and removal of PPE can have adverse health consequences to the health care worker. During the 2003 severe acute respiratory syndrome (SARS) outbreak in Canada, 44 percent of the probable SARS cases were in health care workers. After institutional implementation of SARS-specific infection control precautions, 17 workers developed disease. Fifteen were interviewed to determine their knowledge and work practices that could have contributed to their infection. Only 9 (60 percent) reported they had received formal infection control training; 13 (87 percent) were unsure of the proper order in which to don and remove PPE; 6 (40 percent) reused items (e.g., stethoscopes, goggles, and cleaning equipment) elsewhere on the ward after initial use in the room of a SARS patient; and 8 (54 percent) were personally aware of a breach in infection control precautions. Fatigue and multiple consecutive shifts may have contributed to the transmission.[76]

From the experiences observed during the SARS outbreak, CDC developed training materials to increase the safety of the health care worker environment through improved use of PPE by health care personnel. Posters (bilingual), slides, and video information are available on the CDC Web site: http://www.cdc.gov/ncidod/dhqp/ppe.html.

Consistent Evidence-Based Practices

Professional organizations for infection control and health care epidemiology publish evidence-based guidelines regarding the practice of health care infection control, strategies for surveillance and prevention, and control of HAIs in U.S. health care facilities. These consensus-based scientific publications provide priority recommendations on the basis of the existing scientific data; theoretical rationale; and applicability of well-designed experimental, clinical, or epidemiologic studies to prevent HAIs in different patient care settings. Additionally, the Joint Commission's initiative, Shared Visions—New Pathways 2004 accreditation process, focuses on continuous compliance with its standards, which contributes to health care organizations' maintenance of safe, quality care and improved organizational performance.[77]

Despite the high educational level of health care workers and knowledge of aseptic practices, adherence to published infection control precautions is not consistently applied.[78] In one study, a

self-reported questionnaire demonstrated that although all health care providers knew the appropriate protective barrier equipment required for a particular patient care interaction, their reasons for nonadherence included perceived time constraints (64 percent), inconvenience (52 percent), and presumption that the patient was not infected (34 percent).[79] The observed rate of compliance was inversely related to the years of health care experience.

Translation of evidence-based guidelines into clinical practice may require more than reliance on an individual practitioner's knowledge and intentions. Organizational interventions may be necessary to better understand the barriers that impede the process of effectively reviewing and implementing evidenced-based practices into daily clinical practice.[80–83] Standard policies and standards of practice should be time specific, measurable, and should also define the specific population of patients that will be affected. When the institution implements an evidence-based guideline that updates the current policy, a multidisciplinary intervention should be planned to ensure staff concurrence with the change; agreement that the new approach is crucial; an assurance that there will be adequate staff, knowledge, and resources to implement the change; and a method to evaluate the impact of the change.[84]

Antimicrobial-Resistance Campaign

"In theory, there is no difference between theory and practice. But in practice, there is."
Jan L. A. van de Snepshceut, computer scientist and educator

Background. After the first use of penicillin in the 1950s, antibiotic resistance developed rapidly in some bacteria such as *Staphylococcus aureus.* Over the last several decades, a shift in the etiology of more easily treated pathogens has increased toward more antimicrobial-resistant pathogens with fewer options for therapy. Infections from antimicrobial-resistant bacteria increase the cost of health care, cause higher morbidity and mortality, and lengthen hospital stays compared to infections from organisms susceptible to common, inexpensive antimicrobials. Antimicrobial resistance has continued to emerge as a significant hospital problem affecting patient outcomes by enhancing microbial virulence, causing a delay in the administration of effective antibiotic therapy, and limiting options for available therapeutic agents. In a 2003 Institute of Medicine report, antimicrobial resistance was noted as a paramount microbial threat of the 21st century.[85]

Burden of organisms. Rates of antimicrobial resistance among hospital and community pathogens have increased considerably during the past decade. More than 70 percent of the bacteria that cause hospital-associated infections are resistant to at least one of the drugs most commonly used to treat these infections.[86] According to 2003 National Nosocomial Infections Surveillance System data from ICU patients, 60 percent of *Staphylococcus aureus* isolates were resistant to methicillin, oxacillin, or nafcillin (MRSA)—an 11 percent increase from data reported the year before.[87] There was a nearly 50-percent increase in nonsusceptible *Klebsiella pneumoniae* isolates to 3rd generation cephalosporins between 2002 and 2003. Although the rate of vancomycin-resistant enterococcus (VRE) has shown a less drastic increase than previous years, it still increased 12 percent in 2003 (for a total of 28.5 percent of all enterococci isolates).

Another recent national survey of antimicrobial resistance trends and outbreak frequency was performed among U.S. hospitals (those hospitals having at least 50 beds, both general medical and surgical services, and accreditation by the Joint Commission) using the American Hospital Association annual survey data set.[88] A total of 494 of the 670 hospital laboratories (74 percent) responded. Antimicrobial resistance rates were highest for oxacillin-resistant *Staphylococcus*

aureus (ORSA, also referred to as MRSA) (36 percent); two-thirds of the hospitals reported increasing MRSA rates, 4 percent reported decreasing rates, and 24 percent reported MRSA outbreaks.

Mechanism of antibiotic resistance. The treatment of bacterial infections is not a straightforward process. Bacterial microorganisms are initially susceptible to a new antibiotic, but over time, as use of the antibiotic increases, new generations of the organism will selectively adapt by developing antibiotic resistance. These organisms have the ability to undergo protective spontaneous mutation within themselves or acquire an exogenous antibiotic-resistant gene through genetic transfer from another organism, which enables it to inactivate an antibiotic or nullify its killing activity. The human microbial population includes a combination of susceptible bacteria and antibiotic-resistant bacteria. Antimicrobial usage changes the competitive balance of the microbial population by decreasing the amount of susceptible bacteria, providing an opportunity for resistant bacteria to flourish. Areas within hospitals such as ICUs that have high rates of antimicrobial usage also have the highest rates of antimicrobial resistance.

Patients can acquire an antibiotic-resistant organism through other mechanisms. Increased antibiotic treatments received in community settings can lead to the presence or colonization of antimicrobial-resistant organisms in the community population, which can be introduced into the hospital by patients on admission. These colonized organisms may not be detected if the patient is admitted for noninfectious reasons. This underscores the need for routine hand hygiene after all patient care, not just after care to patients on Contact Precautions. Often, it becomes apparent that silent transmission has occurred when the newly discovered presence of a resistant organism can be traced back to another patient who is later found to have been infected or colonized with the resistant organism. More frequently, however, the exact source of resistant organisms or the source of transmission within the institution remains undetermined.

Prevention of antibiotic-resistant organisms. Authors of evidence-based guidelines on the increasing occurrence of multidrug-resistant organisms propose these interventions: stewardship of antimicrobial use, an active system of surveillance for patients with antimicrobial-resistant organisms, and an efficient infection control program to minimize secondary spread of resistance.[89–91] Antimicrobial stewardship includes not only limiting the use of inappropriate agents, but also selecting the appropriate antibiotic, dosage, and duration of therapy to achieve optimal efficacy in managing infections. A prospective study on hospital mortality due to inadequate antimicrobial treatment demonstrated that the infection-related mortality rate for patients receiving inadequate antimicrobial treatment (42 percent) was significantly greater than the infection-related mortality rate of patients receiving adequate antimicrobial treatment (17.7 percent) in a medical or surgical ICU setting.[92]

Earlier guideline recommendations by professional organizations were published between 1995 and 1997 for the prevention of antimicrobial resistance in hospitals.[93–95] To evaluate the application of the recommendations, a cross-sectional survey was performed to determine what types of antimicrobial-use programs were being used among 47 U.S. hospitals participating in the ICU component of the CDC's National Nosocomial Infections Surveillance System.[96] All 47 hospitals had some established programs, although their practices did not meet all of the published recommendations. For example, one programmatic practice was to consult with an infectious disease physician or pharmacist (used 60–70 percent of the time) to discuss initial antimicrobial options; however, only 40 percent reported a system to measure compliance with administering the recommended antimicrobial agent. The Cochrane Collaboration reviewed 66 published papers to develop "interventions to improve antibiotic prescribing practices for

hospital inpatients."[97] Interventions were aimed at varying outcomes (e.g., increase/decrease treatment, regimen, timing of dosing, restrictive or persuasive methods to reduce unnecessary antibiotic use). Studies showed that about half of the time, hospital physicians were not prescribing antibiotics properly. Nonetheless, most interventions demonstrated some improvement in antibiotic prescribing to reduce antimicrobial resistance or hospital-acquired infections. Hospital campaigns to prevent antimicrobial resistance include steps to (1) employ programs to prevent infections, (2) use strategies to diagnose and treat infections effectively, (3) operate and evaluate antimicrobial use guidelines (stop orders, restrictions, and criteria-based clinical practice guidelines), and (4) ensure infection control practices to reduce the likelihood of transmission.[98] Nurse practitioners have a role as part of the health care team diagnosing and treating infections appropriately and should be familiar with strategies to improve antimicrobial use. All health care workers play a critical role in reducing the risk of transmission.

Based on the factors contributing to antibiotic resistance in health care settings that were identified through data collection, guidelines, professional recommendations, and scientific research, the CDC compiled several tools in 2002 to increase awareness in health care settings. The Campaign to Prevent Antimicrobial Resistance in health care settings utilizes four strategies to increase awareness and encourage the best practices for antibiotic use and interventional programs to prevent resistance: prevent infection, diagnose and treat infection effectively, use antimicrobials wisely, and prevent transmission. Laminated cards, posters, slide sets, and fact sheets that can be used in a health care setting to promote recognition and utilization are listed at http://www.cdc.gov/drugresistance/healthcare/default.htm. A summary of the CDC's 12-step program and specific nursing interventions is provided in Appendix 2.

Summary of key concepts. A program that only scrutinizes and monitors antimicrobial use will not be effective to reduce antimicrobial resistance; it must also implement proper infection control measures and have laboratory, surveillance, and administrative support. The optimal strategy for control of antibiotic-resistant organisms is not the same for every health care facility as this individually depends on the levels of endemic colonization, presence of one or more resistant organisms, and levels of infection (low or outbreak levels). The ICP and hospital epidemiologist at each facility are valuable resources to provide programmatic education and recommend targeted infection control measures (e.g., use of personal protective barriers, hand hygiene resources, patient placement/segregation, and admission surveillance cultures). Similar to the example of antibiotic consultation practices and outcome measures, this plan will have little effect or opportunity to reduce the morbidity and mortality of infectious complications unless there is committed organizational support, including expert recommendations that are adopted into daily practice routines. Nursing personnel have the most patient contact and the most opportunity to interrupt the chain of transmission through adherence to consistent aseptic practices.

Respiratory Hygiene and Cough Etiquette

Respiratory viruses are easily disseminated in a closed setting such as a health care facility and can cause outbreaks that contribute to the morbidity of patients and health care staff. Personnel and patients with a respiratory illness commonly transmit viruses through droplet spread. Droplets are spread into the air during sneezing, talking, and coughing and can settle on surfaces. Transmission occurs by direct contact with mucous membranes or by touching a contaminated surface and self-inoculating mucous membranes. Respiratory viruses can sometimes have aerosol dissemination.

Precautions to prevent the transmission of all respiratory illnesses, including influenza, have been developed.[99] The following infection control measures should be implemented at the first point of contact with a symptomatic or potentially infected person. Occupational health policies should be in place to guide management of symptomatic health care workers.

1. Post visual alerts (in appropriate languages) at the entrance to outpatient facilities instructing patients and escorts (e.g., family, friends) to notify health care personnel of symptoms of a respiratory infection when they first register for care.
2. Patients and health care staff should consistently practice the following:
   a. Cover the nose/mouth when coughing or sneezing.
   b. Use tissues to contain respiratory secretions and dispose of them in the nearest waste receptacle after use.
   c. Perform hand hygiene after having contact with respiratory secretions and contaminated objects or materials.
3. During periods of increased respiratory infection activity in the community or year-round, offer masks to persons who are coughing. Either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties) may be used to contain respiratory secretions. Encourage coughing persons to sit at least 3 feet away from others in common waiting areas.
4. Health care personnel should wear a surgical or procedure mask for close contact (and gloves as needed) when examining a patient with symptoms of a respiratory infection. Maintain precautions unless it is determined that the cause of symptoms is not an infectious agent (e.g., allergies).

Evaluation

The ICP or a nurse on a specific patient care unit should design a periodic evaluation program of infection control practices, including aseptic technique practices. Evaluation methods include a self-assessment survey of intended practices, direct observational assessments by another health care worker or a patient, and self-completion of checklists that review work practices and identify opportunities for improvement within the health care operations. If deficiencies or problems in the implementation of standardized infection control procedures are identified, further evaluation activities (e.g., root-cause analysis) may be indicated to identify and rectify the contributing factors to the problem.[100]

Most evaluation reviews are generated after a major, life-threatening error occurs, which usually happens infrequently. Historically, when an evaluation determined that a process completed by personnel was deficient, problem-solving efforts focused on the identification of the specific individual(s) who "caused" the problem. Later, quality improvement efforts focused on developing a culture of safety and recognized that additional contributions to errors were due to complex, poorly designed systems. The advantage of an evaluation that reviews system problems is that it encourages health care professionals to report adverse events and near misses that might be preventable in the future, while balancing the identification of system problems with holding individual providers responsible for their everyday practices. Improvement is impossible without evaluation reports to provide data on the factors that contribute to mistakes and lead to subsequent individual and system changes that support safer practices.[101]

An evaluation strategy examining process measures include the following examples:

- Document staff use of maximum sterile barriers (cap, mask, sterile gown, sterile gloves, large sterile sheet) and aseptic technique for the insertion of central intravenous catheters or guidewire exchange.
- Document timing of antibiotic prophylaxis when used in surgical patients (e.g., within 1 hour of incision).
- Document if hand hygiene is performed and clean or sterile gloves are worn before assessing a catheter insertion site or changing a dressing on intravascular catheters.
- Document time elapsed from when patient culture (microbiology and susceptibility) results are reported and when the appropriate isolation precautions are instituted (patient room placement, signs, PPE used, disposable equipment used, medical record documentation, etc.).
- Ensure that staff (nurses, doctors, and housekeeping) enter a contact isolation room using the specified personal protective barriers (e.g., gloves, gown) on each entry.
- Ensure that staff properly remove PPE after leaving a patient's room.
- Assess the annual rates of influenza vaccination for health care workers and other personnel eligible to receive vaccination; assess the rates of influenza vaccination for patients.
- Ensure that needle disposal containers are no more than three-quarters full at time of disposal.
- Periodically monitor and record adherence with the hand hygiene guidelines: the number of times personnel washed their hands divided by the number of hand-hygiene opportunities, computed by ward or by service. Provide feedback to personnel regarding their performance.
- Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient days.
- When outbreaks of infection occur, assess the adequacy of health care worker hand hygiene.
- When a patient with a known colonization or infection with a multidrug-resistant organism (e.g., MRSA, VRE) is transferred to your facility, evaluate effectiveness of system notification to health care personnel in the receiving facility.
- Record compliance with hospital policy for catheter-site dressing changes.

Research Implications[*]

1. Research and apply behavioral and management sciences to achieve implementation of evidence-based clinical guidelines and compliance with infection prevention policies.
2. Develop methods to improve the appropriateness of antimicrobial use based on identified antimicrobial control measures and institution microbial susceptibility patterns.
3. Collect data for the economic impact of HAIs and other adverse effects and resulting return of investment for prevention methods.
4. Identify specific components of infection prevention and control programs and staffing in health care institutions that are effective (and cost effective) in reducing rates of infection.

[*] Adapted from Lynch et al. 2001[104] and Aboelela et al. 2006.[105]

5. Improve health care institution information systems for seamless review of appropriateness of infection control-related care based on patient diagnosis.
6. Determine standard indices for measurement of effectiveness and cost of infection control measures.
7. Measure effect of staffing changes (reduced personnel, prolonged work hours, varying levels of formal education) on patient outcomes related to infectious outcomes of morbidity and mortality (e.g., colonization of microorganisms, postoperative wound infections, and catheter-related infections).
8. Design studies so that independent effects of specific interventions can be identified.
9. Monitor the implementation of interventions in a multicenter study to examine a cause-and-effect response and differentiate between efficacy and effectiveness.
10. Develop interdisciplinary research teams to improve the rigor and sophistication of studies conducted.

Conclusions

It is the responsibility of all health care providers to enact principles of care to prevent health care–associated infections, though not all infections can be prevented. Certain patient risk factors such as advanced age, underlying disease and severity of illness, and sometimes the immune status are not modifiable and directly contribute to a patient's risk of infection. Depending on the patient's susceptibility, a patient can develop an infection due to the emergence of their own endogenous organisms or by cross-contamination in the health care setting. Benefits of antimicrobial therapy will alter the microbial flora by reducing one microbial presence but may allow the emergence of another, causing a new infection (e.g., antibiotic-associated diarrhea).

Nurses can reduce the risk for infection and colonization using evidence-based aseptic work practices that diminish the entry of endogenous or exogenous organisms via invasive medical devices. Proper use of personal protective barriers and proper hand hygiene is paramount to reducing the risk of exogenous transmission to a susceptible patient. For example, microorganisms have been found in the environment surrounding a patient and on portable medical equipment used in the room. Environmental surfaces around a patient infected or colonized with a multidrug-resistant organism can also become contaminated. Health care workers should be aware that they can pick up environmental contamination of microorganisms on hands or gloves, even without performing direct patient care. Proper use and removal of PPE followed by hand hygiene will reduce the transient microbial load that can be transmitted to self or to others. Identified aseptic and infection control practices have been proven to reduce the dissemination of organisms to a single patient, to prevent repeated transmissions that contribute to an outbreak situation among multiple patients, or to become established in the health care environment as endemic hospital flora.

Nursing has many complicated scopes of practice, which challenge time management, priority setting, and efficiency of practice. Although system and administrative support is beneficial to supporting aspects of nursing care, direct care is performed by individuals. Every individual nurse focuses on making a difference throughout the daily workloads and enormous responsibilities but changes in a patient's medical condition can become overwhelming. One nurse comes to mind who found the resolve to make significant strides within the patient ward dealing with chronically overwhelming situations. She was administratively responsible for

directing and addressing the challenges of all patients' chronic wound infections, ongoing cross-contamination, lack of needed medical supplies and equipment, severe understaffing, working extra shifts, and still finding time to provide care and comfort to patients. By her personal efforts to improve wound care, aseptic practices, and hand hygiene among all nursing and medical staff, mortality dropped in a dramatic decline from 33 percent to 2 percent within a 9-month period.[102] These sustained and dedicated efforts to reduce patient infections and improve patient care in light of overwhelming adversity set a standard of practice for all nurses to follow. That nurse was Florence Nightingale, defining the art of nursing in the 1850s. Although medical care is more advanced and technically more complex since that time, it was the dedication of a nurse (like you) to ensure aseptic practices despite the significant nursing demands of patient care that makes the difference for the patients—then and now.

National surveys of the public have repeatedly found nursing to be one of the most trusted professions. The public trusts us to provide safe care and employ best practices by following certain principles: (1) to not work while having an infectious illness, (2) to be knowledgeable about the methods to protect our patients from transmission of disease, (3) to perform aseptic practice and monitor patient infections, (4) to participate in quality improvement initiatives to reduce infections, and (5) to provide care even if it means self-risk from infection. As nurses we have an ethical obligation to meet that trust and uphold the highest standards for our patients and the public, whether we are providing direct care, teaching about proper health care, or overseeing nursing practice.[103]

It has been demonstrated that nursing and medical practices can pick up transient microorganisms from intact patient skin and from environmental surfaces. Although the amount of contamination is not quantified and the exact incidence is not apparent, it does occur. Hand hygiene and aseptic practices before caring for a susceptible patient can reduce the transient carriage and transfer of microorganisms. The protective benefits of infection control using evidence-based practices are cost effective and numerous: they not only contribute to the best individual patient care outcome, but also protect health care workers, increase public awareness in all health care settings about infection control issues, and maintain the highest standards in nursing, which positively contributes to our goal for the best possible patient and public health outcomes.

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Appendix 1. Resources

Federal Agencies

Agency for Healthcare Research and Quality
Measuring health care quality, outcomes, and effectiveness, etc.
http://www.ahrq.gov/

Centers for Disease Control and Prevention: CDC for Healthcare Providers
Health care infections, hepatitis, antimicrobial resistance, health care worker protection. Slide presentations. Fact sheets. http://www.cdc.gov/CDCForYou/healthcare_providers.html

Guidelines http://www.cdc.gov/ncidod/dhqp

Prevention of Catheter-Associated Urinary Tract Infections, 1981
Environmental Infection Control in Healthcare Facilities, 2003
Hand Hygiene in Healthcare Settings, 2002
Preventing Healthcare-Associated Pneumonia, 2003
Guidelines for Infection Control in Health Care Personnel, 1998
Infection Prevention and Control in the Long-Term Care Facility, 1997
Guideline for Isolation Precautions in Hospitals, 1996
Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2002
Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006
Guideline for Prevention of Surgical-Site Infection, 1999
Public Health Service Guidelines on the Management of Exposure to HBV, HCV, and HIV with PEP Recommendations, 2001
Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post-Exposure Prophylaxis, 2005
Guidelines for Preventing the Transmission of M. *tuberculosis* in Health Care Settings, 2005

Food and Drug Administration
Information for Health Professionals (Medical Devices, Drugs, etc.)
http://www.fda.gov/oc/oha/default.htm

U.S. Department of Health and Human Services
Pandemic Flu.
http://pandemicflu.gov/

National Institutes of Health: National Institute of Allergy and Infectious Diseases
Health, science, research, research funding, news.
http://www3.niaid.nih.gov/

Occupational Safety and Health Administration
Hospital eTool (health care hazards, infection, housekeeping, nursing homes)
http://www.osha.gov/SLTC/etools/hospital/hazards/infection/infection.html

Professional Organizations

American Nurses Association
Center for Occupational and Environmental Health
Occupational health, RNno harm, influenza posters, safe needles.
http://www.nursingworld.org/MainMenuCategories/OccupationalandEnvironmental.aspx

Association for Professionals in Infection Control and Epidemiology
Educational brochures, assorted topics; Protect Our Patients Campaign.
http://www.apic.org/Content/NavigationMenu/Education/EducationResources/Educational_Brochur.htm
Community-associated MRSA references.
http://www.apic.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentFileID=5801

Joint Commission (Joint Commission on Accreditation of Healthcare Organizations)
Infection control initiatives, standards.
http://www.jointcommission.org/PatientSafety/InfectionControl/

National Quality Forum
Health care quality and reporting.
http://www.qualityforum.org/

Society for Healthcare Epidemiology of America (SHEA)

Guidelines, outbreak resources, drug-resistant organisms.
http://www.shea-online.org/index.cfm

Journals, Articles

MedlinePlus Infection Control (National Library of Medicine)
http://www.nlm.nih.gov/medlineplus/infectioncontrol.html

Infection Control and Hospital Epidemiology online journal (SHEA)
http://www.journals.uchicago.edu/ICHE/home.html

American Journal of Infection Control online journal (APIC)
http://www.apic.org/Content/NavigationMenu/Publications/AJIC/AJIC.htm

Hand Hygiene Resources

Centers for Disease Control and Prevention
Posters, brochures, media kit.
http://www.cdc.gov/handhygiene/default.htm

Institute for Healthcare Improvement
Improving Hand Hygiene. A Guide for Improving Practices among Healthcare Workers.
http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Tools/HowtoGuideImprovingHandHygiene.htm

World Health Organization
Guidelines on Hand Hygiene in Healthcare. Advanced draft available.
http://www.who.int/patientsafety/information_centre/documents/en/index.html

U.S. Department of Veterans Affairs
Infection—Don't Pass It On (posters, stickers, buttons).
http://www.publichealth.va.gov/InfectionDontPassItOn/Default.htm

Appendix 2. Campaign To Prevent Antimicrobial Resistance in Health Care Settings

Centers for Disease Control and Prevention

Adapted from information on http://www.cdc.gov/drugresistance/healthcare/default.htm

Strategy	Steps	Related Fact	Nursing Actions
Prevent Infection	1. Influenza and Pneumococcal vaccinations	Predischarge immunizations of at-risk hospital patients and health care personnel will prevent infections.	♦ Give influenza and *pneumococcal* vaccine to at-risk patients before discharge. ♦ Receive annual influenza vaccinations.
	2. Get the catheter out	Catheters and other invasive devices are the # 1 exogenous cause of hospital-onset infections.	Use catheters— ♦ Only when essential. ♦ With proper insertion and care protocols. ♦ Only as long as needed.
Diagnose and Treat Infection Appropriately	3. Target the pathogen	Appropriate therapy (correct regimen, timing, dosage, route, and duration) saves lives.	♦ Culture the patient. ♦ Verify empiric therapy is to a likely pathogen and definitive therapy is treating a known pathogen.
	4. Access the experts	Infectious disease expert collaboration improves the outcome of serious infections.	Incorporate guidance from infectious disease experts into daily care plan. All full-time, part-time, and contract staff should know and utilize recommendations.
Use Antimicrobials Wisely	5. Practice antimicrobial control	Programs to improve antibiotic use are effective.	Know your pharmacy policies on ordering, restrictions, switching, and stopping. Utilize or develop online ordering with computerized decision support/rationale.
	6. Use local data	The prevalence of resistance can vary by time, locale, patient population, hospital unit, and length of stay.	Know the common organisms in your clinical area and the effective antibiotics used to treat each infection.
	7. Treat infection, not contamination	A major cause of antimicrobial overuse is “treatment” based on results of patient cultures that become contaminated.	Utilize proper protocols to collect patient blood and other specimens for culture. Submit to laboratory in proper medium/collection containers and within the recommended time.
	8. Treat infection, not colonization	A major cause of antimicrobial overuse is “treatment” based on colonization.	Be familiar with practice guidelines for clinical assessments of new symptoms (i.e., fever) in critically ill patients and when cultures are warranted.
	9. Know when to say “no” to vanco	Vancomycin overuse promotes emergence, selection, and spread of resistant pathogens.	Be familiar with hospital policy on proper vancomycin utilization and when it should be discouraged (e.g., routine surgical prophylaxis and the exceptions, etc.).

Strategy	Steps	Related Fact	Nursing Actions
	10. Stop antimicrobial treatment	Failure to stop unnecessary antimicrobial treatment contributes to overuse and resistance.	Be aware of the patient's infection status and need for an antibiotic. Stop or don't use antibiotics when ♦ The infection is cured; ♦ Cultures are negative and infection is unlikely; and ♦ Infection is not diagnosed.
Prevent Transmission	11. Isolate the pathogen	Patient-to-patient spread of microorganisms can be prevented.	Practice strict aseptic technique to prevent transmission of organisms. Strict oversight of proper contact precautions when used and proper room disinfection.
	12. Break the chain of contagion	Health care personnel can spread antimicrobial-resistant pathogens from patient to patient.	Clean hands can pick up and transfer microorganisms. Hand hygiene is essential—set an example for others.

Chapter 42. Targeting Health Care–Associated Infections: Evidence-Based Strategies

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Background

Hospitalization for an acute illness, trauma, chronic care, or other health care conditions is a common occurrence. There were 39.2 million hospital discharges in 2005, with an average length of stay of 4.6 days.[1] Hospitalization brings associated risks, including risk of infection. Nosocomial infections, or hospital-associated infections, are estimated to occur in 5 percent of all acute care hospitalizations, or 2 million cases per year.[2] Hospital-associated infections have been identified as one of the most serious patient safety issues in health care.[3]

Infections that become clinically evident after 48 hours of hospitalization are considered hospital-associated.[2] Risks factors for hospital-associated infections are generally categorized into three areas: iatrogenic, organizational, or patient-related. Iatrogenic risk factors include invasive procedures (e.g., intubation, indwelling vascular lines, urine catheterization) and antibiotic use and prophylaxis. Organizational risk factors include such things as contaminated air-conditioning systems, contaminated water systems, staffing (e.g., nurse-to-patient ratio), and physical layout of the facility (e.g., open beds close together). Examples of patient-related risk factors include severity of illness, immunosuppression, and length of stay.[2]

Nosocomial infections more than double the mortality and morbidity risk for hospitalized patients, resulting in an estimated 20,000 deaths a year.[2] Nosocomial infections increase the costs of hospitalization in addition to increasing morbidity and mortality risk. A meta-analysis of 55 studies examining nosocomial infections and infection control interventions determined that attributable costs are significant; costs associated with bloodstream infections (mean = $38,703) and methicillin-resistant *Staphylococcus aureus* infections (mean = $35,367) are the largest.[3]

Most infections in hospitalized patients are endogenous, meaning they are caused by bacteria that have already colonized the patient's digestive tract prior to infection.[4] The majority (60 percent) of infections in patients hospitalized in an intensive care unit (ICU) setting are caused by bacteria already colonizing the patient on admission (primary endogenous). A lesser amount (23 percent) of infections result from bacteria acquired during the ICU stay, leading to colonization before infection (secondary endogenous). A total of seventeen percent of infections are caused by bacteria introduced from the ICU environment that lead to infection without prior colonization (exogenous). Targeting hospital-associated infections is, therefore, a very important aspect of providing quality health care.

This chapter reviews the evidence-based knowledge on health care–associated infections, highlighting important information for nurses caring for hospitalized patients. The review focuses on hospital-associated pneumonia, urinary tract infection, catheter-related bloodstream infection, sepsis, and antibiotic-resistant infection. An evaluation of the literature, including recent research, and evidence-based practices are presented.

Hospital-Associated Pneumonia

Pneumonia is the second most common hospital-associated infection (after urinary tract infection).[5] In critically ill patients, ventilator-associated pneumonia (VAP) is the most common nosocomial infection. VAP doubles the risk of death, significantly increases ICU length of stay, and adds more than $10,000 to each affected patient's hospital costs.[6]

The current evidence-based recommendations by the Centers for Disease Control and Prevention (CDC) for prevention of nosocomial pneumonia were published in 2004.[5] Although some of the interventions to reduce nosocomial pneumonia are the responsibility of physicians or other health care workers, many of the interventions are the direct responsibility of nurses or can be influenced by nurses. Nursing care can directly contribute to prevention of hospital-associated pneumonia, particularly in patients who are most at risk due to advanced age, postoperative status, or mechanical ventilation. The evidence shows that the most important contributions of nursing care to prevention of hospital-associated pneumonia are in four areas: hand hygiene, respiratory care, patient positioning, and education of staff.

Hand Hygiene

Hand hygiene is an essential component of hospital-associated pneumonia reduction. Evidence-based guidelines have been published for general hand hygiene[7, 8] as well as specific hand hygiene measures related to respiratory care.[6]

Excellent evidence exists that alcohol hand rubs effectively reduce the transmission of potential pathogens from health care workers' hands to patients. For hands that are not visibly soiled, alcohol hand rubs are more effective than hand washing with plain or antimicrobial soap.[8, 9] In the health care setting, the preferred method for cleaning visibly soiled hands is washing with water and antimicrobial soap. Gloves should be worn for handling respiratory secretions or any objects contaminated with respiratory secretions.[5] If soiling from respiratory secretions is anticipated, a gown should also be worn. Hand decontamination and glove changes are required between contacts with different patients, as well as in an encounter with a single patient between contacts with a contaminated body site and the respiratory tract or respiratory equipment.

Respiratory Care

Encouraging patients to do deep-breathing exercises is a common component of nursing care to reduce respiratory complications, particularly in postoperative patients. Most research supports this practice, although some controversy remains regarding the effectiveness of deep-breathing exercises versus incentive spirometry in particular patient populations. Thomas and McIntosh[10] conducted a meta-analysis of literature from 1966 through 1992 that focused on the effects of deep-breathing exercises, incentive spirometry, and intermittent positive pressure breathing on pulmonary complications after upper abdominal surgery. They concluded that both deep-breathing and incentive spirometry were more effective than no treatment, but there was no significant difference between any of the three treatments. More recently, a systematic review of postoperative incentive spirometry studies from 1966 through 2000 concluded that there was not enough evidence to support the use of incentive spirometry to reduce postoperative respiratory complications.[11]

Chumillas and colleagues[12] randomized subjects who had upper abdominal surgery to a breathing exercise program or to no breathing exercise. Postoperative pulmonary complications were reduced in the deep-breathing group (7.5 percent versus 19.5 percent in the control group), and the deep-breathing group had fewer postoperative chest radiograph abnormalities ($P = 0.01$). In a study of 456 abdominal surgery patients, Hall and colleagues[13] found that deep-breathing exercises for low-risk patients, and incentive spirometry plus physiotherapy for high-risk patients, was as effective for prevention of postoperative pulmonary complications as incentive spirometry.

Deep breathing also appears to be effective after coronary artery bypass graft (CABG) surgery. Westerdahl and colleagues[14] randomly assigned subjects for the first 4 postoperative days to hourly deep-breathing exercises during the daytime (n = 48) or to no breathing exercises (n = 42). Compared to the control group, the deep-breathing group had smaller atelectasis on spiral CT scan ($P = 0.045$ at the basal level and $P = 0.01$ at the apical level) and significantly smaller postoperative reduction in lung function (forced vital capacity [FVC], $P = 0.01$; forced expiratory volume [FEV1], $P = 0.01$). In contrast, a randomized study of 56 abdominal surgery patients at high risk for postoperative pulmonary complications demonstrated beneficial results of early postoperative mobilization; however, the study produced no statistically significant difference in outcomes when deep breathing and coughing interventions were added to the early mobilization.[15] Based on current evidence, CDC guidelines encourage deep breathing for all postoperative patients and use of incentive spirometry on postoperative patients who are at high risk for pneumonia.[5]

The earliest CDC guidelines addressing nosocomial pneumonia, published in 1981, placed great emphasis on standardization of practices related to care of respiratory equipment, and this area has been a continued focus in subsequent reports. Recommendations related to procedures for cleaning, sterilizing or disinfecting, and maintaining respiratory equipment now have a strong evidence base, and those recommended procedures are presented in detail in the current CDC report.[5] Compliance with those procedures is primarily the responsibility of respiratory therapy, but it requires the cooperation and support of nurses. Many unresolved issues remain regarding optimal procedures for respiratory tract secretion suctioning, including whether sterile or clean gloves should be used when performing endotracheal suctioning, and whether multiuse closed-system suction catheters or single-use open-system suction catheters are more effective in prevention of pneumonia.

Patient Positioning

Elevation of the head of the bed is believed to reduce the risk of gastroesophageal reflux and aspiration of gastric secretions, and thus to reduce risk of hospital-associated pneumonia. Supine position is an independent risk factor for mortality in mechanically ventilated patients[16, 17] and in all ICU patients.[18] Torres and coworkers[19] conducted a randomized crossover study of the effect of semirecumbent versus supine position in 19 critically ill mechanically ventilated adults. After radiolabeling gastric contents, the researchers found higher radioactive counts in endobronchial aspirates when subjects were in a supine position than when in a semirecumbent position ($P = 0.036$). In a similar design, Orozco-Levi and coworkers[20] introduced radio label through nasogastric tubes in 15 mechanically ventilated subjects and obtained radioactive counts in pharyngeal and endobronchial secretions over a 5-hour period in supine and semirecumbent positions. Bronchial radioactive counts were higher at 5 hours in a supine position compared with baseline ($P < 0.05$) and semirecumbency ($P < 0.01$); importantly, significant reflux

occurred by 5 hours even with semirecumbent positioning. These studies support a relationship between head-of-bed position and aspiration of gastric secretions.

Two clinical trials have examined the effect of head-of-bed position on VAP. Prior to the publication of the 2004 CDC guidelines, Drakulovic and coworkers[21] conducted a randomized clinical trial assigning 86 mechanically ventilated ICU subjects to semirecumbent (45 degree) or supine (0 degrees) positions, with position documented once daily. The trial was stopped early because significant findings at an interim analysis showed that the semirecumbent group had lower frequency of clinically suspected pneumonia ($P = 0.003$) and microbiologically confirmed pneumonia ($P = 0.018$) than the supine group. Both supine body position ($P = 0.006$) and enteral nutrition ($P = 0.013$) were identified as independent risk factors for nosocomial pneumonia. A second, larger multicenter trial by van Nieuwenhoven and colleagues[22] was published in 2006. Mechanically ventilated ICU patients were prospectively randomly assigned to a semirecumbent position (45 degrees, n = 109) or standard care (10 degrees, n = 112). Because backrest elevation was continuously electronically monitored during the first week of mechanical ventilation, the researchers were able to document that subjects assigned to 45-degree elevation achieved the target position only 15 percent of the study time, despite intensive efforts to ensure provider compliance. Average elevations (28 degrees in the group assigned to 45-degree elevation, and 10 degrees in the standard-care group) were significantly different between groups ($P < 0.001$), but differences in VAP were not demonstrated.

These two clinical trials of the effect of head-of-bed elevation on VAP differed in several ways that may have affected study outcomes. Important differences existed in the comparison groups, with Draculovic and colleagues assigning subjects to 0 degree elevation, while the subjects assigned to usual care in the van Nieuwenhoven study had an average elevation of 10 degrees. The nosocomial pneumonia rate in the van Nieuwenhoven standard-care group was 6.5 percent, much lower than the 23 percent reported for the Draculovic control group (23 percent). While current evidence and practice guidelines support the elevation of the head of bed to reduce pneumonia risk, additional research is needed to further determine the optimal level for head-of-bed elevation.

Grap and colleagues[23] examined the relationship of backrest elevation to VAP in a descriptive study of 66 subjects over a total of 276 patient days. Backrest elevation was continuously monitored. Mean backrest elevation for the entire study period was 21.7 degrees, but backrest elevations were less than 30 degrees 72 percent of the time, and less than 10 degrees 39 percent of the time. In a statistical model predicting pneumonia risk on study day 4, 81 percent of the variability ($F = 7.31$, $P = 0.003$) was accounted for by the pneumonia score on study day 1, severity of illness, and percentage of time spent at less than 30 degrees in the first 24 hours. Thus, early initiation of elevated backrest may influence outcomes in patients who are at highest risk.

Elevation of the head of the bed for patients at risk is a simple and inexpensive intervention that has the potential to decrease nosocomial pneumonia. Adverse effects of elevating the head of the bed have not been demonstrated in patients who do not have a medical contraindication. However, most evidence suggests that this intervention is not widely used. The effectiveness of turning or lateral rotation remains an unresolved issue. Additional research is needed to identify optimal or sufficient head-of-bed elevation to prevent nosocomial pneumonia, to determine the effects of turning, and to address barriers to implementation of optimal patient positioning.

The Institute for Healthcare Improvement (IHI) outlines a ventilator bundle, or care strategies, to target VAP. A “bundle” is a group of interventions that when implemented

together, produce better outcomes than when implemented individually.[24] The ventilator bundle incorporates evidence-based interventions aimed at reducing VAP incidence, including head-of-bed elevation greater than 20 degrees, assessment of the need for continued mechanical ventilation, and prophylaxis for stress ulcer disease and deep vein thrombosis.[25]

Additional VAP Prevention Measures

Additional measures for VAP prevention include preventing orophyarngeal colonization through oral care and effective endotracheal tube maintenance. Guidelines for VAP prevention recommend maintaining endotracheal tube cuff pressures above 20 cm H20 to ensure minimal leakage.[26] Continuous aspiration of subglottic secretions has also been advocated for preventing microaspiration. A meta-analysis assessing the impact of continuous aspiration of subglottic secretions in five randomized clinical trials found a 50-percent reduction in VAP and a delayed onset in the development of VAP by 6.8 days,[27] yet further research on the use and cost-effectiveness is needed.

Implementation of oral care protocols can be an effective mechanism to target removal of dental plaque and minimize colonization and aspiration of biofilm. Several studies have demonstrated benefits of tooth brushing and oral suctioning.[28–31] Research assessing the impact of chlorhexidine gluconate (CHG) for oral care hygiene has demonstrated beneficial impact with tooth brushing,[31, 32] however additional research is indicated.[33]

Staff Education and Compliance

The CDC urges education of staff and involvement of health care workers at all levels in implementing interventions to prevent hospital-associated pneumonia, and nurses are an essential component of these preventive efforts. The potential for compliance programs to positively affect nosocomial infections was demonstrated by Won and colleagues[34] in their study of hand hygiene. Following an intensive hand hygiene compliance program in a neonatal ICU, which increased hand hygiene compliance from 43 percent to 80 percent, a significant decrease in all nosocomial infections ($P = 0.003$) was documented. The effect was even more apparent for nosocomial respiratory infection ($P = 0.002$), with a significant correlation between hand washing compliance and nosocomial respiratory infections ($r = –0.385$; $P = 0.014$).

Education aimed at reducing the occurrence of VAP using a self-study module on risk factors and practice modifications demonstrated beneficial results in another study.[35] The education program, directed toward respiratory care practitioners and ICU nurses, was developed by a multidisciplinary task force. Fact sheets and posters reinforcing the study module information were distributed in an urban teaching hospital. Following implementation of the education intervention, the rate of VAP decreased from 12.6 per 1,000 ventilator days to 5.7 per 1,000 ventilator days, a decrease of 57.6 percent ($P < 0.001$).

In addition to promoting best practices for the care of ventilator patients, nurses should advocate for physician practices that reduce the risk of hospital-associated pneumonia. The use of noninvasive modalities whenever possible (for example, positive pressure ventilation by face mask to reduce endotracheal intubation) and removal of invasive devises when they are no longer necessary are important considerations. The IHI bundle focuses on daily assessment of the need for mechanical ventilation as one mechanism for removing invasive devices when indicated. Nurses can also help to educate all hospital personnel about procedures to prevent

pneumonia that are appropriate to the worker's level of responsibility. Table 1 outlines evidence-based guidelines for hospital-associated pneumonia prevention and management, including nursing-based care.

Urinary Tract Infections

The use of indwelling urinary catheters is common in the hospital setting. Urinary tract infection (UTI) is the most common hospital-associated infection, and a major associated cause is indwelling urinary catheters.[36] UTIs account for about 40 percent of hospital-associated infections, and an estimated 80 percent are associated with urinary catheters.[37] Almost 1 million episodes of nosocomial UTI occur each year in the United States,[38] and the most important risk factor is the presence of an indwelling urinary catheter.[39] Biofilm formation by uropathogens on the urinary catheter have been implicated as the underlying cause of catheter-associated UTI.[40] Adverse consequences of a catheter-associated UTI include local and systemic morbidity, secondary bloodstream infection, increased costs, and mortality.[41] In the hospital setting, the ICU has the highest prevalence of nosocomial UTIs with an estimated rate of 8–21 percent.[39] Guidelines for the prevention of catheter-associated UTIs issued by the CDC outline several recommendations, including appropriate use of indwelling catheters, education of personnel on proper catheter insertion using aseptic technique and sterile equipment, and maintenance to ensure closed sterile drainage (see Table 2).[42]

Due to increased risk of infection associated with urinary catheters, a number of practices have been evaluated in an attempt to reduce the incidence of urinary catheter-related infections.[38] These include alternative approaches to use of urinary catheters and antimicrobial urinary catheters.

Alternative Approaches to Urinary Catheterization

A Cochrane systematic review has investigated the advantages and disadvantages of alternative approaches to indwelling catheters for short-term bladder drainage in adults.[37] Of 17 randomized clinical trials, 14 compared indwelling urethral catheterization with suprapubic catheterization, and 3 trials compared indwelling urethral catheterization with intermittent catheterization. Patients managed with an indwelling urinary catheter had higher incidences of bacteriuria (relative risk [RR] = 2.60, 95% confidence interval [CI] = 2.12–3.18), more frequent recatheterizations (RR = 4.12, 95% CI = 2.94–7.56), and more reports of patient discomfort (RR = 2.98, 95% CI = 2.31–3.85). Of the trials assessing indwelling urethral catheters with intermittent catheterization, fewer cases of bacteriuria were found in patients receiving intermittent catheterization (RR = 2.90, 95% CI = 1.44–5.84). The results of the systematic review indicate that suprapubic catheters have advantages over indwelling urinary catheters in terms of incidence of bacteriuria, recatheterization, and patient reports of discomfort. Intermittent catheterization was also associated with a lower risk of bacteriuria compared to indwelling urinary catheters, but supported with limited evidence. However, suprapubic catheterization typically involves percutaneous placement of a urinary catheter directly into the bladder, a technique that is considered minor surgery;[38] therefore, the practical application of this alternative measure is questionable. A previous review of studies assessing the efficacy of suprapubic catheters with standard noncoated catheters also substantiated lower rates of bacteriuria for suprapubic catheters, but highlighted that mechanical complications—including

catheter dislodgement, obstruction, and failed introduction—can occur. The review could not substantiate the overall benefit of routine suprapubic catheterization.[38]

Antimicrobial Catheters

A variety of specialized urethral catheters have been designed to reduce the risk of catheter-associated UTI. These include antiseptic-impregnated catheters and catheters coated with silver alloy or nitrofurazone.[36, 41] A Cochrane systematic review has examined 18 clinical trials to assess the different types of urethral catheters for the management of short-term catheter use in hospitalized patients.[36] Silver oxide catheters were not associated with a statistically significant reduction in bacteriuria, but the confidence intervals were wide (RR = 0.89, 95 percent CI = 0.68–1.15). Silver alloy catheters were found to significantly reduce the incidence of bacteriuria (RR = 0.36, 95 percent CI = 0.24–0.52). The results of the review indicated advantages from silver alloy catheters, including an economic benefit compared to standard catheter use. A previous review of four clinical trials studies assessing silver alloy catheters also substantiated a significant reduction in the development of catheter-associated bacteriuria.[38]

Another systematic review of antimicrobial urinary catheters in the prevention of catheter-associated UTI in hospitalized patients analyzed 12 clinical trials of nitrofurazone-coated or silver alloy-coated urinary catheters. Both nitrofurazone-coated and silver alloy-coated catheters reduced the development of bacteriuria in comparison with latex or silicone control catheters.[41] However data on comparative efficacy is lacking as no trial directly compared nitrofurazone-coated and silver alloy-coated catheters. While evidence exists to support the use of antimicrobial urinary catheters in preventing bacteriuria in hospitalized patients during short-term catheterization, estimates on cost-effectiveness have not been established.[41] Additional strategies for preventing catheter-associated UTI—including hand-held bladder scanners, computerized order/entry system prompts, and education on appropriate use of indwelling urinary catheter—have also proved beneficial.[43]

Table 2 outlines evidence-based strategies for UTI prevention. Nursing-related care aspects include thorough assessment to determine need for indwelling catheter use, aseptic insertion technique, indwelling catheter care to minimize infection risk, and astute monitoring of patients with urinary catheters for signs of UTI. All of these are important measures to decrease the risk of catheter-associated UTI.

Catheter-Related Bloodstream Infection

Central venous catheters (CVCs) are frequently used in hospitalized patients and they carry associated risks, the most common being bloodstream infection (BSI). According to the CDC, up to 250,000 hospital-associated catheter-related bloodstream infections (CR-BSIs) occur annually in U.S. hospitals, with approximately 80,000 of these occurring in ICUs.[44] CVCs of all types are the most frequent cause of nosocomial BSIs.[45]

A CR-BSI is defined as the presence of bacteremia in a patient with an intravascular catheter with at least one positive blood culture and clinical signs of infections (i.e., fever, chills, and/or hypotension), with no apparent source for the BSI except the catheter. Specific criteria for CR-BSI include either a positive culture with the same organism isolated from the catheter and peripheral blood, simultaneous blood cultures with a $\geq$ 5:1 ratio of catheter versus peripheral culture, or a differential period of catheter culture versus peripheral blood culture positivity of >

2 hours.[46] A BSI is considered to be associated with a central line if the line was in place during the 48-hour period before development of the BSI.[46] Although CVSs account for only a small percentage of all intravenous lines, they cause most CR-BSIs.[47] The most common mechanism of CVC-BSI is migration of the organism from the insertion site along the surface of the catheter and colonization of its distal part.[48] CR-BSIs can also occur from contamination of the catheter hub or infusate administered through the device.[45]

Several practices have been evaluated in an attempt to reduce the incidence of CVC-BSI. These include the use of antimicrobial catheters, antimicrobial-impregnated dressings, and interventions related to catheter insertion and maintenance.

Antimicrobial Catheters and Dressings

Catheters impregnated or coated with antimicrobials or antiseptics have been shown to decrease the risk of CVC-BSI. Multiple randomized controlled trials and several meta-analyses have demonstrated that catheters coated on the external surface with chlorhexidine/silver sulfadiazine or minocycline/rifampin reduce the risk for CVC-BSI compared with standard noncoated catheters.[49–52] Chlorhexidine-impregnated dressings have also been found to reduce the rate of CVC colonization.[48] While evidence for the efficacy of CVC catheters coated with antibacterial or antiseptic agents exists, limited information exists related to their cost-effectiveness. Current CDC recommendations include use of CVC catheters coated with antibacterial or antiseptic agents for high-risk patients or situations in which CR-BSI rates are high despite careful attention to guidelines.[52]

Catheter Insertion and Maintenance Interventions To Reduce CVC-BSI

CVC-BSIs often result from contamination of the catheter during insertion.[52] Maximum sterile barrier precautions during insertion are indicated to reduce the incidence of CVC-BSI. Effective barrier precautions include the use of sterile gloves, long-sleeved gowns, full-size drape, masks, and head covers by all personnel involved in the central line insertion procedure.[52]

In addition to maximal barrier precautions during insertions, the 2002 CDC guidelines for the prevention of CVC infections outline other evidence-based practices, including the following:[53]

1. Use of a 2-percent chlorhexidine preparation as the preferred skin antiseptic prior to insertion
2. Education and training of staff who insert and maintain intravenous lines
3. No routine replacement of central lines at scheduled intervals

Additional measures advocated for best practices for CVC care include hand hygiene by washing hands with conventional antiseptic-containing soap and water or with waterless alcohol-based gels or foam before and after palpating insertion sites; and before and after insertion, replacing, accessing, or dressing a CVC.[53] Avoidance of antibiotic ointment at insertion sites, which can promote fungal infections and antibiotic resistance, and restricted use of stopcocks on any tubing other than pressure tubing to minimize contamination are also recommended.[53] Either sterile gauze or transparent, semipermeable dressings can be used, as research has demonstrated similar risks of CVC-BSI.[53] Gauze dressings should be replaced every 2 days and transparent dressings every 7 days or when the dressing becomes damp, loose, or soiled.[53, 54]

The IHI has also published a central line bundle to reduce CVC-BSI.[55] The components of the central line bundle include hand hygiene to prevent contamination of central lines, maximal

barrier precautions and CHG antisepsis for central line insertion, optimal catheter site selection with the subclavian vein as the preferred site for nontunneled catheters, and daily review of line necessity with removal of unnecessary lines.[55]

Educational measures related to CVC insertion and maintenance have proven effective in several studies.[56–58] Focused aspects of education included proper insertion and maintenance, a catheter insertion cart, a checklist to ensure adherence to evidence-based guidelines, and empowering nurses to stop the catheter insertion procedure if a violation of guidelines is observed. Table 3 outlines evidence-based strategies for CVC-BSI prevention. Nursing-related care aspects include maximal barrier precaustings during CVC insertion; maintenance of central line site to minimize infection risk; prevention of contamination of CVC ports during blood sampling, infusion of intravenous fluids, or medication administration; maintenance of sterile technique for dressing changes; intravenous tubing changes based on protocol guidelines; and astute monitoring of patients with central lines for signs of infection.

Sepsis

Sepsis, or clinical manifestation of the systemic response to infection, represents a significant condition that results in increased mortality for hospitalized patients. The incidence of sepsis is increasing, with more than 750,000 cases occurring in the United States each year.[59] Severe sepsis, which occurs when sepsis progresses to involve acute organ dysfunction, results in more than 200,000 annual fatalities, and the number of cases are projected to increase.[59] Epidemiological studies indicate that between 11 percent and 27 percent of ICU admissions have severe sepsis, with mortality rates ranging from 20 percent to more than 50 percent.[59–62] As infections can progress to sepsis, heightened monitoring of hospitalized patients for signs of sepsis are indicated for any patient with a suspected or confirmed infection. Focal areas pertinent to sepsis include monitoring, treatment, and prevention.

Monitoring for Sepsis Risk

Many risk factors exist for the development and progression of sepsis, including advanced age, compromised immune system response, chronic illness, broad spectrum antibiotic use, and exposure to infection risk associated with surgical and invasive procedures.[63] The severity of sepsis varies widely. Some patients experience a controlled inflammatory response to systemic infection.[64] However, the majority of patients with sepsis develop organ dysfunction (severe sepsis) with hypotension and a resultant state of decreased tissue perfusion. In addition to inflammation, severe sepsis is associated with activation of coagulation and impairment of fibrinolysis, which further impairs perfusion. The development of organ system failure can occur in the initial stages of severe sepsis, but the duration and progression of organ failure are influential in predicting survival.[65] Septic shock is the most severe form of sepsis: hypotension is resistive to fluid resuscitation, a condition which is often associated with high mortality rates.[64] Identified risk factors for increased mortality in sepsis include the microbiological etiology of sepsis; the site of the infection, with increased mortality associated with intra-abdominal or lower respiratory tract infections; presence of underlying disease; presence of shock; need for vasopressors; multiple organ failure; and neutropenia.[66] Many factors contribute to multiple organ dysfunction syndrome in sepsis, including inadequate tissue/organ perfusion, cellular injury, ischemia, and diffuse endothelial cell injury.[63] The progression of sepsis can be deterred

by early recognition and treatment, including early goal-directed therapy focusing on establishing adequate perfusion and targeted measures for sepsis treatment.[24, 67]

Treatment of Sepsis

The Surviving Sepsis Campaign evidence-based guidelines for the treatment of sepsis were released in 2004 and have been promoted to improve outcomes for patients with severe sepsis.[24, 68] The guidelines outline recommendations for targeting treatment of patients at risk of developing severe sepsis and septic shock. The guideline recommendations are aimed at providing resuscitation for sepsis-induced hypoperfusion and enhancing perfusion, antibiotic administration to combat infection, cultures to identify the source of infection, mechanical ventilation to optimize oxygenation, and source control to contain the infection. Additional treatment practices include glycemic control, steroid administration for adrenal insufficiency, prophylaxis measures for deep vein thrombosis and stress ulcer prevention, renal replacement therapies, administration of recombinant human activated protein C (rhAPC), blood product administration, sedation and analgesia, and consideration for limitation of support in critically ill patients.[68] These evidence-based guidelines are outlined in Table 4.

Bundles are also established for recognition and treatment of severe sepsis. The severe sepsis bundles are categorized into 6- and 24-hour bundles. The 6-hour bundle outlines the following interventions, which should be implemented immediately and within the first 6 hours of identification of severe sepsis:

1. Measure serum lactate.
2. Obtain blood cultures prior to antibiotics.
3. Administer broad-spectrum antibiotics within 3 hours from time of presentation in the emergency room and 1 hour for nonemergency room ICU admissions.
4. For hypotension and/or lactate > 4 mmol/L,
    a. Administer an initial minimum of 20 ml/kg of crystalloid (or colloid equivalent).
    b. Administer vasopressor for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure $\geq$ 65 mm Hg.
5. With persistent hypotension despite fluid resuscitation and/or lactate > 4 mmol/L,
    a. Achieve a central venous pressure (CVP) $\geq$ 8 mm Hg.
    b. Achieve a central venous oxygen saturation ($S_{CV}O_2$) of $\geq$ 70 percent.

The 24-hour bundle outlines the following interventions, which should be implemented immediately and within the first 24 hours of identification of severe sepsis:

1. Administer low-dose steroids for septic shock based on a standardized ICU policy.
2. Administer drotrecogin alfa (activated) based on a standardized ICU policy.
3. Maintain glucose control $\geq$ lower limit of normal, but < 150 mg/dL.
4. Maintain inspiratory plateau pressures < 30 mm H_20 for mechanically ventilated patients.

Implementation of the Surviving Sepsis Campaign guidelines, including the sepsis bundles, can favorably influence the course of sepsis. Additional focused approaches to the management of sepsis include early rapid-resuscitation shock protocols,[69] comprehensive interdisciplinary sepsis treatment protocols,[70] and algorithm-based or goal-directed care.[71]

Prevention of Sepsis

Nursing-related implications for early detection and treatment of sepsis include assessing patients for signs of infection, obtaining cultures for suspected infection, providing medical treatments for sepsis, and infection-prevention measures.[72] Awareness of the risk factors, clinical signs and symptoms, pathophysiology, and updates in the management of sepsis can enhance the nursing care for patients with severe sepsis and promote best practices for sepsis care in the ICU. Infection-prevention measures for sepsis include general infection control practices, hand-washing principles, and measures to prevent nosocomial infections (oral care and proper positioning to prevent nosocomial pneumonia, care of invasive catheters, skin care, wound care, identifying patients at risk for infection, prioritizing cultures for patients with suspected infection, and providing astute clinical assessment for early detection of sepsis).[73] Table 5 outlines general infection-prevention measures, highlighting nursing care considerations. A Cochrane systematic review is currently underway to assess the impact of the use of preoperative bathing or showering with skin antiseptics in reducing surgical-site infections.[74] Keeping up to date with evidence-based and research practices aimed at preventing health care–associated infections is an additional essential aspect of nursing care.

Antibiotic-Resistant Infections

Both the CDC and the World Health Organization have identified antibiotic resistance as an important public health concern.[75] The emergence of antimicrobial resistance in hospitals has been attributed to antibiotic use patterns as well as the capability of bacterial strains to develop resistance mechanisms through genetic alterations.[76] It is estimated that up to 50 percent of antibiotic use in hospitals is inappropriate.[77] According to the CDC, more than 70 percent of the bacteria that cause hospital-associated infections are resistant to at least one of the drugs most commonly used to treat them.[78]

When compared to infections caused by susceptible bacteria, infections caused by multidrug-resistant bacteria are associated with higher incidences of mortality, morbidity, and increased hospital length of stay.[77] Hospitalized patients who contract an infection with an antibiotic-resistant organism also have more costly management and therapies, and encounter more medical complications, than patients who do not acquire an infection or become infected with sensitive organisms.[79–80]

Data from many sources, including the CDC, indicate that antibiotic resistance to all the commonly used drug classes is increasing.[79] For example, between 1998 and 2003, the following increases in resistant organisms have occurred in critically ill patients: 11 percent increase in methicillin-resistant *Staphylococcus aureus* (MRSA); 12 percent increase in vancomycin-resistant *enterococci* (VRE); 47 percent increase in 3rd generation cephalosporin-resistant *Kliebsiella pneumoniae*; and a 20 percent increase in 3rd generation cephalosporin-resistant *Pseudomonas aeruginosa*.[81] An additional nosocomial infection that has been linked to antibiotic use in the hospital setting is *Clostridium difficile* (*C. difficile*). Although *C. difficile* is not an antibiotic-resistant infection, increased incidences in hospitalized settings have heightened awarenes.[82]

Because of the widespread increases in resistant organisms with the concomitant difficulties associated with treatment and complications, addressing the issue of resistant organisms has become one of the CDC's major concerns. Several main areas of focus for the prevention of

antibiotic-resistant infections include control of antibiotic use, determining the right antibiotic, and control of patient-to-patient spread.

Control of Antibiotic Use

Antibiotics are effective in treating infections because they kill or inhibit the growth of susceptible bacteria; however, they are not effective against viral infections. In an ever-increasing number of instances, one of more of the bacteria causing the infection are able to survive. Those bacteria are then able to multiply and begin to proliferate a new strain of bacteria that have developed the inherent ability to survive in the presence of the antibiotics that are designed to eradicate them. The more exposure bacteria have to various antibiotics, the more likely it is that resistant organisms develop.

According to the CDC, the biggest contribution to the development and continuing increase in resistant organisms is the overuse of antibiotics. Therefore, decreasing inappropriate antibiotic administration is the best way to control resistance. In 1995, the CDC[83] launched a national campaign to reduce antimicrobial resistance. The two major goals of this campaign are (1) to reduce inappropriate antibiotic use, and (2) to reduce the spread of resistance to antibiotics. Following are the three major CDC recommendations for supporting and achieving these goals:

- Prescribe antibiotic therapy only when it is likely to be beneficial.
- Use an agent that targets the likely pathogens.
- Order the antibiotic for the appropriate dose and duration.

Determining the Right Antibiotic

To effectively reduce antimicrobial resistance, prescribing health care providers must keep themselves informed about the most common infectious organisms present in the patient populations that they treat. For example, both VAP and hospital-associated pneumonia due to MRSA are becoming more common, and treatment strategies have emerged. Data compiled by an expert panel of the American Thoracic Society[26] support the following recommendations:

1. Apply early, appropriate, broad-spectrum antibiotic therapy at adequate doses; avoid excessive antibiotics through appropriate antibiotic deescalation.
2. Empiric regimens should include agents from a different antibiotic class than the patient has recently received.
3. Combination therapy should be used judiciously.
4. Linezolid may be an appropriate alternative to vancomycin.
5. Shorten antibiotic duration to the minimum effective period, and use short-course therapy whenever possible.
6. Use local microbiologic data to adapt treatment recommendations to the clinical setting.

Research has demonstrated the benefit of focused interventions aimed at improving antibiotic prescribing practices for hospital patients. A Cochrane systematic review of 66 studies revealed that interventions to improve antibiotic prescribing, dosing, timing of first dose, and duration of treatment are successful in reducing antimicrobial resistance.[77] Specific interventions included distribution of educational materials; reminders provided verbally, on paper, or by computer; formulary restrictions; therapeutic substitutions; automatic stop orders; antibiotic policy change strategies, including cycling, rotation, and crossover studies; computerized order entry; and Web-based antimicrobial approval systems.[77, 84] Other strategies, such as selective decontamination of

the digestive tract and use of CHG for daily bathing of hospitalized patients, have demonstrated efficacy in single-site controlled trials, but require further study.[4, 85]

Control Patient-to-Patient Spread

Controlling the patient-to-patient spread of bacteria is one of the least expensive, most basic, and effective means for controlling the spread of resistant organisms. Both MRSA and VRE, two of the most troublesome resistant organisms, are spread primarily from person-to-person contact. In hospitalized patients, this includes transmission by the hands of a health care provider caring for an infected patient. Diligent hand washing is therefore of the utmost importance, and nurses can have a major influence. Both MRSA and VRE can also survive on equipment and surfaces, such as floors, sinks, and blood pressure cuffs.

Specific CDC recommendations to prevent the spread of antimicrobial-resistant infections in hospitalized patients are outlined in Table 6. Focused measures include monitoring antimicrobial resistance of both community and nosocomial isolates on a regular basis, monitoring use of antimicrobials, increasing clinical staff awareness, and use of the CDC's guidelines for isolation precautions in hospitals.[76, 78] Preventative nursing care measures are essential in minimizing infection risk for hospitalized patients. Table 5 outlines additional essentials of infection-prevention measures for reducing the risk of health care associated infection among hospitalized patients.

Evidence-Based Practice Implications

Implementation of evidence-based practices, such as those that follow, can have a significant impact on lowering the incidence of health care–associated infections:

- Preventing health care–associated infections is an important component of ensuring a safe health care environment for hospitalized patients.
- Hand hygiene is an essential aspect of hospital-associated infection-reduction strategies.
- Nursing care measures can directly contribute to prevention of central line infections, urinary tract infections, sepsis, and antibiotic-resistant infections.
- Nursing care can directly contribute to prevention of hospital-associated pneumonia, particularly in patients who are most at risk related to advanced age, postoperative status, or mechanical ventilation. The evidence shows that the most important contributions of nursing care to prevention of hospital-associated pneumonia are in four areas: hand hygiene, respiratory care, patient positioning, and education of staff.
- Nursing-related care aimed at preventing urinary tract infections includes thorough assessment to determine need for indwelling catheter use, aseptic insertion technique, indwelling catheter care to minimize infection risk, and astute monitoring of patients with urinary catheters for signs of infection.
- Nursing-related measures to reduce the incidence of central line-associated infections include ensuring maximal barrier precautions during line insertion, maintenance of the central line site to minimize infection risk, prevention of contamination of central line ports during blood sampling, and maintenance of sterile techniques for dressing changes.

- Infection-prevention measures for sepsis include general infection control practices, hand-washing principles, and measures to prevent nosocomial infections (oral care and proper positioning to prevent nosocomial pneumonia, care of invasive catheters, skin care, wound care, identifying patients at risk for infection, prioritizing cultures for patients with suspected infection, and providing astute clinical assessment for early detection of sepsis).
- The main areas of focus for the prevention of antibiotic-resistant infections include control of antibiotic use, determining the right antibiotic, and control of patient-to-patient spread.
- Controlling patient-to-patient spread of infection with hand hygiene and general infection control practices are the most effective means for controlling the spread of resistant organisms.
- Keeping up to date with evidence-based and research practices aimed at preventing health care–associated infections is an essential aspect of nursing care.

Research Implications

Given the gaps in the current evidence base, additional research is needed in the following areas:

1. Continuous aspiration of subglottic secretions for VAP prevention
2. Semirecumbent position for VAP prevention
3. Silver alloy-coated catheters to prevent hospital-associated UTI
4. Suprapubic catheters to prevent hospital-associated UTI
5. Strategies to ensure use of full barrier precautions (gowns and gloves, dedicated equipment, dedicated personnel) during central line insertion
6. Tunneling short-term CVCs to decrease central line infections
7. Antibiotic limitations on hospital-associated infections due to antibiotic-resistant organisms
8. Strategies to promote appropriate antibiotic administration in hospitals, including the use of informatics technology (e.g., computer-assisted decision support) to assist in point-of-care prescribing and patient-outcome monitoring
9. Source control measures such as chlorhexidine gluconate for bathing, oral care protocols, and selective decontamination of the digestive tract
10. Strategies to improve hand-washing compliance (education/behavior change, sink technology and placement) to reduce hospital-associated infections

Conclusion

A number of factors can lead to the development of health care–associated infections in the hospital setting, including increasing patient acuity levels, chronically ill and acutely ill patients who harbor antibiotic-resistant bacteria, and frequent use of broad-spectrum antibiotics. Health care–associated infections can significantly impact patient outcomes, including morbidity and mortality rates, length of hospital stay, and costs of care. Therefore, focusing on health care–associated infections is an important aspect of providing quality health care.

A targeted approach to infection in hospitalized settings includes prevention measures, early recognition and treatment of infection, appropriate use of antimicrobials, and measures to prevent the transmission of infection among hospitalized patients. This chapter has reviewed the evidence-based knowledge on health care–associated infections—including hospital-associated pneumonia, urinary tract infection, catheter-related bloodstream infection, sepsis, and antibiotic-resistant infections—highlighting important information for nurses caring for hospitalized patients. Nurses can play a key role in the prevention, identification, and management of infections in hospitalized patients through the use of evidence-based measures to ensure a safe health care environment for hospitalized patients.

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85. Vernon MO, Hayden MK, Trick WE, et al Chlorhexidine gluconate to cleanse patients in a medical intensive care unit. Arch Intern Med 2006;166:306-12.

Table 1. Evidence-Based Guidelines for Prevention and Management of Hospital-Associated Pneumonia

- Hand hygiene as an essential component of hospital-associated pneumonia reduction.
- Respiratory care with encouragement of deep-breathing exercises.
- Head-of-bed elevation to between 30 and 45 degrees.
- Daily assessment of readiness for extubation.
- Control of oral-tracheal secretions and oral care to minimize colonization and aspiration of biofilm.
- Staff education about the significance of nosocomial pneumonias in patients and how interventions can reduce VAP.
    - Consider forming a multidisciplinary team (nurses, physicians, respiratory therapist, clinical pharmacist) or a unit group of staff to address VAP practice changes.
    - Develop communication strategies to alert and remind staff of the importance of VAP interventions.

Sources: Adapted from Institute for Healthcare Improvement. *Getting Started Kit: Prevent Ventilator Associated Pneumonia,* 2006, http://www.ihi.org/NR/rdonlyres/A448DDB1-E2A4-4D13-8F02-16417EC52990/0/VAPHowtoGuideFINAL.pdf (accessed March 11, 2006); and the American Association of Critical Care Nurses practice alert: Ventilator-Associated Pneumonia, http://www.aacn.org (accessed March 5, 2006).

Table 2. Evidence-Based Strategies for Urinary Tract Infection Prevention

- Indwelling urinary catheters should be inserted using aseptic technique and sterile equipment.
- Only hospital personnel who know the correct technique of aseptic insertion and maintenance of the catheter should handle catheters.
- Hospital personnel should be provided with periodic in-service training stressing the correct techniques and potential complications of urinary catheterization.
- Indwelling urinary catheters should be inserted only when necessary and left in place only for as long as necessary.
- Other methods of urinary drainage such as condom catheter drainage, suprapubic catheterization, and intermittent urethral catheterization should be considered as alternatives to indwelling urethral catheterization.
- Hand washing should be done immediately before and after any manipulation of the indwelling urinary catheter site or apparatus.
- Indwelling catheters should be properly secured after insertion to prevent movement and urethral traction.
- A sterile, continuously closed drainage system should be maintained.
- The catheter and drainage tube should not be disconnected unless the catheter must be irrigated, and irrigation should be used only for suspected obstruction.
- If breaks in aseptic technique, disconnection, or leakage occur, the collecting system should be replaced using aseptic technique after disinfecting the catheter-tubing junction.
- Specimen collections should be obtained from the distal end of the catheter, preferably from the sampling port after cleansing with a disinfectant and then the urine specimen aspirated with a sterile needle and syringe.
- Consider the use of antimicrobial catheters for indwelling urinary catheters.

Source: Adapted from Wong ES, *Guideline for Prevention of Catheter-Associated Urinary Tract Infections.* http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html.

Table 3. Evidence-Based Strategies for Central Line Infection Prevention

- Education and training should be provided for staff who insert and maintain intravenous lines.
- Maximal sterile barriers should be used during catheter insertion (cap, mask, sterile gown and gloves, and a large sterile drape).
- A 2% chlorhexidine preparation is the preferred skin antiseptic, to be applied prior to insertion.
- Antiseptic- or antibiotic-impregnated catheters should be reserved for very high-risk patients or situations in which catheter-related BSI rates are high despite careful attention to these recommendations.
- Replace peripheral intravenous sites in the adult patient population at least every 96 hours but no more frequently than every 72 hours. Peripheral venous catheters in children should be left in until the intravenous therapy is completed, unless complications such as phlebitis or infiltration occur.
- Replace intravenous tubing at least every 96 hours but no more frequently than every 72 hours.
- Replace intravenous catheters as soon as possible when adherence to aseptic technique during catheter insertion cannot be ensured (i.e., prehospital, code situation).
- Central lines should not routinely be replaced at scheduled intervals.
- Consider use of a central line insertion checklist to ensure all processes related to central line insertion are executed for each line placement.
- Consider use of a central line insertion cart to avoid the difficulty of finding necessary equipment to institute maximal barrier precautions.
- Replace central line dressings whenever damp, loose, or soiled or at a frequency of every 2 days for gauze dressings and every 7 days for transparent dressings.
- Avoid use of antibiotic ointment at insertion sites because it can promote fungal infections and antibiotic resistance.
- Include daily review of line necessity.
- Assess competency of staff who insert and care for intravascular catheters.

Sources: Adapted from: O'Grady NP, et al., *Guidelines for the Prevention of Intravascular Catheter-Related Infections,* Centers for Disease Control and Prevention, MMWR Recomm Rep 2002;51(RR-10):1–29; Institute for Healthcare Improvement, *Getting Started Kit: Prevent Central Line Infections,* 2006, available at: http://www.ihi.org/NR/rdonlyres/BF4CC102-C564-4436-AC3A-0C57B1202872/0/CentralLinesHowtoGuideFINAL720.pdf (accessed March 11, 2006); and American Association of Critical Care Nurses practice alert: *Preventing Catheter-Related Bloodstream Infections,* www.aacn.org (accessed March 5, 2006).

Table 4. Evidence-Based Guidelines for Sepsis

The Surviving Sepsis Campaign guidelines outline evidence-based recommendations for targeting treatment of patients at risk of developing severe sepsis and septic shock.

The following grading system was used to classify the treatment recommendations:

A. Supported by at least two level I investigations (large, randomized trials with confident results)
B. Supported by one level I investigation
C. Supported by level II investigations only (small, randomized trials with uncertain results)
D. Supported by at least one level III investigation (nonrandomized study)
E. Supported by level IV (nonrandomized, historical controls, and expert opinion) or level V evidence (case series, uncontrolled studies, and expert opinion)

a. Initial resuscitation for sepsis-induced hypoperfusion—grade B
   - Fluid resuscitation to a central venous pressure of 8–12 mmHg
   - Early goal-directed therapy

- Transfusion of packed red blood cells to achieve a hematocrit of ≥ 30 percent
- Administration of inotropic infusion (e.g., dobutamine)

b. Diagnosis
- Obtain cultures: at least two blood cultures with one drawn percutaneously and one drawn through each vascular access device; cultures of other sites such as urine, wounds, respiratory secretions should be obtained *before* antibiotic therapy is initiated—grade D
- Diagnostic studies (e.g., ultrasound, imaging studies)—grade E

c. Antibiotic therapy
- Empirical antibiotics—grade E

d. Source control
- Removal of potentially infected device, drainage of abscess, debridement of infected necrotic tissue—grade E

e. Enhance perfusion
- Fluid therapy—grade C
- Vaspressors—grade E
- Inotropic therapy—grade E

f. Steroids
- For patients with relative adrenal insufficiency—grade C

g. Recombinant human activated protein C (rhAPC)—grade B
- For patients with sepsis-induced multiple organ failure with no absolute contraindication related to bleeding risk

h. Blood product administration
- To target hemoglobin of 7.0 to 9.0 g/dL—grade B

i. Mechanical ventilation
- Lung protective ventilation for acute lung injury/acute respiratory distress syndrome—grade B

j. Sedation, analgesia, and neuromuscular blockade
- To provide comfort yet avoid prolonged sedation—grade B

k. Glucose control
- To maintain blood glucose <150 mg/dL—grade D

l. Renal replacement
- For acute renal failure—grade B

m. Prophylaxis measures
- Deep vein thrombosis—grade A
- Stress ulcer—grade A

n. Consideration for limitation of support
- Discuss end-of-life care for critically ill patients—grade E
- Promote family communication to discuss use of life-sustaining therapies—grade E

Source: Adapted from Dellinger et al. Surviving Sepsis Campaign guidelines for management of severe sepsis and septic shock. Crit Care Med 2004;32:858-72.

Table 5. General Infection-Prevention Measures

- Standard precautions apply to the care of all patients.
- Contact precautions apply to patients with a known or suspected infection with pathogens that can be transmitted by direct or indirect contact.
- Droplet precautions apply to patients with a known or suspected infection with pathogens that can be transmitted by infectious droplets.
- Airborne precautions apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route.

Categories of Infection-Prevention Measures

- Hand washing: after touching blood, body fluids, secretions, excretions, and contaminated items, whether or not gloves are worn; after gloves are removed, between patient contacts, between tasks and procedures
- Gloves: when touching blood, body fluids, secretions, excretions, and contaminated items; before touching mucous membranes and nonintact skin; between tasks and procedures; after contact with potentially contaminated material
- Mask, eye protection, face shield: to protect mucous membranes of the eyes, nose, and mouth during procedures and patient-care activities with the potential to generate splashes or sprays of blood, body fluids, secretions, and excretions
- Gown: to protect skin and prevent soiling of clothing during procedures and patient-care activities with the potential to generate splashes or sprays of blood, body fluids, secretions, or excretions
- Patient care equipment: appropriate handling of used patient-care equipment soiled with blood, body fluids, secretions, and excretions to prevent skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to other patients and environments; to ensure that reusable equipment is not used until it has been cleaned and reprocessed appropriately; to ensure that single-use items are discarded properly
- Environmental control: to ensure adherence with procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other frequently touched surfaces
- Linen: procedures for handling, transporting, and processing used linen soiled with blood, body fluids, secretions, and excretions to prevent skin and mucous membrane exposures and contamination of clothing; to avoid spread of microorganisms to other patients and environments
- Patient placement: placement of patients with the potential to contaminate the environment in a private room

Source: Adapted from CDC, *Standard Precautions.* http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html. Accessed February 21, 2006

Table 6. Measures To Prevent Antimicrobial Resistance in Hospitalized Patients

- Establish systems for monitoring bacterial resistance and antibiotic use.
- Place limitations on antibiotic use.
- Establish systems for monitoring both process and outcome measures for infected patients, such as appropriate use of universal precautions, compliance with hand washing, length of hospital stay, or complication rates.
- Adopt the recommendations of the CDC's guidelines for isolation precautions in hospitals to prevent colonization and/or spread of resistant microorganisms.
- Place infected patients in private rooms or only with other infected patients.
- Hospital staff should wear gloves and gowns whenever they enter the room of an infected patient, even if there is no direct patient contact, because these organisms can extensively contaminate the environment.
- Patient-care items should be single-patient use whenever possible.
- Use a notification system so that staff are aware of the detection of cases where antimicrobial-resistant infections such as MRSA and VRE have been detected.
- Ensure that clinical staff are knowledgeable about hospital policies regarding antimicrobial-resistant infections such as MRSA and VRE colonizing in or infecting patients.

Source: Adapted from Centers for Disease Control, *Antimicrobial Resistence in Healthcare Settings,* 2005. http://www.cdc.gov/ncidod/dhqp/ar.html. Accessed February 20, 2006.

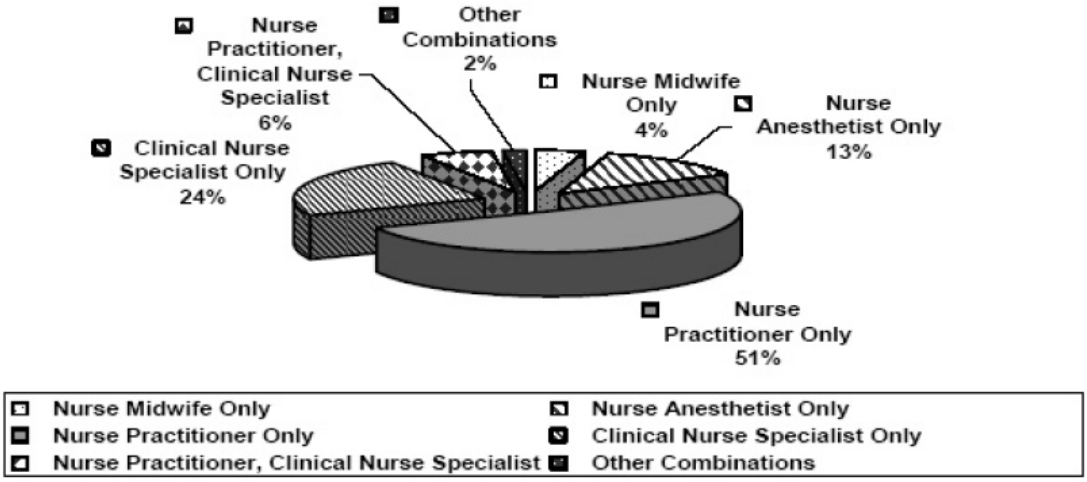
Chapter 43. Advanced Practice Registered Nurses: The Impact on Patient Safety and Quality

Eileen T. O'Grady

Background

This chapter will define the role of advanced practice nurses (APNs), review a selected sample of the literature regarding what we know about APNs and patient safety/quality, and describe the research gaps and limitations. Advanced practice registered nurse is a term used to encompass certified nurse-midwife (CNM), certified registered nurse anesthetist (CRNA), clinical nurse specialist (CNS), and nurse practitioner (NP). Advanced practice nursing is broadly defined as nursing interventions that influence health care outcomes, including the direct care of individual patients, management of care for individuals and populations, administration of nursing and health care organizations, and the development and implementation of health policy.[1] In 2004, the number of registered nurses (RNs) prepared to practice in at least one advanced practice role was estimated to be 240,461, or 8.3 percent of the total RN population. As noted in figure 1 below, the largest group among the APNs was NPs, followed by CNSs. The APN movement has been growing exponentially with APNs employed in every health care sector. According to the Bureau of Labor Statistics,[2] the demand for APNs is expected to continue to increase over the next decade and beyond, as the need and demand for effective health care increases, especially in rural, inner-city, and other underserved areas.

Figure 1. Registered Nurses Prepared for Advanced Practice, March 2004



Source: 2004 National Sample Survey of Registered Nurses, U.S. Department of Health and Human Services, Health Resources and Services Administration. http://bhpr.hrsa.gov/healthworkforce/reports/rnpopulation/preliminaryfindings.htm.

Direct clinical practice is a core competency of any APN role, although the actual skill set varies according to the needs of the patient population.[3] APNs build on the competence of the

RN skill set and demonstrate a greater depth and breadth of knowledge, a greater synthesis of data, increased complexity of skills and interventions, and significant role autonomy. The APN is prepared to assume responsibility and accountability for health promotion and the assessment, diagnosis, and management of patient problems, including the use and prescription of pharmacologic and nonpharmacologic interventions.[4]

Advanced Practice Nurses Evolve to the Doctoral Level

The American Association of Colleges of Nursing envisions all APN master's-level programs will evolve to a doctorate of nursing practice (DNP) by 2015.[5] This evolution to the doctoral level for APN education stems from the three Institute of Medicine (IOM) reports, *Too Err is Human*,[6] *Crossing the Quality Chasm*,[7] and *Health Professions Education: A Bridge to Quality*,[8] which emphasized widespread problems related to patient safety and called for dramatic restructuring of traditional health professions education. These reports recommended all health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidenced-based practice, quality improvement, and informatics. It was emphasized that the best-prepared senior-level nurses should be in key leadership positions and participating in executive decisions. Complex practice and delivery system demands create a mandate to expand the clinical education and leadership capacity of APNs. Graduates of DNP programs are expected to use advanced communication skills/processes to lead quality improvement and patient safety initiatives in health care systems.

Research Evidence

Certified Nurse-Midwife

CNMs are licensed health care practitioners educated in the two disciplines of nursing and midwifery. They provide primary health care to women of childbearing age, including prenatal care, labor and delivery care, care after birth, gynecological exams, newborn care, assistance with family planning decisions, preconception care, menopausal management, and counseling in health maintenance and disease prevention. CNMs attend more than 10 percent of the births in the United States; 96 percent of these are in hospitals.[9]

What we know. MacDorman and Singh[10] used logistic regression models to examine differences between CNMs and physician-delivered births in infant perinatal mortality on all singleton vaginal births between 35 and 43 weeks gestation in the United States (n = 810,790) in 1991. After controlling for all social and health risk factors, the CNM risk of infant death was 19 percent lower, neonatal mortality was 3 percent lower, and low-birth-weight infants were 31 percent fewer than with the physician-delivered babies. The mean birth weight was 37 grams heavier for the CNM-attended births. The researchers concluded that CNMs provide a safe and viable alternative to maternity care in the United States, particularly for low- to moderate-risk women. The retrospective study design could not address the inherent selection bias of mothers who choose midwives versus mothers who choose physicians to assist with delivery.

Rosenblatt and colleagues[11] compared a random sample of records of Washington State obstetricians, family physicians, and CNMs for low-risk women over a 1-year period (n = 1,322). The researchers found that CNM patients were less likely to receive continuous fetal monitoring and had lower rates of labor induction, epidural injections, and caesarean sections

and overall used fewer resources. The researchers concluded that overall, in Washington State, low-risk patients of CNMs received fewer obstetrical interventions than similar patients cared for by family physicians or obstetricians, especially lower cesarean rates and resource use. There was no controlling for maternal risk factors such as maternal age and birth weight in this study, and the degree of selection bias in pregnant women choosing a CNM versus a physician could have influenced these results.

Oakley and colleagues[12] compared the pregnancy outcomes (n = 1,181) of low-risk pregnant women cared for by either an obstetrician or a CNM. After controlling for maternal risk and selection bias, the nurse-midwife group had statistically significant fewer infant abrasions, perineal lacerations, and complications; higher satisfaction with care; and lower hospital and professional fee charges. The researchers concluded that important significant differences were found between the CNMs and obstetricians and that CNMs are contributing significantly to lowering maternity care costs and improving maternal outcomes of low-risk women.

While most of the research on CNM quality covered low-risk women, Davidson[13] explored the effectiveness of CNM care for high-risk women. Outcomes of high-risk women cared for by CNMs in an inner-city hospital (n = 803) were compared with all women who delivered in the United States in 1994. The comparison suggests that CNMs can provide safe care to women with high-risk conditions. The single site of the study sample and lack of a controlled pair group make generalizability of these findings difficult.

Nurse Anesthetist

A CRNA is a registered nurse who is educationally prepared for and competent to engage in the practice of nurse anesthesia. CRNAs administer approximately 27 million anesthetics in the United States each year, practice in every setting where anesthesia is available, and are the sole anesthesia providers in more than two-thirds of all rural hospitals.[14] CNRAs can also administer every type of anesthetic and provide care for every type of surgery or procedure, from open heart to cataract to pain management. CRNAs are both responsible for and accountable to others for their individual professional practices. In addition, CRNAs are capable of exercising independent professional judgment within their scope of competence and licensure.[3] CRNAs provide anesthetics to patients in collaboration with surgeons, anesthesiologists, dentists, podiatrists, and other qualified health care professionals. When anesthesia is administered by a nurse anesthetist, it is recognized as the practice of nursing and is not a medically delegated act.[14]

What we know. In 1988, the Centers for Disease Control and Prevention (CDC)[15] conducted a pilot study to explore anesthesia outcomes. The study concluded that anesthesia-caused mortality and severe morbidity were too low to warrant a broader study. The CDC found that precise estimates would require studying 290 hospitals and would cost $15 million over 5 years, which was not deemed feasible. According to the IOM,[6] it is estimated that death occurs only once for every 200,000–300,000 anesthetics administered. This low incidence of error makes studying the safety of CRNAs as a distinct provider group extremely difficult as it would require an enormous number of study subjects.

To answer questions about surgical patients' safety with regard to CRNAs versus anesthesiologists, Pine and colleagues[16] studied 404,194 anesthesia cases across 22 States. Risk adjustment was conducted for case mix, risk factors, hospital characteristics, geographic location, and surgical procedure. The study found no statistically significant difference in the mortality rate for CRNAs and anesthelogists working together versus working individually. There was no statistically significant difference between hospitals staffed by CRNAs (without

anesthesiologists) versus hospitals in which anesthesiologists provided or directed the anesthesia care. The researchers concluded that, based on the surgical procedures included in the study, inpatient surgical mortality is not affected by whether the anesthesia provider is a CRNA or an anesthesiologist.

Anesthesia-related accidents are infrequent, largely due to systemic quality improvements in applied technology, anesthetic agents, multimodal pain management, and development and adoption of practice guidelines in the broad field of anesthesiology over the last 40 years. The dramatic decrease in anesthesia-related deaths since 1960 may be largely attributable to the disciplinewide sharp focus on safety issues such as increased vigilance during long operations and rapid response teams. The pulse oximeter, standardization of equipment, and changes in education, including the use of simulation, have also contributed to threshold improvement in patient safety. In fact, anesthesia as a health care discipline is an exemplar case study of how local but complex, high-risk, dynamic patient care has noticeably reduced its error rate[6] (p. 164). The administration of anesthesia is built on a foundation of sound safety principles and has been a strong leader in creating systems built around patient safety.

Clinical Nurse Specialist

The CNS is an expert clinician in a specialized area of nursing practice. The specialty may be a population (e.g., pediatrics), a setting (e.g., critical care), a disease (e.g., cardiovascular or mental health), or a type of problem (e.g., wound or pain). CNSs are engaged in direct clinical practice; function as consultants in their area of expertise; provide expert coaching and guidance; interpret, evaluate, and participate in research; provide clinical and professional leadership; collaborate; and employ ethical decisionmaking.[3]

What we know. In 2001, a randomized controlled clinical trial by Brooten, Youngblut, and colleagues[17] looked at prenatal, infant (194) and maternal (173) outcomes where half of the prenatal care was delivered in the home by CNSs. Results found that the group cared for in the home by CNSs experienced fewer fetal/infant deaths, fewer preterm infants, fewer prenatal hospitalizations, and fewer rehospitalizations compared to the control group. Researchers concluded that the CNS prenatal home care saved 750 hospital days or about $2.5 million dollars.

Topp, Tucker, and Weber[18] conducted a retrospective chart review on 491 hospitalized congestive heart failure patients over a 12-month period. Results indicated that length of stay and hospital charges were significantly less in patients who were case-managed by a CNS.

Naylor and colleagues[19] conducted a randomized clinical control trial with 276 patients and 125 caregivers to show the effects of a comprehensive discharge planning protocol. The discharge planning protocol was specifically designed for elderly medical and surgical patients and implemented by a gerontological CNS. From the initial discharge until 6 weeks after discharge, the medical intervention group had fewer readmissions, fewer total days of rehosptilization, lower readmission charges, and lower charges for all health care services after discharge compared to the control group and the surgical intervention group.

Brooten, Kumar, Brown, and colleagues[20] conducted a randomized clinical trial on the effectiveness of CNS home care on the early hospital discharge of very low-birth-weight infants (n = 79). The researchers found that hospital costs were 27 percent less than for the control group. The researchers concluded that early hospital discharge for very low-birth-weight infants was safe with CNSs conducting home followup care.

Nurse Practitioner

NPs are registered nurses who are prepared, through advanced education and clinical training, to provide a wide range of preventive and acute health care services to individuals of all ages. NPs take health histories and provide complete physical examinations; diagnose and treat many common acute and chronic problems; interpret laboratory results and x-rays; prescribe and manage medications and other therapies; provide health teaching and supportive counseling, with an emphasis on prevention of illness and health maintenance; and refer patients to other health professionals as needed.[21] Hughes and colleagues[22] have categorized the 40-year history of NP research into succinct eras, chronicling the evidence base on NPs, by far the largest of all of the four APN roles. The current era is characterized by strategies to combat rising costs and tension-building between NPs and the medical profession. The authors provide keen insight into why benchmarking NP care against physician care may have taken us to the end of that research road.

What we know. Lambing and colleagues[23] sought to build the evidence base for NP effectiveness in the acute care setting. They conducted a descriptive, comparative research design on 100 randomly selected hospitalized geriatric patients and a sample of 17 professional providers who staffed 3 hospital units over a 1-month period. The researchers found that the patients of NPs were older and sicker at the time of discharge and that readmission and mortality rates were similar amongst NPs and physicians. The researchers concluded that NPs provide effective care to hospitalized geriatric patients, particularly to those who are older and sicker.

Mundinger, Kane, and colleagues[24] conducted the most definitive research on NPs and quality by exploring the outcomes of care in patients randomly assigned either to a physician or to a nurse practitioner for primary care after an emergency or urgent care visit. The NP practice had the same degree of independence as the physicians, making this study unique. Patient interviews and health services utilization data were used on a total of 1,316 patients, and it was determined that the health status of the NP patients and the physician patients were comparable at initial visits, 6 months, and 12 months. A followup study conducted in 2004[25] showed that patients 2 years later confirmed continued comparable outcomes for the two groups of patients. No differences were identified in patient outcomes such as health status; physiologic measures; satisfaction; and use of specialists, emergency room, or inpatient services. The researchers concluded that NP care and physician care was comparable.

A study by Avorn and colleagues[26] used a sample of 501 physicians and 298 NPs who responded to a hypothetical scenario regarding a patient with epigastic pain (acute gastritis). They were able to request additional information before recommending treatment. If adequate history taking was performed, the provider would have learned that the patient ingested aspirin, coffee, and alcohol, and was under a great deal of psychosocial stress. Compared to NPs, the physician group was more likely to prescribe a medication without seeking the relevant history. NPs, in contrast, asked more questions, obtained a complete history, and were less likely to recommend prescription medication. This study suggests that NP-delivered care may be superior to that of physicians when a diagnosis is history dependent.

Summary of APN Research on Quality

A selected sample of research on APNs and quality and safety was conducted because much of the APN research lacked randomization, had sample sizes too small to be generalizable to the national health care system, or was not relevant to quality or safety. The summary of the preceding research samples suggests that APN[*]-delivered care, across settings, is at least equivalent to that of physician-delivered care as regards safety and quality. In the case of the CNSs, it appears that CNSs demonstrate competence and cost savings as case managers for patients transitioning from acute care to home care. Overall, however, the study designs and sample sizes are too limited to draw conclusions that are generalizable to the United States population. Widely accepted methodological techniques and research best practices outlined in the report of the Agency for Healthcare Research and Quality (AHRQ), *Evidence Report to Rate the Strength of Scientific Evidence*[27] (see Table 1), have not been applied to the emerging research on APN practice and quality. Methodologic quality has been defined as the extent to which all aspects of a study's design and conduct can be shown to protect against systematic bias, nonsystematic bias, and inferential error. Not met were certain design elements in the preceding APN research design, conduct, or analysis that have been shown through empirical work to protect against bias or that are long-accepted practices in epidemiology and related research fields. These research evaluation criteria include quality, quantity, and consistency that are well-established variables for characterizing how confidently one can conclude that a body of knowledge provides information on which clinicians or policymakers can act. As the research on APN and quality evolves over time, the rigor of the research and its capacity to influence policy will improve.

Table 1. Important Domains and Elements for Systems To Grade the Strength of Evidence

Quality:	The aggregate of quality ratings for individual studies, predicated on the extent to which bias was minimized.
Quantity:	Magnitude of effect, numbers of studies, and sample size or power.
Consistency:	For any given topic, the extent to which similar findings are reported using similar and different study designs.

These studies are also limited in looking specifically at patient safety as a subset of health care quality. According to *Crossing the Quality Chasm*,[7] the American health care system is in need of fundamental change because health care frequently harms and fails to deliver its potential benefits. The preceding literature compared APNs to physicians within the context of a health care system that is not necessarily patient safety focused. Comparing APN to physician outcomes was an important validation of APN practice as these professions evolved. Given the current mandate for fundamental system change, new research questions on APN practice as they relate to patient safety have emerged. Most outcome studies to date have focused on acute care

[*] No studies comparing CNSs to physicians have been conducted.

nurse staffing and nursing-sensitive outcomes such as decubitus ulcers.[28] The research to measure APN outcomes with valid tools has yet to be developed.

While the summary of research related to the safety and quality of APNs validates them as competent and comparable to physicians in many aspects, more research is needed to reduce errors and enhance patient safety. Threshold improvement cannot be accomplished without interdisciplinary practice approaches—which are going to require revolutionary change to flatten the educational and cultural silos between medicine and nursing education.[29] It is crucial that APNs are separated out as distinct provider types in all interdisciplinary research and administrative and clinical datasets. It has taken the nursing profession decades to untangle nursing's unique role and value within the hospital and decouple professional registered nursing from the "hotel costs" of a hospital stay. RNs have historically been characterized as a cost center rather than a highly valued revenue source within hospitals. If all professional nursing activity was billed for separately, such as is done with physician care, nursing's value would not have to be debated. As the evidence base on interdisciplinary teams is built, APNs must not become invisible on the health care team. Building a research portfolio on APN practice will require adherence to methodological quality that explores APN practice within an interdisciplinary context. Practice Implications—Barriers to APN Practice

Lack of Collaboration

Health professionals work together in small groups providing care, be it oncology, the operating room, end of life, or primary care. These team members, however, are educated in their health professional silo and likely have little knowledge of their team members' skill sets. The IOM report, *To Err is Human*,[6] suggested that health professionals should be educated in teams using evidenced-based methods employed in aviation such as simulation and checklists. People make fewer errors when they work in teams because it forces processes to be planned and standardized, forces team members to have a clear role and to look out for one another, noticing errors before they become an accident. In an effective interdisciplinary team, members come to trust one another's judgments and attend to one another's safety concerns.

In no uncertain terms, the IOM declares that most care delivered today is done by teams of people, yet training often remains focused on individual responsibilities, leaving practitioners inadequately prepared to enter complex settings. The silos created through training and organization of care impede safety improvements.[6]

The *Quality First* report highlighted "… the need for clinicians to develop a broader systems perspective. Specifically, the commission states that '… in health care organizations, much of the learning is aimed at improving individual physicians learning to become better physicians, nurses learning to become better nurses, rather than learning how the system as a whole can improve.'"[30] Irrespective of health care setting, there is a high premium placed on medical autonomy and perfection and a historical lack of interprofesional cooperation and effective communication.[6]

Learning and working in a true interdisciplinary context is a requirement for improved patient safety, and the silo systems in place now are viewed as wholly inadequate. It is the space between the disciplines that may create the most opportunity for patient safety improvement. The following quote expresses the opportunity created in this interdisciplinary space as John Brown, an information technology leader, discusses how his company lost the commercial market share on the world's first personal computer solely due to a lack of interdisciplinary collaboration:

> First of all, we were fundamentally noncollaborative, there was surprisingly little cross-disciplinary work. There were turf wars and physicists, for example, were not allowed to talk to computer scientists . . . To me the white space between fields is the place to explore. . . . If you get multiple disciplines together working around the root of a problem, it pulls you out of your own discipline and fuses different points of view that lead to a reframing.[31]

Exemplars in collaborative models have demonstrated quality and safety improvements in two divergent settings, acute and chronic care. The Rapid Response Team (RRT)—known by some as the Medical Emergency Team (MET)—is a team of clinicians who bring critical care expertise to the patient's bedside (or wherever it is needed) in the acute care setting. The concept is relatively simple: create a small but powerful team experienced at assessing patients' symptoms and make that team continuously and readily available to any provider who wants a second opinion about a patient, particularly a patient showing signs of potential decline, as patients often exhibit signs and symptoms of physiological instability for some period of time prior to a cardiac arrest.[32]

Another model, the Chronic Care Model, also has great potential to improve health care quality by employing a team of providers to apply a high standard of scientific evidence to groups of patients with a chronic illness.[33] Yet the role of providers, the community, and patients with chronic care needs can be unclear and at times disjointed.

Missing in the APN research is the notion of team-delivered care as it relates to quality. One study[34] explored only cost implications, and not quality per se, of multidisciplinary teams of hospitalists, nonhospitalist attending physicians, and NPs. The study model employed NPs to supplement physician care and ensure continuity of care, comparing this approach for managing 581 general medicine patients in one unit of a large academic medical center during hospitalization and for 30 days after discharge with usual care for 626 patients in another general medicine unit. The research findings indicated that reduced hospital length of stay (LOS) and increased hospital profits occurred in the collaborative model when compared with physician-only care. This approach reduced the average LOS from 6 to 5 days. By reducing the number of hospital days after the first 4 days, which are the most profitable ones, hospital profits increased by $1,591 per day for each patient without increasing hospital readmission or mortality rates.[34]

State Regulation of APN Practice

The 50 States and the District of Columbia have vastly different laws governing APN practice. The 51 nurse practice acts currently lack any clear framework or congruence amongst each other.[35] This high degree of variation suggests that the regulatory framework for APN practice is not evidence-based and that States are not promulgating APN regulations with a coherent patient safety orientation.

By way of example, some States employ a joint board of nursing-board of medicine to regulate APNs, while others require physicians and APNs to be in collaborative or even supervisory relationships with each other. Some States consider APN practice a medically delegated act and require physician, dentist, or podiatrist supervision of APNs, while other States require physicians to be in contact with the APN periodically throughout the week or to be physically within a defined radius (defined in miles) of the NP. Some States require APNs with doctorates to "hide" their doctoral degree credential from patients, and other States do not require APNs to be nationally certified to practice. These practice acts vary even within States

(urban or rural) and can specify the types of medical conditions APNs are permitted to treat. The current APN regulatory environment has numerous issues that foster poor quality or impair patient safety. Regulatory barriers that directly impact patient safety include onerous entry into APN practice; cryptic scope of practice regulations; polices that restrict APN hospital and prescriptive privileges and impede continuity of care, the capacity of NPs to serve as primary care providers (NP empanelment), to receive third-party payment, or the pharmacist from printing the prescribing APN name on the prescription bottle, making it difficult for pharmacists or patients to contact the prescribing APN. The APRN Joint Dialogue Group[36] of the National Council of State Boards of Nursing (NCSBN) recommends sole board of nursing regulation for APN practice and that APNs be independent practitioners with no regulatory requirement for supervision from another discipline across all States. Standardizing nurse practice acts will establish the groundwork necessary to move to a mutual recognition (interstate compact) for APNs.

This high degree of variation across the States for APN regulation has spotlighted the need to ensure that regulation serves the public, promotes public safety, and does not present unnecessary barriers to patients' access to care. Likewise, the regulatory bodies overseeing APN practice are slow or unable to keep pace with changes in health care. Moreover, the Internet has rendered geographic boundaries irrelevant, and as technology and national delivery systems infiltrate care delivery, these practice acts will strangle innovation. The *Crossing the Quality Chasm* report notes that State practice acts that limit nonphysician providers, e-health, and multidisciplinary teams act as a barrier to innovative health care because these innovations can help care for patients across settings and over time[7] (p. 215). *Crossing the Quality Chasm* recommends greater coordination and communication among professional boards, both within and across States, as the patchwork of NP regulations are resolved over time.

The IOM's *Crossing the Quality Chasm* recommends that regulators create an infrastructure to support evidence-based practice, facilitate the use of information technology, align payment incentives, and prepare the workforce to better serve patients in a world of expanding knowledge and rapid change[7] (p. 5). The report stresses that if innovative programs are to flourish, regulatory environments will be required to foster innovation in organizational arrangements, work relationships, and use of technology. The 21st century health care system described in *Crossing the Quality Chasm* simply cannot be achieved in the current environment of regulation and oversight. The report summarizes the current patchwork of regulatory frameworks as inconsistent, contradictory, duplicative, outdated, and counter to best practices. Moving the NCSBN's vision for APN regulation into reality across all of the States is requisite to promote APNs and patient safety.

APN Invisibility

Many polices have rendered APN practices "invisible" or established barriers that adversely impact accurate measurement of quality-related data. By way of example, Medicare has a policy that allows physician practices to bill Medicare for NP-provided services as "incident-to" the physician. This allows medical practices to bill for NP care through a physician, creating perverse incentives to make NPs invisible, as NPs are reimbursed 100 percent of the physician rate when billing Medicare "incident-to." When APNs bill Medicare directly, they bill at 85 percent of the physician rate. The cost savings of using a less expensive provider are passed onto the physician practice, not the patient or the payer.

Another startling example of APN invisibility is that the most comprehensive ambulatory care data, the National Ambulatory Medical Care Survey (NAMCS) produced by the National Center for Health Statistics, does not include APNs. This important national survey is conducted annually on the provision and use of ambulatory medical care services in the United States. Findings are based on a sample of visits to nonfederally employed office-based physicians who are primarily engaged in direct patient care. Each physician is randomly assigned to a 1-week reporting period. During this period, data for a systematic random sample of visits are recorded by the physician or office staff on an encounter form provided for that purpose. Data are obtained on patients' symptoms, physicians' diagnoses, and medications ordered or provided. The survey also provides statistics on the demographic characteristics of patients and services provided, including information on diagnostic procedures, patient management, and planned future treatment. APNs practicing in ambulatory care are not surveyed or discussed in the 906 million visits to physician offices.[37]

In that same vein, the Center for Studying Health System Change (HSC), whose mission is "to inform policy makers about how local and national changes in the financing and delivery of health care affect people … strives to provide high-quality, timely and objective research and analysis that leads to sound policy decisions, with the ultimate goal of improving the health of the American public."[38] HSC employs rigorous surveys and in-depth case studies and chronicles trends in the health care system; however, their provider surveys include only physicians. HSC unquestionably influences decisionmakers on all sides of the issues and guides those crafting health care policy in Government and private industry. More must be done to encourage thought leaders to think about health system change more broadly.

APNs are also invisible in the basic county-specific Area Resource File (ARF), a database containing more than 6,000 variables for each of the Nation's counties. ARF contains information on health facilities; health professions; and measures of resource scarcity, health status, economic activity, health training programs, and socioeconomic and environmental characteristics. In addition, the basic file contains geographic codes and descriptors that enable it to be linked to many other files and to aggregate counties in various geographic groupings. This database is used to establish Health Professional Shortage Areas (HPSAs), using criteria of population-to-clinician ratios. It is difficult to include APNs in the ratio as there is no uniform data source at the ZIP Code level on APNs. HPSA designation is important to communities because of the enormous funding priority they receive in more than 34 Federal programs that depend on the shortage designation to determine eligibility.[39] About 20 percent of the U.S. population reside in primary medical care HPSAs, and APNs are not considered full-time equivalent providers in the designation because of the lack of data. Fully counting APNs could thus impact the distribution of Federal funds to counties.

The Federal requirement that CRNAs must be in a supervisory relationship with anesthesiologists creates enormous barriers to adequate measuring of patient safety data, as the CRNA may not be identified as a distinctive provider group, rendering CRNA-delivered anesthesia invisible. This policy also has a detrimental effect on rural States that cannot staff their hospitals with anesthesiologists; therefore, many States have opted out of the Federal requirement for CRNA supervision in order to meet their patients' needs.

These policies, in each of the preceding examples, remove or marginalize the APN from all administrative and clinical data systems or survey designs. This lack of inclusion in these national research endeavors makes it impossible to understand the full dimensions and value of NP practice.

Practice Implications

The intense drive to measure quality is a deep concern for payers, regulators, and increasingly consumers. As data systems evolve and payers insist on "paying for performance," a level of accountability and transparency will be required regardless of provider type or health care setting. As these quality measures are developed, the current focus seems to be entirely on physician-delivered care. Quality data will be embedded with health information systems, so it will be imperative that APNs are involved in both the development of quality measures and the inclusion of APN practice as distinct from that of other providers. The database on nurse-sensitive indicators is being built at the inpatient level of hospitals. As many APNs practice in settings outside of the hospital, the need to create APN-sensitive measures cannot be overemphasized. The Medicare objective to align quality incentives through payment creates enormous opportunity for APNs. As Medicare gathers the evidence on effective strategies, it will phase in new payment systems intended to promote transformational quality improvement in the health care industry. This realignment will encourage innovation and efficiency and promote coordination of care across time and settings.[40] These activities are central to the APN function and have historically been undervalued and invisible in the fee-for-service model.

Pay-for-performance initiatives are occurring outside of Government as well. Bridges to Excellence (http://www.bridgestoexcellence.org/) is a multistate, multiemployer coalition developed by employers, physicians, health care services researchers, and other experts. Its mission is to reward quality across the health care system. In Bridges to Excellence's three program areas, physicians are targeted exclusively by certifying physicians in diabetes, cardiac care, and electronic office systems. The physician receives a financial bonus of up to $180 per year per patient treated. There are no other providers included in this program, despite the claimed mission to improve health care across the health care system.

Health Services Research Field Gains Strength

Over the last 20 years, the evolution of health services research (HSR), a distinct area of scholarship, has grown dramatically in both resources and influence and is currently funded publicly at $1.5 billion annually. HSR is important to APNs because it addresses questions that require observational or quasi-experimental design. This form of research includes determining the comparative effectiveness of interventions across a range of different settings, economic evaluation of different financing and organizational decisions, and qualitative designs that help us understand the how and why of social interactions.[41] The HSR field is uniquely suited to exploring APN practice because it provides a mixing bowl of interdisciplinary perspectives working on similar problems. As HSR methods become increasingly more prestigious and influential, APN research must be framed within a broader HSR and patient safety context.

Research Implications

The rapid growth and success of the APN movement has been described as a disruptive innovation—in that APNs can in many ways provide the same care or better care than physicians, at a lower cost in a more convenient setting. This disruption has contributed to professional turf battles that do not promote quality and patient safety. Strong leadership to study

innovative models on interdisciplinary team approaches that foster patient safety, including how to eliminate barriers to interdisciplinary education and practice, is required.

Turning the disruption of APNs toward improved patient safety will require a more robust evidence base and laser beam focus by these professionals. APNs must demonstrate specific clinical performance and patient outcomes. To develop this research agenda, stakeholders must convene and map out a vigorous research agenda that distinguishes APNs in the context of interdisciplinary practice. APN organizations along with the governmental and private research enterprise must come together and build a strategic plan identifying the most critical research questions. This research agenda would address strategies for APN inclusion in electronic administrative and clinical data systems, quality measurement, cost containment, as well as influential surveys such as the NAMCS and HSC. As pay-for-performance initiatives are transformed into payment policy, it is essential that researchers include APNs in the quality measurement process. This research agenda must be highly relevant to address today's health care problems and overcome APN invisibility; it must recognize APNs' unique contribution and discipline.

APN research must expand to an HSR orientation. This includes developing a research agenda that has methodological dialogue with other disciplines and fits within a framework of agreed-upon methods in the field of HSR. This research agenda must consistently and systematically translate APN research into sound health policy. Applying randomized thinking to nonrandomized problems is seldom useful to inform public policy because the researcher cannot expose a randomized group to the policy on a qualitative problem. The research must help the policymaker see the intended and unintended consequences that follow enactment of policies over time.

The Agency for Healthcare Research and Quality (AHRQ) has emerged as the premier funder for HSR, and this funding source should be explored to a far greater degree by APN researchers. While the National Institutes of Health focus on the biomedical aspect of diseases, AHRQ focuses on patient outcomes, cost, use of services, access disparities, quality of care, and patient safety. The focus of AHRQ is becoming increasingly important as the delivery system undergoes transformation, driven by transparency and quality. AHRQ's goal is to ensure that the knowledge gained through HSR is translated into measurable improvements in the health care system and better care for patients.[42] This goal could be shared by members of the APN community by sharpening and aligning the APN research focus on systems of care.

There are a number of informational or empirical issues lacking in the current APN evidence base. Future research must be independent, longitudinal, and directed to authoratitively answer the most urgent policy-relevant questions concerning APNs. Following are some of the questions that research into APN practice should address.

Cost and Quality

- Do APNs create value for payers to improve the quality in health care? Is APN practice economically efficient and effective? Are APNs a competitive advantage in the health care marketplace? Does APN practice demonstrate a threshold improvement in lowering cost, reducing misuse, overuse, and errors?
- What is the most reliable, valid, and feasible approach(es) to measuring quality of care delivered by APNs?
- Are there certain settings (acute care, palliative care) or content areas (obesity, cardiac disease) that APNs are most effective?

- How does APN practice uniquely respond to patient preferences?
- What are the outcomes of APN interventions targeted at changing patient behaviors and lifestyle? Do APNs uniquely or qualitatively employ effective strategies to promote health and human wholeness and prevent disease?
- What is the most effective health care team composition for acute care? Primary care? Palliative care? How do we build an evidence base on interdisciplinary approaches or "collaboratories" to function as incubators and disseminators of team-delivered care?
- How do State nurse practice acts enhance or create barriers to safe, effective, and innovative APN-delivered care?

Medicare

- What is the advantage to Medicare to include APNs in its pay-for-performance initiatives? Do APNs, as central members of the health care team, demonstrate threshold quality improvements? How do these findings inform Medicare's Graduate Medical Education program currently targeting primarily physicians?
- How can the cost savings on APN practice be passed onto consumers, Medicare, and other payers?

Access

- What impact do APNs have on vulnerable segments of the population? How do they impact the uninsured? Elderly? Children? Rural residents? How do APNs participate in the safety net?
- How are access and quality of care impacted once a State has adopted NCSBNs regulatory vision for APN practice, which eliminates barriers to APN practice?
- Does APN practice improve health care disparities? Do improvements benefit minority populations preferentially?

Educational Issues

- How are APNs demonstrating interdisciplinary patient safety curricula with educational simulation techniques for use early in professional schooling, continuing throughout training, and at intervals during professional practice?
- How do APNs maintain continued competence throughout their career trajectory?
- What would be included in a curriculum that demonstrated competency in patient safety?

Data and Dissemination Issues

- How can the Health Resources and Services Administration's National Sample Survey of RNs be conducted more frequently, expanded and designed to include a sample of APNs? How frequently should the survey be conducted in order to yield the most timely workforce projections?
- How do APNs get built into the Area Resource File?
- How can a database on APNs answer the following questions?
    - How many ANPs are there?
    - Where do they practice, what do they practice, and who do they care for?
    - What constitutes a full-time equivalent APN?

- When do APNs enter the workforce, and when and how to they leave/retire?
- How should APNs be included in shortage designation methodologies?
- What would a national, integrated workforce planning initiative look like?
- What is the best way to communicate APN-related research to the public, policymakers, payers, and media?

Conclusion

In addition to developing a robust APN research agenda, APN organizations must strategize to have APNs appointed to Federal and private advisory commissions that oversee or develop quality improvement measures. APN organizations must also identify key corporate boards and develop long-term strategies and political capital to get APNs appointed to those influential boards. This sector of the health policymaking process is increasingly influential as payers seek to know more about what they are getting from their health care dollar vis-à-vis pay-for-performance initiatives.

Findings from APN research must be published in journals outside of nursing to reach a broader policymaking and public audience. Key policymakers as well as the public could be made more aware of the contributions that APNs make in reducing health care costs and improving access and quality of care. Achieving broader recognition, reducing APN invisibility, and removing barriers to APN practice will be contingent on APNs communicating methodologically sound APN research that produces results that are generalizable to the larger delivery system.

Search Strategy

Both MEDLINE® and CINAHL® databases were searched to locate literature for this review. The search terms were “advanced practice nursing,” “certified nurse midwives,” “certified registered nurse anesthetists,” “clinical nurse specialists,” “nurse practitioners,” “quality,” “safety,” and “outcomes.” For both databases, the searches were limited to research articles published in the English language between 1991 and 2006 and restricted to research within the United States.

There were 97 articles identified in the CINAHL search and 54 identified by the MEDLINE search, with some duplication in the citations identified by the two databases. All abstracts were reviewed and most were eliminated from further consideration because they were not evidence based or there were methodology concerns. For example, articles about advanced practice roles, delivery models, theoretical papers, educational and curriculum issues, international issues, advanced practice nursing in defined specific populations (e.g., rural, emergency departments, gerontological) or diseases (e.g., sexually transmitted infection, heart disease), and all meta-analyses and studies with fewer than 70 subjects were omitted from this review. Once the unrelated articles were eliminated, a complete copy of each of these papers was acquired and read. Four professional associations were contacted to obtain the strongest research papers on the four APN roles (American College of Nurse Midwives, American Association of Nurse Anesthetists, the American Association of Clinical Nurse Specialists, and the American College of Nurse Practitioners). Dominant among the reasons for excluding papers were that they were not research based, they were short reports that were lacking essential details, or there were methodological concerns.

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Evidence Table. Advanced Practice Nurses: Impact on Safety and Quality of Care

Source	Safety/Quality Issue Related to Clinical Practice	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Quality Evidence on CNMs					
Davidson 2002[13]	High-risk obstetrical care	Level 3. Univariate analysis on vaginal births after cesarean, forceps, and vacuum-assisted deliveries, cesarean delivery, 5 minute Apgar score, maternal fever, and meconium stained amniotic fluid outcomes.	High-risk mothers who received care from an urban, mid-Atlantic hospital-based OB clinic during a 10-year period from 1988 to 1998, N = 803.	Risk factors managed by CNMs compared to the national population.	83% of the CNM deliveries were spontaneous vaginal births, compared to the national average of 79%. Seventy four percent of the CNM births after cesarean births delivered vaginally, significantly higher than the national average of 28%. Instrument delivery rates were considerably lower for the CNM group (4%) compared to the national average (9%). Only 12% of the CNM group had cesarean sections, compared to the national average of 21%. The researcher concludes that CNMs provide high-quality care to high-risk women in an urban setting.
MacDorman 1998[10]	Birth outcomes and infant survival	Level 3. Logistic regression on infant, neonatal, post-neonatal mortality and risk of low birth weights.	All singleton vaginal births at 35–43 weeks gestation in the United States in 1991, N = 810,790.	CNM care compared to physician-delivered births.	After controlling for medical and social risk factors, the risk of experiencing an infant death was 19% lower for CNM-attended than for physician-attended births, the risk of neonatal mortality was 33% lower, and risk of delivering a low-birth-weight infant was 31% lower. National data demonstrate that CNMs have excellent birth outcomes amongst low- to moderate-risk women.
Oakley 1996[12]	Pregnancy/ perinatal outcomes	Level 3. Logistic regression analyzed outcome measures: infant and maternal outcomes, 30 clinical indicators, satisfaction with care, and monetary charges.	At intake, all women qualified for CNM care and a convenience sample identified 710 low-risk, singleton pregnant women cared for by obstetricians and 471 cared for by CNMs in private practice.	CNM care compared to obstetrician care.	After controlling for social and health risk factors, multivariate analysis found statistically significant ($P \leq 0.05$) differences between obstetricians and CNMs on 7 outcome measures. Infant abrasion (7% OB vs. 4% CNM), infant remaining with mother for the entire hospital stay (15%OB vs. 27%CNM), 3rd or 4th degree perineal lacerations (23% OB vs. 7%CNM), number of complications (0.7 OB vs. 0.4 CNM), satisfaction with care, average hospital charges ($5,427 OB vs. $4,296 CNM), average professional fee charges ($3,425 OB vs. $3,237 CNM). It was concluded that CNMs provide a safe, effective maternity care for low-risk women and that CNMs contribute to lowering maternity care costs and improving maternal outcomes of low-risk women.

Source	Safety/Quality Issue Related to Clinical Practice	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rosenblatt 1997[11]	Patterns of obstetric care	Level 3. Provider behavior pattern was the unit of analysis; outcomes included cost of prenatal and intrapartum care.			In Washington State, CNMs were more likely to deliver babies without an operative intervention. Obstetricians were more likely to conduct amniocentesis in the prenatal period (7%) compared to family physicians (1%) or CNMs (2%). Obstetricians were far more likely to perform C-section (15 %) than family physicians (14%) or CNMs (9%). CMNs were far less likely to induce or augment (episiotomy, epidural, fetal monitoring) their patients during delivery. The authors conclude that CNMs have a different approach to intrapartum care than their physician colleagues, which uses fewer resources.
Quality Evidence on CRNAs					
Pine 2003[16]	Surgical patient safety related to type of anesthesia provider	Level 3. Surgical mortality restricted to carotid endartectomies, cholecystectomies, herniorrhaphies, mastectomies, hysterectomies, prostatectomies, and knee replacements.	Retrospective observation on Medicare patients, N = 404,194, from 22 States from 1995 to 1997.	Anesthesia-related deaths among anesthetists vs. nurse anesthetists.	There is no statistically significant difference in the mortality rate for CRNAs and anesthesiologists working together or individually. Inpatient surgical mortality is not affected by whether the anesthesia provider is a CRNA or an anesthesiologist.
Quality Evidence on CNSs					
Brooten 2001[17]	Prenatal, maternal, and infant outcomes	Level 1. Randomized clinical trial n = 173 women and 194 infants.	1-year study period in one delivery system of women at high risk for delivering low-birth-weight infants.	Half of the study sample received prenatal care in the home by CNS while they received traditional obstetrical care.	Group cared for in the home had 2 fetal infant deaths compared to the control group (9); fewer preterm infants, 78% of twin pregnancies carried to term (9), control group = 33%); 4 prenatal hospitalizations, 18 infant rehospitalizations (control group = 24). CNS home care saved 750 total hospital days or about $2.5 million.

Source	Safety/Quality Issue Related to Clinical Practice	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Brooten 1996[20]	Safety and cost effectiveness of care by CNSs.	Level 1. Randomized clinical trial, n = 79 patients in one system. Outcomes included hospital costs, physician fees, home followup care by CNSs.	Very low-birth-weight infants discharged from a hospital early.	Home care followup by CNS.	Mean hospital costs were 27% less than the control group ($47,520 vs. $64,940, $P < 0.01$); the mean physician charge was 22% ($P < 0.01$) less in the group cared for in the home by CNS. The mean cost of home care was $576, yielding a net savings of $18,560
Naylor 1994[19]	Hospital transition to home for frail elderly	Level 1. Randomized clinical trial; initial hospital discharge until 6 weeks after discharge.	Medical and surgical patient and caregiver posthospital discharge outcomes and cost of care, N = 276 patients and 125 caregivers	Comprehensive CNS-delivered discharge planning protocol.	The medical patient group had fewer hospital readmissions, fewer total days of hospital readmission, lower readmission charges. The surgical intervention group showed no significant differences with the control group during the discharge period.
Topp 1998[18]	Effect of CNS case management	Level 4. Quasi-experimental comparative, correlational. Outcomes included nursing interventions, length of stay, complication rate.	Chart review of 164 post-op total knee replacements in one delivery system.	CNS case management	Patients in the units with CNSs received more nursing interventions, had shorter lengths of stay.
Quality Evidence on NPs					
Avorn 1991[26]	Treatment comparisons between NPs and MDs	Level 4. Randomized selection of MDs and NPs given a case vignette.	501 MDs and 298 NPs were presented a case vignette.	Hypothetical scenario involving epigastic pain	More than one-third of the physicians chose to initiate therapy without seeking a relevant history. Nearly half of all physicians indicated that a prescription would be the single most effective therapy; 65% recommended a histamine antagonist. By contrast, only 19% of NPs opted to treat without taking further history; the nurse sample asked an average of 2.6 questions vs. 1.6 for physicians. These findings suggest that NPs ask more questions and were less likely to recommend prescription medication when not indicated by clinical circumstances.

Source	Safety/Quality Issue Related to Clinical Practice	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lambing 2004[23]	Acute care outcomes of frail elderly	Level 4. Descriptive comparative, research using a convenience sample of providers and self report. Outcomes measures obtained from claims data include charges for length of stay, hospital readmission, and mortality rates.	Random selection of 100 inpatient geriatric patients and a convenience sample of 17 professional providers who cared for them in one hospital in the Midwest over 1 month.	MD vs. NP provider	NP patients were older ($P < 0.022$) and sicker at admission ($P \leq 0.001$) and discharge ($P \leq 0.001$). Charges for length of stay were lower ($P \leq 0.001$) for the physician provider group, and patients in that group had shorter stays ($P = 0.001$). Readmission and mortality rates were similar for both MD and NP groups. The authors conclude that NPs provide effective care to hospitalized geriatric patients, particularly to those who are older and sicker.
Mundinger 2000[24]	NP outcomes in primary care after an urgent or urgent care visit.	Level 2. Randomized clinical trial between August 1995 and October 1997 with patient interviews at 6 months after initial appointment and health services utilization.	Four community-based primary care clinics (17 physicians) and 1 primary care clinic (7 NPs) at an urban academic medical enter, N = 1,316.	NP practice with the same degree of independence as MDs, compared to MD process outcomes.	No significant differences were found in patients' health status at 6 months. Physiologic status for patients with diabetes or asthma were no different. For hypertensive patients, the diastolic value was significantly lower for NP patients (82 vs.88 mg Hg; $P < 0.04$). No significant differences were found in health services utilization after 6 months or 1 year. There were no differences in satisfaction ratings following the initial appointment. Satisfaction ratings at 6 months differed for 1 of 4 dimensions measured (provider attributes), with MD rates higher(4.2 vs. 4.5 on a scale where 5 = excellent; $P = 0.05$). Authors conclude that primary care outcomes of NPs are comparable to MDs when NPs have the same level of authority, responsibilities, productivity, and administrative requirements.
Lenz 2004[25]	2-year followup of outcomes on patients followed by NPs and MDs	Level 2. Randomized clinical trial (of same sample in Mundinger, 2000)	N = 406 adults	Health status, disease-specific physiologic measures, satisfaction or use of specialist, emergency or inpatient services.	Results consistent with 6-month findings (see Mundinger, 2000). The body of evidence suggests that the quality of primary care delivered by NPs is equivalent to that of MDs.

CNM = clinical nurse midwife; CRNA = clinical registered nurse anesthetist; CNS = clinical nurse specialist; NP = nurse practitioner.

Chapter 44. Tools and Strategies for Quality Improvement and Patient Safety

Ronda G. Hughes

Background

The necessity for quality and safety improvement initiatives permeates health care.[1, 2] Quality health care is defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"[3] (p. 1161). According to the Institute of Medicine (IOM) report, *To Err Is Human*,[4] the majority of medical errors result from faulty systems and processes, not individuals. Processes that are inefficient and variable, changing case mix of patients, health insurance, differences in provider education and experience, and numerous other factors contribute to the complexity of health care. With this in mind, the IOM also asserted that today's health care industry functions at a lower level than it can and should, and it put forth the following six aims of health care: effective, safe, patient-centered, timely, efficient, and equitable.[2] The aims of effectiveness and safety are targeted through process-of-care measures, assessing whether providers of health care perform processes that have been demonstrated to achieve the desired aims and avoid those processes that are predisposed toward harm. The goals of measuring health care quality are to determine the effects of health care on desired outcomes and to assess the degree to which health care adheres to processes based on scientific evidence or agreed to by professional consensus and is consistent with patient preferences.

Because errors are caused by system or process failures,[5] it is important to adopt various process-improvement techniques to identify inefficiencies, ineffective care, and preventable errors to then influence changes associated with systems. Each of these techniques involves assessing performance and using findings to inform change. This chapter will discuss strategies and tools for quality improvement—including failure modes and effects analysis, Plan-Do-Study-Act, Six Sigma, Lean, and root-cause analysis—that have been used to improve the quality and safety of health care.

Measures and Benchmarks

Efforts to improve quality need to be measured to demonstrate "whether improvement efforts (1) lead to change in the primary end point in the desired direction, (2) contribute to unintended results in different parts of the system, and (3) require additional efforts to bring a process back into acceptable ranges"[6] (p. 735). The rationale for measuring quality improvement is the belief that good performance reflects good-quality practice, and that comparing performance among providers and organizations will encourage better performance. In the past few years, there has been a surge in measuring and reporting the performance of health care systems and processes.[1, 7–9] While public reporting of quality performance can be used to identify areas needing improvement and ascribe national, State, or other level of benchmarks,[10, 11] some providers have been sensitive to comparative performance data being published.[12] Another audience for public reporting, consumers, has had problems interpreting the data in reports and

has consequently not used the reports to the extent hoped to make informed decisions for higher-quality care.[13–15]

The complexity of health care systems and delivery of services, the unpredictable nature of health care, and the occupational differentiation and interdependence among clinicians and systems[16–19] make measuring quality difficult. One of the challenges in using measures in health care is the attribution variability associated with high-level cognitive reasoning, discretionary decisionmaking, problem-solving, and experiential knowledge.[20–22] Another measurement challenge is whether a near miss could have resulted in harm or whether an adverse event was a rare aberration or likely to recur.[23]

The Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum, the Joint Commission, and many other national organizations endorse the use of valid and reliable measures of quality and patient safety to improve health care. Many of these useful measures that can be applied to the different settings of care and care processes can be found at AHRQ's National Quality Measures Clearinghouse (http://www.qualitymeasures.ahrq.gov) and the National Quality Forum's Web site (http://www.qualityforum.org). These measures are generally developed through a process including an assessment of the scientific strength of the evidence found in peer-reviewed literature, evaluating the validity and reliability of the measures and sources of data, determining how best to use the measure (e.g., determine if and how risk adjustment is needed), and actually testing the measure.[24, 25]

Measures of quality and safety can track the progress of quality improvement initiatives using external benchmarks. Benchmarking in health care is defined as the continual and collaborative discipline of measuring and comparing the results of key work processes with those of the best performers[26] in evaluating organizational performance. There are two types of benchmarking that can be used to evaluate patient safety and quality performance. Internal benchmarking is used to identify best practices within an organization, to compare best practices within the organization, and to compare current practice over time. The information and data can be plotted on a control chart with statistically derived upper and lower control limits. However, using only internal benchmarking does not necessarily represent the best practices elsewhere. Competitive or external benchmarking involves using comparative data between organizations to judge performance and identify improvements that have proven to be successful in other organizations. Comparative data are available from national organizations, such as AHRQ's annual National Health Care Quality Report[1] and National Healthcare Disparities Report,[9] as well as several proprietary benchmarking companies or groups (e.g., the American Nurses Association's National Database of Nursing Quality Indicators).

Quality Improvement Strategies

More than 40 years ago, Donabedian[27] proposed measuring the quality of health care by observing its structure, processes, and outcomes. Structure measures assess the accessibility, availability, and quality of resources, such as health insurance, bed capacity of a hospital, and number of nurses with advanced training. Process measures assess the delivery of health care services by clinicians and providers, such as using guidelines for care of diabetic patients. Outcome measures indicate the final result of health care and can be influenced by environmental and behavioral factors. Examples include mortality, patient satisfaction, and improved health status.

Twenty years later, health care leaders borrowed techniques from the work of Deming[28] in rebuilding the manufacturing businesses of post-World War II Japan. Deming, the father of Total

Quality Management (TQM), promoted "constancy of purpose" and systematic analysis and measurement of process steps in relation to capacity or outcomes. The TQM model is an organizational approach involving organizational management, teamwork, defined processes, systems thinking, and change to create an environment for improvement. This approach incorporated the view that the entire organization must be committed to quality and improvement to achieve the best results.[29]

In health care, continuous quality improvement (CQI) is used interchangeably with TQM. CQI has been used as a means to develop clinical practice[30] and is based on the principle that there is an opportunity for improvement in every process and on every occasion.[31] Many in-hospital quality assurance (QA) programs generally focus on issues identified by regulatory or accreditation organizations, such as checking documentation, reviewing the work of oversight committees, and studying credentialing processes.[32] There are several other strategies that have been proposed for improving clinical practice. For example, Horn and colleagues discussed clinical practice improvement (CPI) as a "multidimensional outcomes methodology that has direct application to the clinical management of individual patients"[33] (p. 160). CPI, an approach lead by clinicians that attempts a comprehensive understanding of the complexity of health care delivery, uses a team, determines a purpose, collects data, assesses findings, and then translates those findings into practice changes. From these models, management and clinician commitment and involvement have been found to be essential for the successful implementation of change.[34–36] From other quality improvement strategies, there has been particular emphasis on the need for management to have faith in the project, communicate the purpose, and empower staff.[37]

In the past 20 years, quality improvement methods have "generally emphasize[d] the importance of identifying a process with less-than-ideal outcomes, measuring the key performance attributes, using careful analysis to devise a new approach, integrating the redesigned approach with the process, and reassessing performance to determine if the change in process is successful"[38] (p. 9). Besides TQM, other quality improvement strategies have come forth, including the International Organization for Standardization ISO 9000, Zero Defects, Six Sigma, Baldridge, and Toyota Production System/Lean Production.[6, 39, 40]

Quality improvement is defined "as systematic, data-guided activities designed to bring about immediate improvement in health care delivery in particular settings"[41] (p. 667). A quality improvement strategy is defined as "any intervention aimed at reducing the quality gap for a group of patients representative of those encountered in routine practice"[38] (p. 13). Shojania and colleagues[38] developed a taxonomy of quality improvement strategies (see Table 1), which infers that the choice of the quality improvement strategy and methodology is dependent upon the nature of the quality improvement project. Many other strategies and tools for quality improvement can be accessed at AHRQ's quality tools Web site (www.qualitytools.ahrq.gov) and patient safety Web site (www.patientsafety.gov).

Table 1. Taxonomy of Quality Improvement Strategies With Examples of Substrategies

QI Strategy	Examples
Provider reminder systems	• Reminders in charts for providers • Computer-based reminders for providers • Computer-based decision support
Facilitated relay of clinical data to providers	• Transmission of clinical data from outpatient specialty clinic to primary care provider by means other than medical record (e.g., phone call or fax)

QI Strategy	Examples
Audit and feedback	• Feedback of performance to individual providers • Quality indicators and reports • National/State quality report cards • Publicly released performance data • Benchmarking – provision of outcomes data from top performers for comparison with provider's own data
Provider education	• Workshops and conferences • Educational outreach visits (e.g., academic detailing) • Distributed educational materials
Patient education	• Classes • Parent and family education • Patient pamphlets • Intensive education strategies promoting self-management of chronic conditions
Patient reminder systems	• Materials and devices promoting self-management
Promotion of self-management	• Postcards or calls to patients
Organizational change	• Case management, disease management • TQM, CQI techniques • Multidisciplinary teams • Change from paper to computer-based records • Increased staffing • Skill-mix changes
Financial incentives, regulation, and policy	Provider directed: • Financial incentives based on achievement of performance goals • Alternative reimbursement systems (e.g., fee-for-service, capitated payments) • Licensure requirements Patient directed: • Copayments for certain visit types • Health insurance premiums, user fees Health system directed: • Initiatives by accreditation bodies (e.g., residency work hour limits) • Changes in reimbursement schemes (e.g., capitation, prospective payment, salaried providers)

Note: Reprinted with permission from AHRQ[38] (pp. 17–18).

Quality improvement projects and strategies differ from research: while research attempts to assess and address problems that will produce generalizable results, quality improvement projects can include small samples, frequent changes in interventions, and adoption of new strategies that appear to be effective.[6] In a review of the literature on the differences between quality improvement and research, Reinhardt and Ray[42] proposed four criteria that distinguish the two: (1) quality improvement applies research into practice, while research develops new interventions; (2) risk to participants is not present in quality improvement, while research could pose risk to participants; (3) the primary audience for quality improvement is the organization, and the information from analyses may be applicable only to that organization, while research is intended to be generalizable to all similar organizations; and (4) data from quality improvement is organization-specific, while research data are derived from multiple organizations.

The lack of scientific health services literature has inhibited the acceptance of quality improvement methods in health care,[43, 44] but new rigorous studies are emerging. It has been asserted that a quality improvement project can be considered more like research when it involves a change in practice, affects patients and assesses their outcomes, employs

randomization or blinding, and exposes patients to additional risks or burdens—all in an effort towards generalizability.[45–47] Regardless of whether the project is considered research, human subjects need to be protected by ensuring respect for participants, securing informed consent, and ensuring scientific value.[41, 46, 48]

Plan-Do-Study-Act (PDSA)

Quality improvement projects and studies aimed at making positive changes in health care processes to effecting favorable outcomes can use the Plan-Do-Study-Act (PDSA) model. This is a method that has been widely used by the Institute for Healthcare Improvement for rapid cycle improvement.[31, 49] One of the unique features of this model is the cyclical nature of impacting and assessing change, most effectively accomplished through small and frequent PDSAs rather than big and slow ones,[50] before changes are made systemwide.[31, 51]

The purpose of PDSA quality improvement efforts is to establish a functional or causal relationship between changes in processes (specifically behaviors and capabilities) and outcomes. Langley and colleagues[51] proposed three questions before using the PDSA cycles: (1) What is the goal of the project? (2) How will it be known whether the goal was reached? and (3) What will be done to reach the goal? The PDSA cycle starts with determining the nature and scope of the problem, what changes can and should be made, a plan for a specific change, who should be involved, what should be measured to understand the impact of change, and where the strategy will be targeted. Change is then implemented and data and information are collected. Results from the implementation study are assessed and interpreted by reviewing several key measurements that indicate success or failure. Lastly, action is taken on the results by implementing the change or beginning the process again.[51]

Six Sigma

Six Sigma, originally designed as a business strategy, involves improving, designing, and monitoring process to minimize or eliminate waste while optimizing satisfaction and increasing financial stability.[52] The performance of a process—or the process capability—is used to measure improvement by comparing the baseline process capability (before improvement) with the process capability after piloting potential solutions for quality improvement.[53] There are two primary methods used with Six Sigma. One method inspects process outcome and counts the defects, calculates a defect rate per million, and uses a statistical table to convert defect rate per million to a σ (sigma) metric. This method is applicable to preanalytic and postanalytic processes (a.k.a. pretest and post-test studies). The second method uses estimates of process variation to predict process performance by calculating a σ metric from the defined tolerance limits and the variation observed for the process. This method is suitable for analytic processes in which the precision and accuracy can be determined by experimental procedures.

One component of Six Sigma uses a five-phased process that is structured, disciplined, and rigorous, known as the define, measure, analyze, improve, and control (DMAIC) approach.[53, 54] To begin, the project is identified, historical data are reviewed, and the scope of expectations is defined. Next, continuous total quality performance standards are selected, performance objectives are defined, and sources of variability are defined. As the new project is implemented, data are collected to assess how well changes improved the process. To support this analysis, validated measures are developed to determine the capability of the new process.

Six Sigma and PDSA are interrelated. The DMAIC methodology builds on Shewhart's plan, do, check, and act cycle.[55] The key elements of Six Sigma is related to PDSA as follows: the plan phase of PDSA is related to define core processes, key customers, and customer requirements of Six Sigma; the do phase of PDSA is related to measure performance of Six Sigma; the study phase of PDSA is related to analyze of Six Sigma; and the act phase of PDSA is related to improve and integrate of Six Sigma.[56]

Toyota Production System/Lean Production System

Application of the Toyota Production System—used in the manufacturing process of Toyota cars[57]—resulted in what has become known as the Lean Production System or Lean methodology. This methodology overlaps with the Six Sigma methodology, but differs in that Lean is driven by the identification of customer needs and aims to improve processes by removing activities that are non-value-added (a.k.a. waste). Steps in the Lean methodology involve maximizing value-added activities in the best possible sequence to enable continuous operations.[58] This methodology depends on root-cause analysis to investigate errors and then to improve quality and prevent similar errors.

Physicians, nurses, technicians, and managers are increasing the effectiveness of patient care and decreasing costs in pathology laboratories, pharmacies,[59–61] and blood banks[61] by applying the same principles used in the Toyota Production System. Two reviews of projects using Toyota Production System methods reported that health care organizations improved patient safety and the quality of health care by systematically defining the problem; using root-cause analysis; then setting goals, removing ambiguity and workarounds, and clarifying responsibilities. When it came to processes, team members in these projects developed action plans that improved, simplified, and redesigned work processes.[59, 60] According to Spear, the Toyota Production System method was used to make the "following crystal clear: which patient gets which procedure (output); who does which aspect of the job (responsibility); exactly which signals are used to indicate that the work should begin (connection); and precisely how each step is carried out"[60] (p. 84).

Factors involved in the successful application of the Toyota Production System in health care are eliminating unnecessary daily activities associated with "overcomplicated processes, workarounds, and rework"[59] (p. 234), involving front-line staff throughout the process, and rigorously tracking problems as they are experimented with throughout the problem-solving process.

Root Cause Analysis

Root cause analysis (RCA), used extensively in engineering[62] and similar to critical incident technique,[63] is a formalized investigation and problem-solving approach focused on identifying and understanding the underlying causes of an event as well as potential events that were intercepted. The Joint Commission requires RCA to be performed in response to all sentinel events and expects, based on the results of the RCA, the organization to develop and implement an action plan consisting of improvements designed to reduce future risk of events and to monitor the effectiveness of those improvements.[64]

RCA is a technique used to identify trends and assess risk that can be used whenever human error is suspected[65] with the understanding that system, rather than individual factors, are likely

the root cause of most problems.[2, 4] A similar procedure is critical incident technique, where after an event occurs, information is collected on the causes and actions that led to the event.[63]

An RCA is a reactive assessment that begins after an event, retrospectively outlining the sequence of events leading to that identified event, charting causal factors, and identifying root causes to completely examine the event.[66] Because it is a labor-intensive process, ideally a multidisciplinary team trained in RCA triangulates or corroborates major findings and increases the validity of findings.[67] Taken one step further, the notion of aggregate RCA (used by the Veterans Affairs (VA) Health System) is purported to use staff time efficiently and involves several simultaneous RCAs that focus on assessing trends, rather than an in-depth case assessment.[68]

Using a qualitative process, the aim of RCA is to uncover the underlying cause(s) of an error by looking at enabling factors (e.g., lack of education), including latent conditions (e.g., not checking the patient's ID band) and situational factors (e.g., two patients in the hospital with the same last name) that contributed to or enabled the adverse event (e.g., an adverse drug event). Those involved in the investigation ask a series of key questions, including what happened, why it happened, what were the most proximate factors causing it to happen, why those factors occurred, and what systems and processes underlie those proximate factors. Answers to these questions help identify ineffective safety barriers and causes of problems so similar problems can be prevented in the future. Often, it is important to also consider events that occurred immediately prior to the event in question because other remote factors may have contributed.[68]

The final step of a traditional RCA is developing recommendations for system and process improvement(s), based on the findings of the investigation.[68] The importance of this step is supported by a review of the literature on root-cause analysis, where the authors conclude that there is little evidence that RCA can improve patient safety by itself.[69] A nontraditional strategy, used by the VA, is aggregate RCA processes, where several simultaneous RCAs are used to examine multiple cases in a single review for certain categories of events.[68, 70]

Due the breadth of types of adverse events and the large number of root causes of errors, consideration should be given to how to differentiate system from process factors, without focusing on individual blame. The notion has been put forth that it is a truly rare event for errors to be associated with irresponsibility, personal neglect, or intention,[71] a notion supported by the IOM.[4, 72] Yet efforts to categorize individual errors—such as the Taxonomy of Error Root Cause Analysis of Practice Responsibility (TERCAP), which focuses on "lack of attentiveness, lack of agency/fiduciary concern, inappropriate judgment, lack of intervention on the patient's behalf, lack of prevention, missed or mistaken MD/healthcare provider's orders, and documentation error"[73] (p. 512)—may distract the team from investigating systems and process factors that can be modified through subsequent interventions. Even the majority of individual factors can be addressed through education, training, and installing forcing functions that make errors difficult to commit.

Failure Modes and Effects Analysis

Errors will inevitably occur, and the times when errors occur cannot be predicted. Failure modes and effects analysis (FMEA) is an evaluation technique used to identify and eliminate known and/or potential failures, problems, and errors from a system, design, process, and/or service before they actually occur.[74–76] FMEA was developed for use by the U.S. military and has been used by the National Aeronautics and Space Administration (NASA) to predict and evaluate potential failures and unrecognized hazards (e.g., probabilistic occurrences) and to

proactively identify steps in a process that could reduce or eliminate future failures.[77] The goal of FMEA is to prevent errors by attempting to identifying all the ways a process could fail, estimate the probability and consequences of each failure, and then take action to prevent the potential failures from occurring. In health care, FMEA focuses on the system of care and uses a multidisciplinary team to evaluate a process from a quality improvement perspective.

This method can be used to evaluate alternative processes or procedures as well as to monitor change over time. To monitor change over time, well-defined measures are needed that can provide objective information of the effectiveness of a process. In 2001, the Joint Commission mandated that accredited health care providers conduct proactive risk management activities that identify and predict system weaknesses and adopt changes to minimize patient harm on one or two high-priority topics a year.[78]

HFMEA. Developed by the VA's National Center for Patient Safety, the health failure modes and effects analysis (HFMEA) tool is used for risk assessment. There are five steps in HFMEA: (1) define the topic; (2) assemble the team; (3) develop a process map for the topic, and consecutively number each step and substep of that process; (4) conduct a hazard analysis (e.g., identify cause of failure modes, score each failure mode using the hazard scoring matrix, and work through the decision tree analysis);[79] and (5) develop actions and desired outcomes. In conducting a hazard analysis, it is important to list all possible and potential failure modes for each of the processes, to determine whether the failure modes warrant further action, and to list all causes for each failure mode when the decision is to proceed further. After the hazard analysis, it is important to consider the actions needed to be taken and outcome measures to assess, including describing what will be eliminated or controlled and who will have responsibility for each new action.[79]

Research Evidence

Fifty studies and quality improvement projects were included in this analysis. The findings were categorized by type of quality method employed, including FMEA, RCA, Six Sigma, Lean, and PDSA. Several common themes emerged: (1) what was needed to implement quality improvement strategies, (2) what was learned from evaluating the impact of change interventions, and (3) what is known about using quality improvement tools in health care.

What Was Needed To Implement Quality Improvement Strategies?

Substantial and strong leadership support,[80–83] involvement,[81, 84] consistent commitment to continuous quality improvement,[85, 86] and visibility,[87] both in writing and physically, [86] were important in making significant changes. Substantial commitment from hospital boards was also found to be necessary.[86, 88] The inevitability of resource demands associated with changing process required senior leadership to (1) ensure adequate financial resources[87–89] by identifying sources of funds for training and purchasing and testing innovative technologies[90] and equipment;[91] (2) facilitate and enable key players to have the needed time to be actively involved in the change processes,[85, 88, 89] providing administrative support; [90] (3) support a time-consuming project by granting enough time for it to work;[86, 92] and (4) emphasize safety as an organizational priority and reinforce expectations, especially when the process was delayed or results were periodically not realized.[87] It was also asserted that senior leaders needed to understand the impact of high-level decisions on work processes and staff time,[88] especially when efforts were

underway to change practice, and that quality improvement needed to be incorporated into systemwide leadership development.[88] Leadership was needed to make patient safety a key aspect of all meetings and strategies,[85, 86] to create a formal process for identifying annual patient safety goals for the organization, and to hold themselves accountable for patient safety outcomes.[85]

Even with strong and committed leadership, some people within the organization may be hesitant to participate in quality improvement efforts because previous attempts to create change were hindered by various system factors,[93] a lack of organization-wide commitment,[94] poor organizational relationships, and ineffective communication.[89] However the impact of these barriers were found to be lessened if the organization embraced the need for change,[95] changed the culture to enable change,[90] and actively pursued institutionalizing a culture of safety and quality improvement. Yet adopting a nonpunitive culture of change took time,[61, 90] even to the extent that the legal department in one hospital was engaged in the process to turn the focus to systems, not individual-specific issues.[96] Also, those staff members involved in the process felt more at ease with improving processes, particularly when cost savings were realized and when no layoff policies were put in place to protect job security even when efficiencies were realized.[84]

The improvement process needed to engage[97] and involve all stakeholders and gain their understanding that the investment of resources in quality improvement could be recouped with efficiency gains and fewer adverse events.[86] Stakeholders were used to (1) prioritize which safe practices to target by developing a consensus process among stakeholders[86, 98] around issues that were clinically important, i.e., hazards encountered in everyday practice that would make a substantial impact on patient safety; (2) develop solutions to the problems that required addressing fundamental issues of interdisciplinary communication and teamwork, which were recognized as crucial aspects of a culture of safety; and (3) build upon the success of other hospitals.[86] In an initiative involving a number of rapid-cycle collaboratives, successful collaboratives were found to have used stakeholders to determine the choice of subject, define objectives, define roles and expectations, motivate teams, and use results from data analyses.[86] Additionally, it was important to take into account the different perspectives of stakeholders.[97] Because variation in opinion among stakeholders and team members was expected[99] and achieving buy-in from all stakeholders could have been difficult to achieve, efforts were made to involve stakeholders early in the process, solicit feedback,[100] and gain support for critical changes in the process.[101]

Communication and sharing information with stakeholders and staff was critical to specifying the purpose and strategy of the quality initiative;[101] developing open channels of communication across all disciplines and at all levels of leadership/staff, permitting the voicing of concerns and observations throughout the process of creating change;[88] ensuring that patients and families were appropriately included in the dialogue; ensuring that everyone involved felt that he or she was an integral part of the health care team and was responsible for patient safety; sharing lessons learned from root-cause analysis; and capturing attention and soliciting buy-in by sharing patient safety stories with staff and celebrating successes, no matter how small.[85] Yet in trying to keep everyone informed of the process and the data behind decisions, some staff had difficulty accepting system changes made in response to the data.[89]

The successful work of these strategies was dependent upon having motivated[80] and empowered teams. There were many advantages to basing the work of the quality improvement strategies on the teamwork of multidisciplinary teams that would review data and lead change.[91]

These teams needed to be comprised of the right staff people,[91, 92] include peers,[102] engage all of the right stakeholders (ranging from senior managers to staff), and be supported by senior-level management/leadership.[85, 86] Specific stakeholders (e.g., nurses and physicians) had to be involved[81] and supported to actually make the change, and to be the champions[103] and problem-solvers within departments[59] for the interventions to succeed. Because implementing the quality initiatives required substantial changes in the clinician's daily work,[86] consideration of the attitude and willingness of front-line staff for making the specific improvements[59, 88, 104] was needed.

Other key factors to improvement success were implementing protocols that could be adapted to the patient's needs[93] and to each unit, based on experience, training, and culture.[88] It was also important to define and test different approaches; different approaches can converge and arrive at the same point.[81] Mechanisms that facilitated staff buy-in was putting the types and causes of errors in the forefront of providers' minds, making errors visible,[102] being involved in the process of assessing work and looking for waste,[59] providing insight as to whether the improvement project would be feasible and its impact measurable,[105] and presenting evidence-based changes.[100] Physicians were singled out as the one group of clinicians that needed to lead[106] or be actively involved in changes,[86] especially when physician behaviors could create inefficiencies.[84] In one project, physicians were recruited as champions to help spread the word to other physicians about the critical role of patient safety, to make patient safety a key aspect of all leadership and medical management meetings and strategies.[85]

Team leaders and the composition of the team were also important. Team leaders that emphasized efforts offline to help build and improve relationships were found to be necessary for team success.[83, 93] These teams needed a dedicated team leader who would have a significant amount of time to put into the project.[84] While the leader was not identified in the majority of reports reviewed for this paper, the team on one project was co-chaired by a physician and an administrator.[83] Not only did the type and ability of team leaders affect outcomes, the visibility of the initiative throughout the organization was dependent upon having visible champions.[100] Multidisciplinary teams needed to understand the numerous steps involved in quality improvement and that there were many opportunities for error, which essentially enabled teams to prioritize the critical items to improve within a complex process and took out some of the subjectivity from the analysis. The multidisciplinary structure of teams allowed members to identify each step from their own professional practice perspective, anticipate and overcome potential barriers, allowed the generation of diverse ideas, and allowed for good discussion and deliberations, which together ultimately promoted team building.[100, 107] In two of the studies, FMEA/HFMEA was found to minimize group biases by benefiting from the diversity within multidisciplinary composition of the team and enabling the team to focus on a structured outline of the goals that needed to be accomplished.[107, 108]

Teams needed to be prepared and enabled to meet the demands of the quality initiatives with ongoing education, weekly debriefings, review of problems solved and principles applied,[84] and ongoing monitoring and feedback opportunities.[92, 95] Education and training of staff [95, 80, 95, 101, 104] and leadership [80] about the current problem, quality improvement tools, the planned change in practice intervention, and updates as the project progressed were key strategies.[92] Training was an ongoing process [91] that needed to focus on skill deficits[82] and needed to be revised as lessons were learned and data was analyzed during the implementation of the project.[109] The assumption could not be made that senior staff or leadership would not need training.[105] Furthermore, if the team had no experience with the quality tools or successfully creating change, an additional

resource could have been a consultant or someone to facilitate the advanced knowledge involved in quality improvement techniques.[106] Another consideration was using a model that intervened at the hospital-community interface, coupled with an education program.[97]

The influence of teamwork processes enabled those within the team to improve relationships across departments.[89] Particular attention needed to be given to effective team building,[110] actively following the impact of using the rapid-cycle (PDSA) model, meeting frequently, and monitoring progress using outcome data analysis at least on a monthly basis.[86] Effective teamwork and communication, information transfer, coordination among multiple hospital departments and caregivers, and changes to hospital organization culture were considered essential elements of team effectiveness.[86] Yet the impact of team members that had difficulty in fully engaging in teamwork because of competing workloads (e.g., working double shifts) was dampened.[97] Better understanding of each other's role is an important project outcome and provides a basis for continuing the development of other practices to improve outcomes.[97] The work of teams was motivated through continual sharing of progress and success and celebration of achievements.[87]

Teamwork can have many advantages, but only a few were discussed in the reports reviewed. Teams were seen as being able to increase the scope of knowledge, improve communication across disciplines, and facilitate learning about the problem.[111] Teams were also found to be proactive, [91] integrating tools that improve both the technical processes and organizational relationships,[83] and to work together to understand the current situation, define the problem, pathways, tasks, and connections, as well as to develop a multidisciplinary action plan.[59] But teamwork was not necessarily an easy process. Group work was seen as difficult for some and time consuming,[111] and problems arose when everyone wanted their way,[97] which delayed convergence toward a consensus on actions. Team members needed to learn how to work with a group and deal with group dynamics, confronting peers, conflict resolution, and addressing behaviors that are detrimental.[111]

What Was Learned From Evaluating the Impact of Change Interventions?

As suggested by Berwick,[112] the leaders of the quality improvement initiatives in this review found that successful initiatives needed to simplify;[96, 104] standardize;[104] stratify to determine effects; improve auditory communication patterns; support communication against the authority gradient; [96] use defaults properly; automate cautiously; [96] use affordance and natural mapping (e.g., design processes and equipment so that the easiest thing to do is the right thing to do); respect limits of vigilance and attention; [96] and encourage reporting of near hits, errors, and hazardous conditions.[96] Through the revision and standardization of policies and procedures, many of these initiatives were able to effectively realize the benefit of making the new process easier than the old and decrease the effect of human error associated with limited vigilance and attention.[78, 80–82, 90–92, 94, 96, 102, 103, 113, 114]

Simplification and standardization were found to be effective as a forcing function by decreasing reliance on individualized decisionmaking. Several initiatives standardized medication ordering and administration protocols,[78, 87, 101, 103, 106–108, 109, 114–116] realizing improvements in patient outcomes, nurse efficiency, and effectiveness.[103, 106, 108, 109, 114–116] One initiative used a standardized form for blood product ordering.[94] Four initiatives improved pain

assessment and management by using standardized metrics and assessment tools.[80, 93, 100, 117] In all of these initiatives, simplification and standardization were effective strategies.

Related to simplification and standardization is the potential benefit of using information technology to implement checks, defaults, and automation to improve quality and reduce errors, in large part to embedding forcing functions to remove the possibility of errors.[96, 106] The effects of human error could be mitigated by using necessary redundancy, such as double-checking for certain types of errors; this was seen as engaging the knowledge and abilities of two skilled practitioners [61, 101] and was used successfully to reduce errors associated with dosing.[78] Information technology was successfully used to (1) decrease the opportunity for human error through automation;[61] (2) standardize medication concentrations[78] and dosing using computer-enabled calculations,[115, 116] standardized protocols,[101] and order clarity;[116] (3) assist caregivers in providing quality care using alerts and reminders; (4) improve medication safety (e.g., implementing bar coding and computerized provider order entry); and (5) track performance through database integration and indicator monitoring. Often workflow and procedures needed to be revised to keep pace with technology.[78] Using technology implied that organizations were committed to investing in technology to enable improvement,[85] but for two initiatives, the lack of adequate resources for data collection impacted analysis and evaluation of the initiative.[93, 97]

Data and information were needed to understand the root causes of errors and near errors,[99] to understand the magnitude of adverse events,[106] to track and monitor performance,[84, 118] and to assess the impact of the initiatives.[61] Reporting of near misses, errors, and hazardous conditions needs to be encouraged.[96] In part, this is because error reporting is generally low and is associated with organizational culture[106] and can be biased, which will taint results.[102] Organizations not prioritizing reporting or not strongly emphasizing a culture of safety may have the tendency to not report errors that harm patients or near misses (see Chapter 35. "Evidence Reporting and Disclosure"). Using and analyzing data was viewed as critical, yet some team members and staff may have benefited from education on how to effectively analyze and display findings.[106] Giving staff feedback by having a transparent process[39] of reporting findings[82] was viewed as a useful trigger that brought patient safety to the forefront of the hospital.[107] It follows then that not having data, whether because it was not reported or not collected, made statistical analysis of the impact of the initiative[115] or assessing its cost-benefit ratio not possible.[108] As such, multi-organizational collaboration should have a common database.[98]

The meaning of data can be better understood by using measures and benchmarks. Repeated measurements were found to be useful for monitoring progress,[118] but only when there was a clear metric for measuring the degree of success.[83] The use of measures could be used as a strategy to involve more clinicians and deepened their interest, especially physicians. Using objective, broader, and better measures was viewed as being important for marking progress, and provided a basis for "a call to action" and celebration.[106] When measures of care processes were used, it was asserted that there was a need to demonstrate the relationship between specific changes to care processes and outcomes.[61]

When multiple measures were used, along with better documentation of care, it was easier to assess the impact of the initiative on patient outcomes.[93] Investigators from one initiative put forth the notion that hospital administrators should encourage more evaluations of initiatives and that the evaluations should focus on comprehensive models that assess patient outcomes, patient satisfaction, and cost effectiveness.[114] The assessment of outcomes can be enhanced by setting realistic goals, not unrealistic goals such as 100 percent change,[119] and by comparing organizational results to recognized State, regional, and national benchmarks.[61, 88]

The cost of the initiative was an viewed as important factor in the potential for improvement, even when the adverse effects of current processes were considered as necessitating rapid change.[106] Because of this, it is important to implement changes that are readily feasible[106] and can be implemented with minimal disruption of practice activities.[99] It is also important to consider the potential of replicating the initiative in other units or at other sites.[99] One strategy to improve the chances of replication is to standardize processes, which will most likely incur some cost.[106] In some respects, the faster small problems were resolved, the faster improvements could be replicated throughout the entire system.[84, 106] Recommendations that did not incur costs or had low costs and could be demonstrated to be effective were implemented expeditiously.[93, 107] A couple of investigators stated that their interventions decreased costs and patients' length of stay,[103] but did not present any data to verify those statements. It was also purported that the costs associated with change will be recouped either in return on investment or in reduced patient risk (and thus reduced liability costs).[61]

Ensuring that those implementing the initiative receive education is critical. There were several examples of this. Two initiatives that targeted pain management found that educating staff on pain management guidelines and protocols for improving chronic pain assessment and management improved staff understanding, assessment and documentation, patient and family satisfaction, and pain management.[80, 93] Another initiative educated all staff nurses on intravenous (IV) site care and assessment, as well as assessment of central lines, and realized improved patient satisfaction and reduced complications and costs.[109]

Despite the benefits afforded by the initiatives, there were many challenges that were identified in implementing the various initiatives:

- Lack of time and resources made it difficult to implement the initiative well.[82]
- Some physicians would not accept the new protocol and thwarted implementation until they had confidence in the tool.[103]
- Clear expectations were lacking. [86]
- Hospital leadership was not adequately engaged.[86]
- There was insufficient emphasis on importance and use of measures.[86]
- The number and type of collaborative staffing was insufficient.[86]
- The time required for nurses and other staff to implement the changes was underestimated.[120]
- The extent to which differences in patient severity accounted for results could not be evaluated because severity of illness was not measured.[89]
- Improvements associated with each individual PDSA cycle could not be evaluated.[89]
- The full impact on the costs of care, including fixed costs for overhead, could not be evaluated.[89]
- Failure to consider the influence of factors such as fatigue, distraction, time pressures.[82]
- The Hawthorne effect may have caused improvements more so than the initiative.[118]
- Many factors were interrelated and correlated.[96]
- There was a lack of generalizability because of small sample size.[93, 119]
- Addressing some of the problems created others (e.g., implementing computerized physician order entry (CPOE)).[110]
- Targets set (e.g., 100 percent of admissions) may have been too ambitious and were thus always demanding and difficult-to-achieve service improvements.[119]

Despite the aforementioned challenges, many investigators found that it was important to persevere and stay focused because introducing new processes can be difficult, [84, 100] but the reward of quality improvement is worth the effort.[84] Implementing quality improvement initiatives was considered time consuming, tedious, and difficult for people who are very action oriented; it required an extensive investment of resources (i.e., time, money, and energy);[94] and it involved trial and error to improve the process.[91] Given theses and other challenges, it was also important to celebrate the victories.[84]

Other considerations were given to the desired objective of sustaining the changes after the implementation phase of the initiative ended.[105] Investigators asserted that improving quality through initiatives needed to be considered as integral in the larger, organizationwide, ongoing process of improvement. Influential factors attributed to the success of the initiatives were effecting practice changes that could be easily used at the bedside;[82] using simple communication strategies; [88] maximizing project visibility, which could sustain the momentum for change;[100] establishing a culture of safety; and strengthening the organizational and technological infrastructure.[121] However, there were opposing viewpoints about the importance of spreading the steps involved in creating specific changes (possibly by forcing changes into the redesign of processes), rather than only relying on only adapting best practices.[106, 121] Another factor was the importance of generating enthusiasm about embracing change through a combination of collaboration (both internally and externally)[103] and healthy competition. Collaboratives could also be a vehicle for encouraging the use of and learning from evidence-based practice and rapid-cycle improvement as well as identifying and gaining consensus on potentially better practices.[86, 98]

What Is Known About Using Quality Improvement Tools in Health Care?

Quality tools used to define and assess problems with health care were seen as being helpful in prioritizing quality and safety problems[99] and focusing on systems,[98] not individuals. The various tools were used to address errors and growing costs[88] and to change provider practices.[117] Several of the initiatives used more than one of the quality improvement tools, such as beginning with root-cause analysis then using either Six Sigma, Toyota Production System/Lean, or Plan-Do-Study-Act to implement change in processes. Almost every initiative included in this analysis performed some type of pretesting/pilot testing.[92, 99] Investigators and leaders of several initiatives reported advantages of using specific types of quality tools. These are discussed as follows:

Root-cause analysis was reported to be useful to assess reported errors/incidents and differentiate between active and latent errors, to identify need for changes to policies and procedures, and to serve as a basis to suggest system changes, including improving communication of risk.[82, 96, 102, 105]

Six Sigma/Toyota Production System was reported to have been successfully used to decrease defects/variations[59, 61, 81] and operating costs[81] and improve outcomes in a variety of health care settings and for a variety of processes.[61, 88] Six Sigma was found to be a detailed process that clearly differentiated between the causes of variation and outcome measures of process.[61] One of the advantages of using Six Sigma was that it made work-arounds and rework difficult because the root causes of the preimplementation processes were targeted.[59, 88] Additionally, investigators reported that the more teams worked with this strategy, the better they

became at implementing it and the more effective the results.[84] Yet it was noted that to use this strategy effectively, a substantial commitment of leadership time and resources was associated with improved patient safety, lowered costs, and increased job satisfaction.[84] Six Sigma was also an important strategy for problem-solving and continuous improvement; communicating clearly about the problem; guiding the implementation process; and producing results in a clear, concise, and objective way.[59]

Plan-Do-Study-Act (PDSA) was used by the majority of initiatives included in this analysis to implement initiatives gradually, while improving them as needed. The rapid-cycle aspect of PDSA began with piloting a single new process, followed by examining results and responding to what was learned by problem-solving and making adjustments, after which the next PDSA cycle would be initiated. The majority of quality improvement efforts using PDSA found greater success using a series of small and rapid cycles to achieve the goals for the intervention, because implementing the initiative gradually allowed the team to make changes early in the process[80] and not get distracted or sidetracked by every detail and too many unknowns.[87, 119, 122] The ability of the team to successfully use the PDSA process was improved by providing instruction and training on the use of PDSA cycles, using feedback on the results of the baseline measurements,[118] meeting regularly,[120] and increasing the team's effectiveness by collaborating with others, including patients and families,[80] to achieve a common goal.[87] Conversely, some teams experienced difficulty in using rapid-cycle change, collecting data, and constructing run charts,[86] and one team reported that applying simple rules in PDSA cycles may have been more successful in a complex system.[93]

Failure modes and effects analysis (FMEA) was used to avoid events and improve or maintain the quality of care.[123] FMEA was used prospectively to identify potential areas of failure[94] where experimental characterization of the process at the desired speed of change could be assessed,[115] and retrospectively to characterize the safety of a process by identifying potential areas of failure, learning about the process from the staff's point of view.[94] Using a flow chart of the process before beginning the analysis got the team to focus and work from the same document.[94] Information learned from FMEA was used to provide data for prioritizing improvement strategies, serve as a benchmark for improvement efforts,[116] educate and provide a rationale for diffusion of these practice changes to other settings,[115] and increase the ability of the team to facilitate change across all services and departments within the hospital.[124] Using FMEA facilitated systematic error management, which was important to good clinical care in complex processes and complex settings, and was dependent upon a multidisciplinary approach, integrated incident and error reporting, decision support, standardization of terminology, and education of caregivers.[116]

Health failure modes and effects analysis (HFMEA) was used to provide a more detailed analysis of smaller processes, resulting in more specific recommendations, as well as larger processes. HFEMA was viewed as a valid tool for proactive analysis in hospitals, facilitating a very thorough analysis of vulnerabilities (i.e., failure modes) before adverse events occurred.[108] This tool was considered valuable in identifying the multifactoral nature of most errors[108] and the potential risk for errors,[111] but was seen as being time consuming.[107] Initiatives that used HFMEA could minimize group biases through the multidisciplinary composition of the team[78, 108, 115] and facilitate teamwork by providing a step-by-step process,[107] but these initiatives required a paradigm shift for many.[111]

Evidence-Based Practice Implications

From the improvement strategies and projects assessed in this review, several themes emerged from successful initiatives that nurses can use to guide quality improvement efforts. The strength of the following practice implications is associated with the methodological rigor and generalizability of these strategies and projects:

1. The importance of having strong *leadership* commitment and support cannot be overstated. Leadership needs to empower staff, be actively involved, and continuously drive quality improvement. Without the commitment and support of senior-level leadership, even the best intended projects are at great risk of not being successful. Champions of the quality initiative and quality improvement need to be throughout the organization, but especially in leadership positions and on the team.
2. A *culture of safety and improvement* that rewards improvement and is driven to improve quality is important. The culture is needed to support a quality infrastructure that has the resources and human capital required for successfully improving quality.
3. Quality improvement teams need to have the right *stakeholders* involved.
4. Due to the complexity of health care, *multidisciplinary teams and strategies* are essential. Multidisciplinary teams from participating centers/units need to work closely together, taking advantage of communication strategies such as face-to-face meetings, conference calls, and dedicated e-mail listservs, and utilize the guidance of trained facilitators and expert faculty throughout the process of implementing change initiatives when possible**.**
5. Quality improvement teams and stakeholders need to *understand the problem and root causes*. There must be a consensus on the definition of the problem. To this end, a clearly defined and universally agreed upon metric is essential. This agreement is as crucial to the success of any improvement effort as the validity of the data itself.
6. Use a *proven, methodologically sound approach* without being distracted by the jargon used in quality improvement. The importance given to using clear models, terms, and process is critical, especially because many of the quality tools are interrelated; using only one tool will not produce successful results.
7. *Standardizing care processes* and ensuring that everyone uses those standards should improve processes by making them more efficient and effective—and improve organizational and patient outcomes.
8. *Evidence-based practice* can facilitate ongoing quality improvement efforts.
9. Implementation plans need to be *flexible* to adapt to needed changes as they come up
10. Efforts to change practice and improve the quality of care can have *multiple purposes*, including redesigning care processes to maximize efficiency and effectiveness, improving customer satisfaction, improving patient outcomes, and improving organizational climate.
11. *Appropriate use of technology* can improve team functioning, foster collaboration, reduce human error, and improve patient safety.
12. Efforts need to have *sufficient resources*, including protected staff time.
13. *Continually collect and analyze data and communicate results* on critical indicators across the organization. The ultimate goal of assessing and monitoring quality is to use findings to assess performance and define other areas needing improvement.
14. *Change takes time*, so it is important to stay focused and persevere.

Research Implications

Given the complexity of health care, assessing quality improvement is a dynamic and challenging area. The body of knowledge is slowly growing in this area, which could be due to the continued dilemma as to whether a quality improvement initiative is just that or whether it meets the definition of research and employs methodological rigor—even if it meets the requirements for publication. Various quality improvement methods have been used since Donabedian's seminal publication in 1966,[27] but only recently has health care quality improvement used the Six Sigma methodology and published findings; when it has, it has been used only on a single, somewhat isolated component of a larger system, making organizational learning and generalizability difficult. Because of the long standing importance of quality improvement, particularly driven by external sources (e.g., CMS and the Joint Commission) in the past few years, many quality improvement efforts within organizations have taken place and are currently in process, but may not have been published and therefore not captured in this review, and may not have necessarily warranted publication in the peer-reviewed literature. With this in mind, researchers, leaders and clinicians will need to define what should be considered generalizable and publishable in the peer-reviewed literature to move the knowledge of quality improvement methods and interventions forward.

While the impact of many of the quality improvement projects included in this analysis were mentioned in terms of clinical outcomes, functional outcomes, patient satisfaction, staff satisfaction, and readiness to change, cost and utilization outcomes and measurement is important in quality improvement efforts, especially when variation occurs. There are many unanswered questions. Some key areas are offered for consideration:

- How can quality improvement efforts recognize the needs of patients, insurers, regulators, patients, and staff and be successful?
- What is the best method to identify priorities for improvement and meet the competing needs of stakeholders?
- What is the threshold of variation that needs to be attained to produce regular desired results?
- How can a bottom-up approach to changing clinical practice be successful if senior leadership is not supportive or the organizational culture does not support change?

In planning quality improvement initiatives or research, researchers should use a conceptual model to guide their work, which the aforementioned quality tools can facilitate. To generalize empirical findings from quality improvement initiatives, more consideration should be given to increasing sample size by collaborating with other organizations and providers. We need to have a better understanding of what tools work the best, either alone or in conjunction with other tools. It is likely that mixed methods, including nonresearch methods, will offer a better understanding of the complexity of quality improvement science. We also know very little about how tailoring implementation interventions contributes to process and patient outcomes, or what the most effective steps are that cross intervention strategies. Lastly, we do not know what strategies or combination of strategies work for whom and in what context, why they work in some settings or cases and not others, and what the mechanism is by which these strategies or combination of strategies work.

Conclusions

Whatever the acronym of the method (e.g., TQM, CQI) or tool used (e.g., FMEA or Six Sigma), the important component of quality improvement is a dynamic process that often employs more than one quality improvement tool. Quality improvement requires five essential elements for success: fostering and sustaining a culture of change and safety, developing and clarifying an understanding of the problem, involving key stakeholders, testing change strategies, and continuous monitoring of performance and reporting of findings to sustain the change.

Search Strategy

To identify quality improvement efforts for potential inclusion in this systematic review, PubMed and CINAL were searched from 1997 to present. The following key words and terms were used: "Failure Modes and Effects Analysis/FMEA," "Root Cause Analysis/RCA," "Six Sigma," "Toyota Production System/Lean," and "Plan Do Study Act/PDSA." Using these key words, 438 articles were retrieved. Inclusion criteria included reported processes involving nursing; projects/research involving methods such as FMEA, RCA, Six Sigma, Lean, or PDSA; qualitative and quantitative analyses; and reporting patient outcomes. Projects and research were excluded if they did not involve nursing on the improvement team, did not provide sufficient information to describe the process used and outcomes realized, nursing was not directly involved in the patient/study outcomes, or the setting was in a developing country. Findings from the projects and research included in the final analysis were grouped into common themes related to applied quality improvement.

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Evidence Table. Quality Methods

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Failure Modes and Effects Analysis (FMEA)						
Adachi 2005[78]	Medication safety	Quality improvement	Medication errors, targeting wrong dose errors (Level 4)	422-bed hospital in California	FMEA used to develop strategies – Standard order sets were revised, items from the formulary were removed, and the use of unapproved abbreviations was eliminated. – Used IV pumps with enhanced safety features.	1 year after medication strategies were implemented, medication errors associated with IV infusion were reduced slightly (from 59 to 46), and error related to IV pumps decreased from 41% of dosing errors to 22%. Errors related to wrong drug concentration were completely eliminated.
Apkon 2004[115]	Medication safety	Quality improvement	Infusion drug errors (Level 4)	11-bed pediatric intensive care unit (ICU) in a children's hospital	None	Standardization of the infusion delivery process, with the combined effect of prolonging infusion hang times from 24 to 72 hours, shifting preparation to the pharmacy, and purchasing premanufactured solutions resulted in 1,500 fewer infusions prepared by nurses per year; process changes preferred by nurses and patients.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Burgmeier 2002[94]	Blood transfusion	Quality improvement	Errors associated with blood products administered to patients (Level 4)	1 hospital in Ohio	Following the FMEA, implemented the following changes: a standardized form listing choices for blood products and documenting medical necessity, form is faxed to the blood bank; used a blood-barrier system; required staff training; and changes in policies and procedures.	Following the new process changes for blood transfusions, no outcome errors were reported within the first 3 months. New process continued to be assessed, finding more failures to be addressed, and data are aggregated and reported monthly. Flowcharting before beginning the FMEA process itself was important. FMEA process was time consuming, tedious, and difficult.
Day 2006[124]	Dialysis treatment	Quality improvement	Risks for error in the process of administering dialysis (Level 4)	1 hospital in Utah	None	Risk factors included inconsistent nephrology consult/dialysis communication process; dialysis technicians performing beyond their scope of work; scheduling treatments for chronic dialysis patients without a formal consult/order; nurses inconsistently involved in dialysis process; nurses not reviewing dialysis orders or treatment plan before treatment; and lack of a formal handoff report before treatment.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Esmail 2005[107]	Medication safety	Quality improvement	Systematic analysis for improvement in the ordering and administration of potassium chloride and potassium phosphate using HFMEA (Level 4)	4 adult ICUs in 3 hospitals in Canada	Implemented standardized protocol for potassium chloride and potassium phosphate.	Using the HFMEA, recommendations were made for the hospital and ICUs, including who, where, and how the drugs should be mixed, and identifying and developing standard labels for look-alike and sound-alike products. HFMEA helped prioritize the critical steps of a complex medication process (from ordering to administration), making it more objective. While the process took time to conduct, it was instrumental in discovering that the vials of intravenous potassium needed to be stored and packaged differently.
Gering 2005[123]	Patient transfer	Pretest and post-test, quality improvement	Adverse events (Level 3)	2 VA medical centers	A series of strategies to merge patients into one facility	Nurses were critical in the actual move of patients from one hospital to the next. After integration, there were no disruptions in patient care, operating room (OR) cancellations decreased, there were no MRSA infections, and clinic wait times decreased.
Kim 2006[116]	Medication safety, CPOE	Pretest, post-test study	Medication order errors (Level 3)	Pediatric oncology patients in 1 academic medical center in Maryland	Implementation of a CPOE system	After CPOE implementation, there was a decrease in improper dosing, incorrect dosing calculations, missing cumulative dose calculations, and incomplete nursing checklists. There was no difference in the likelihood of improper dosing on treatment plans, and a higher likelihood of not matching medication orders to treatment plans.
Papastrat 2003[111]	Medication safety	Changing practice project	Error detection associated with medication administration (Level 4)	First-semester baccalaureate nursing students at 1 university in Pennsylvania	New teaching method	Problem-based learning enabled students to use findings from topic-specific research to develop solutions for clinical problems. Students applied knowledge to clinical settings.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Semple 2004[92]	Patient monitoring	Quality improvement	Response time (Level 4)	1 unit with telemetry in a hospital in Connecticut	Procedure changes to enable nurse to respond to telemetry alarms	Problem areas were identified as the nurses' inability to see critical alarm screen color change, hear critical alarms, and to know when their patient's alarm is sounding. A series of changes were implemented to enable nurse response. Response to telemetry alarms decreased from 12 minutes to 1.57 minutes.
Singh 2004[107]	Error risk detection	Pretest, post-test study	Perceived type/cause of error (Level 3)	1 academic rural primary care practice with 32 staff members	Implementation of electronic medical record	Perceived risk of errors decreased in nurse-physician and physician-chart interactions, but hazards increased in physician-patient interaction in the assessment stage as well as nurse-chart interactions.
Singh 2007[99]	Error risk detection	Quality improvement	Perceived type/cause of error (Level 4)	2 primary care practices serving rural populations in New York	None	Nurses perceived being in a hurry, fatigued, stressed, or ill as well as not using available resources for help as the most prevalent type and cause of errors. Hazard scores at site 2 were consistently higher, indicating that staff perceived greater frequency and/or severity of the errors in their practice.
Smith 2005[87]	Medication safety	Quality improvement	Medication errors and adverse drug events (ADEs) (Level 4)	1 hospital in Illinois	Pharmacist staffing on patient care units to review orders and stock medications reduced errors by 45%; adult IV medications were standardized, and nonstandard doses were prepared by the pharmacy.	There was a significant (a 66% drop in the FMEA score) reduction in ADEs.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
van Tilburg 2006[108]	Medication safety, CPOE	Quality improvement	Errors associated with chemotherapy (Level 4)	Pediatric oncology patients in a hospital in the Netherlands	None	Because changes in ordered prescriptions could be made without being noticed by the nurse, a standardized procedure for changes in chemotherapy treatment schedules was made. Because of administration errors, the procedure was changed so that only pediatric oncologists were allowed to administer vincristine via peripheral IV access.
Weir 2005[101]	Medication safety	Quality improvement	ADEs associated with patient-controlled analgesia (PCA) (Level 4)	1 hospital and clinics in California	None	Areas needing change included using a standard IV PCA dosage or concentration protocol; adding the patient's age to CPOE medication order screen; handwritten orders; PCA pumps programmed incorrectly; and monitoring patients using PCAs. 71% of ADEs were associated with PCA programming error, followed by human factors (15%), equipment problems (9%), and ordering errors (5%).
Plan-Do-Study-Act (PDSA)						
Baird 2001[103]	Medication safety	Quality improvement	Patient outcomes and reduced costs in the ICU (Level 4)	Physicians, nurses, and clinical pharmacists in a 115 adult ICU beds in 1 large medical center in Texas	Using a new heparin administration protocol in ICU	Initial findings with 10 patients found that 90% of patients received optimal bolus doses (compared to 8.6% of the historical patients) and all received optimal infusion doses (compared to 3.4% of historical patients). Patients received better heparin therapy because they received the right loading dose, reached a therapeutic level of the drug more quickly, and maintained the therapeutic level. Nursing efficiency improved with fewer dose changes and laboratory tests. Medication and laboratory test costs decreased as did the patient's length of stay.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Bolch 2005[97]	Care transitions	Quality improvement	Patients having a documented discharge plan, patients screened for risk, patients receiving followup care within 10 days of discharge (Level 4)	Patients ages ≥ 65, admitted to a hospital in South Australia	Modified the nursing assessment/risk assessment tool	Improvements in the initiation and followup of discharge planning resulted in more documented discharge plans, increased risk assessment, increased referrals to community services, and improved communication between hospital staff and community providers.
Buhr 2006[80]	Pain management	Quality improvement	Improved assessment and management of chronic pain (Level 4)	Patients and nurses (licensed practical nurses (LPNs), certified nursing assistants (CNAs), and registered nurses (RNs)) in 1 nursing home in North Carolina	Increased knowledge of chronic pain assessment and management through education. Implemented updated policies and procedures, and used new tools for pain assessment and management. Revised standing orders for pain management.	Pain assessment and management understanding improved in staff, especially in the CNAs. Patient and family satisfaction increased, and feeling that pain was adequately addressed increased.
Docimo 2000[89]	Throughput in emergency department (ED)	Quality improvement	Time in ED for minor illnesses and injuries (Level 4)	1 ED in 1 hospital in Maryland	Improved both the processes and relationships of hospital staff using PDSA cycles	Nonacute patients were fast-tracked to an average time of 1 hour, 47 minutes by not waiting behind higher-acuity patients for registration. Physician assistants, nurses, and technicians reported improved working conditions and team spirit.
Dodds 2006[119]	Practice variation	Quality improvement	Length of stay, reduced variation in process of care (Level 4)	Patients with chronic obstructive pulmonary disease (COPD)	Redesigned service delivery by using a continuous quality improvement methodology and PDSA cycles	Decrease in average length of stay. Increase in the numbers of patients admitted directly to the emergency medical unit and transferred to the respirator department. Improved the management of patient information and communication with patients.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dunbar 2006[100]	Pain management Practice variation	Quality improvement	Frequency of painful procedures, managing pain associated with painful procedures (Level 4)	11 neonatal ICUs	Implemented evidence-based practices for pain management and sedation in neonates using PDSA cycles	The combination of using collaborative quality improvement techniques and local quality improvement efforts resulted in better patient outcomes.
Eisenberg 2002[109]	IV incidents	Quality improvement	IV care patient outcomes (Level 4)	4 community hospitals	Education of all staff nurses on IV site care and assessment, as well as assessment of central line, total parenteral nutrition (TPN**)**. Revised 35 IV policies into 5, revised documentation flow sheets, and provided a resource manual.	Reductions in complications and costs. Improved patient satisfaction. No formal complaints about IV care.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Erdek 2004[93]	Pain management	Prospective study	Pain management and assessment (Level 4)	2 surgical ICUs in 1 hospital in Maryland	Implemented 4 PDSA cycles, including educating staff on pain management, modifying pain scales at patients' bedsides, residents documenting pain scores for past 24 hours, and creating expectation that pain > 3 is a defect.	Pain assessment improved from 42% to 71%, and pain management improved from 59% to 97%. Documentation of pain assessment improved among nurses.
Farbstein 2001[106]	Medication safety	Quality improvement	Types of medication administration errors (Level 4)	6 improvement projects in hospitals in Massachusetts	Implementation of best practices, using PDSA to assess impact	The results presented from the 6 improvement projects included faster therapeutic anticoagulation for patients receiving heparin; fewer look-alike/sound-alike errors; fewer PCA administration adverse events; safer administration of coumadin; improved patient information on their medication; and improved processing of the morning dispensing of medications in the pharmacy. The investigators described success factors of medication safety projects as using data to measure outcomes; using forcing functions built into the process; pacing changes sequentially, not all at one time; low cost of changes; using a consultant to mentor team leaders; and using reported errors to assess implementation impact.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Horbar 2003[98]	Neonatal intensive care	Quality improvement	Improved quality and safety of neonatal intensive care (Level 4)	34 centers	Implemented, applying 4 key habits for improvement using rapid-cycle PDSA	Developed 51 potentially better practices that were implemented by multidisciplinary neonatal ICU teams in identifying, testing, and implementing change in practice.
Horner 2005[117]	Pain management	Pretest and post-test study	Improved pain assessment and management of residents (Level 3)	9 nursing homes in North Carolina	Chart audit and data feedback on quality indicators, provider education, and technical support for systems change using PDSA	The number of residents receiving pain assessments increased from 8% to 29%. Residents receiving nonpharmacological pain treatments increased from 31% to 42%. Residents with daily moderate or excruciating pain had increased probability of pain medication use.
Leape 2006[86]	Medication reconciliation, communicating critical test results	Quality improvement	Implementation of safe practices (Level 4)	58 hospitals (88%) in Massachusetts	Institute for Healthcare Improvement model for improvement to care practices	Participating hospitals did so because of the following factors: the intrinsic appeal of the practice, access to experts, and the availability of implementation strategies. Project success was associated with active engagement of senior management, physician engagement, increased use of PDSA cycles, participation in collaborative meetings.
Pronovost 2000[83]	Access to care	Quality improvement	Number of ambulance bypass hours (Level 4)	1 hospital in Maryland	PDSA to act on identified root causes, targeting bed sharing for patients needing ICU care that were managed in the ED	Significant reduction in hours with an estimated $6 million in additional hospital revenue. Success was achieved by teams integrating tools that improved processes and collaborative relationships.
Salvador 2003[114]	Medication safety	Quality improvement	Safety of hospital-based antenatal home care for high-risk women (Level 4)	Physicians, nurses, and clinical pharmacists in 115 adult ICU beds in 1 large medical center in Texas	Using a new heparin administration protocol in ICU	New heparin protocol resulted in better patient care, improved nursing efficiency and work satisfaction, and reduced costs by $885 on average. There were no differences in maternal or newborn health outcomes.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
van Tiel 2006[118]	Health care associated infections	Quality improvement	Compliance with infection control measures (Level 4)	1 ICU and OR in a 715-bed university hospital in the Netherlands	Instruction and training of nursing and medical staff on PDSA cycles	Not wearing a face mask during procedures decreased to 0%; not wearing jewelry decreased to 33%. Improved compliance with wound care, including hand washing before and after wound care and the use of disposable surgical wound sets.
Warburton 2004[120]	Adverse outcomes in EDs	Quality improvement	Detect patients at risk for adverse outcomes, provide a plan of care, and target care services (Level 4)	1 small hospital in Canada	Implementation of the Elder Alert program using PDSA cycles	Process evaluation audits and regular meetings of providers and academic collaborators were essential improvement tools. Screening criteria had to be adapted to the patient population.
Wojciechowski 2006[122]	PDSA	Quality improvement	Increasing access to patient education resources (Level 4)	1 rehabilitation facility in a city in the Midwest	Implementation of a new patient education system for medication and disease information using PDSA cycles	Designing a new Web-based patient education system benefits from a process promoting change incrementally and collaboration.
Root-Cause Analysis (RCA)						
Gowdy 2003[90]	Patient falls	Quality improvment	Incidence of inpatient falls (Level 4)	1 hospital in North Carolina	Implemented an action plan to prevent patient falls	RCA identified risks for falls associated with confusion, gait disturbance, and self-toileting. Inpatient fall rate decreased from 6.1 to 2.6 falls per 1,000 patient days (a 43% decrease during the study period).
Luther 2002[104]	Adverse events	Quality improvement	Incidence of ADEs, ventilator-acquired pneumonia, central-venous-catheter-related bloodstream infections (Level 4)	2 hospitals in Texas	Increased staffing levels and improved education. Conducted RCA to identify issues needing to be addressed by leadership and staff.	Adverse events targeted by nurses using protocols decreased ADEs by 45%, ventilator-acquired pneumonia from 47.8/1,000 ventilator days to 10.9/1,000, and decreased central-venous-catheter-related bloodstream infections from the 90th to the 50th percentile of the National Nosocomial Infection Surveillance System. Implementation of protocols decreased length of stay from 8.1 to 4.5 days.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Middleton 2007[105]	Root causes of errors	Cross-sectional study	Adoption of recommendations detected from RCA (Level 4)	12 physicians (86% response rate) and 17 nurses (100% response rate) in Sydney, Australia	None	Nurses were more likely than physicians to view RCA recommendations as "relevant to the causal statement," "understandable," "achievable," and "measurable." Physicians and nurses involved in the RCA were significantly more likely to believe that the RCA recommendations would "eliminate" or "control" future risks. Some recommendations rated as "relevant to the causal statement" by nurses were significantly less likely to also be rated as "achievable."
Mills 2005[82]	Patient falls	Quality improvement	Incidence of falls and major injuries due to falls (Level 4)	100 VA acute and long-term care facilities	Aggregate RCA was used to support implementation of fall prevention strategies.	61.4% of strategies were fully implemented, and 20.9% were partially implemented. 34% of the facilities reported a reduction in the number of falls, and 38.9% reported a reduction in major injures related to falls. The impact of the interventions could have been hampered by making specific clinical changes without changing policies and providing staff education.
Mutter 2003[95]	Medication safety	Quality improvement	Frequency of medication administration errors (Level 4)	1 451-bed acute care hospital in New Jersey	After assessing causes of errors, established a nonpunitive environment to encourage error reporting and interviewed providers who reported errors.	Improvement requires constant and continual assessment of errors. Rapid-cycle improvement was used to decrease medication administration errors and to inform changes.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Plews-Ogan 2004[102]	Voluntary reporting of near miss/adverse events	Cross-sectional study	Error reporting (Level 4)	1 ambulatory site of a large teaching hospital	System analysis and redesign using RCA.	Two-thirds of the 70 recommended recommendations were level 1, 23% level 2 (i.e., involving more complex interventions usually requiring significant groundwork), and 10% level 3 (i.e., involving other services). Using RCA increased error reporting as system issues were addressed, not through individual blame. RCA identified the underlying causes of reported errors, and improvements were made on an ongoing basis.
Rex 2000[96]	Medication safety	Quality improvement	Rates of ADEs (Level 4)	1 hospital in Texas	Implemented policy changes to use forcing or constraining functions and better personnel support	RCA identified environmental factors (e.g., patient acuity, change of shit) and staffing issues (e.g., new staff). ADEs decreased by 45%. Implementing blame-free RCA enabled identification and prioritization of performance improvement initiatives and focus on systems issues.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Willeumier 2004[85]	Medication safety Health care associated infections	Quality improvement	Rates of medication error reporting and ventilator-associated pneumonia (VAP) rates (Level 4)	8-hospital system in northern Illinois	Improved medication availability, standardized nursing reassessment of medications, reinforced the 5 rights of medication administration, provided medication information, revised medication policies, and standardized nursing documentation of medication administration. Redesigned oral hygiene processes, used head positioning, and used collection and culture techniques for better diagnosis.	Identified strategies based on proactive risk assessment (a composite of RCA and FMEA). Medication error reporting increased and VAP rates decreased. Greatest challenges were implementing and sustaining a culture of safety, the complexity of the health care system, underreporting of patient safety events, and medical staff's acceptance of the disclosure policy. Improvement is dependent upon the involvement of leadership, communication with staff, and the use of the appropriate technology.
Six Sigma						
Germaine 2007[91]	Surgical site infections OR patient throughput	Quality improvement	OR turnover (Level 4)	1 hospital in Michigan	Implemented OR turnaround protocol	Turnover decreased from 34 minutes to an average of 18 minutes, allowing volume to increase by 5%. Surgical site infections decreased from 2.14% to 1.07%.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Guinane 2004[81]	Groin injury in cardiac catheterization patients	Quality improvement	Groin injury rates (Level 4)	A team of physicians, nurses, and administrators involved in the care of cardiac catheterization patients in 1 hospital	Implemented groin management process to decrease injury rates, reduce the cost of care, and improve customer satisfaction	Groin injuries decreased from 4% to less than 1% (e.g., 41,666 defects to 8,849.5 defects) – sigma value improved from 3.23 to 3.87. Length of stay that exceeded the specified upper limit decreased from 16% of the time to only 3% of the time. Operating costs that exceeded the specified upper limit decreased from 18% to 3% of the time.
Johnson 2005[125]	Chest pain management	Quality improvement	Time for diagnosis and evidence-based treatment of patients with chest pain	1 hospital in New York	Implemented an algorithm, preprinted orders, and use of cardiac nurse practitioners from presentation in ED through discharge	Increases in diagnosis of cardiac disease, cardiac catheterization, and stenting/bypass surgery, especially in women, Latinos, and patients > 60 years old.
Pexton 2004[113]	Surgical site infections	Quality improvement	Rate of colon and vascular surgical site infections (Level 4)	1 medical center in West Virginia	A preoperative order set with a checklist including recommended antibiotics and weight-based dosages, education of team members, physician report cards, and anesthetists and nurses prompting surgeons to use antibiotics.	Surgical site infection rates decreased by 91% (2.86 sigma), with an estimated potential annual savings of more than $1 million.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Toyota Production System (TPS)/Lean						
Aldarrab 2006[126]	Emergency care of patients with ST-elevation myocardial infarction (MI)	Quality improvement	Patients with appropriate reperfusion and adjunctive pharmacological treatment (Level 4)	3-site tertiary/quaternary facility in Canada	Implementation of evidence-based guidelines for ST-elevation in MI patients	An RCA was used to understand current processes and to assess what could be standardized. Targets were achieved in terms of using the appropriate reperfusion strategy, meeting the median time of < 30 minutes for thrombolytic therapy and 90 minutes for percutaneous coronary intervention, appropriate thrombolytic and adjunctive treatment use. It was noted that without continued reinforcement of the new protocol, the process would regress to prior levels of performance.
Furman 2007[39]	Error reporting	Quality improvement	Near-miss error reports (Level 4)	1 medical center in Virginia	Implemented an error reporting system, including a 24-hour hotline	Nurses reported 44% of the near misses, physicians 8%, managers 20%, nonclinical staff 23%. Over a period of 3 years, the number of error reports increased because there was a transparent discussion and feedback process.
Jimmerson 2005[88]	Medication safety Access to medical equipment	Quality improvement	Efficiency of testing patient's glucose level at the bedside (Level 4)	1 medical-surgical ICU in a hospital in Utah	Installed glucometers in each room in the ICU	Reduced time to do glucose check from 17 to 4 minutes. Improved ability to consistently implement the protocol. No unlabeled specimens at risk of erroneous identification. Fewer RN interruptions and frustration.
Nowinski 2006[121]	Medication administration	Quality improvement	Medication administration errors (Level 4)	1 hospital in Pennsylvania	Revised and streamlined medication administration process based on finding from an RCA	Rapid, substantial, and continuing improvements in patient care were achieved. Nursing staff reported higher levels of satisfaction.

Source	Quality or Safety Issue Related to Clinical Practice	Design Type	Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Printezis 2007[59]	Using TPS in health care	Literature review	Reviewed five quality improvement projects to reduce medical errors in hospitals (Level 4)	Improvement projects in hospitals	None	Simple pathways of root causes lead to better operational performance. Organizing principles of TPS improve reliability and effectiveness of health care delivery systems. Problem-solver on projects should not be a consultant, but someone who is a stakeholder. Many problems are associated with relationships with other departments. TPS makes work-around and rework difficult to continue. TPS helps staff learn and identify waste in daily activities. Front-line staff need to be enthusiastic about making improvements. Clear, concise, and objective communication is key.
Thompson 2003[84]	Medication administration	Quality improvement	Missing medications Complexity of the medication administration process (Level 4)	Pharmacy and nursing units at 1 hospital in Pennsylvania	Implemented: specific	Rapid, substantial, and continuing improvements in medication administration processes were achieved. Nursing staff reported higher levels of satisfaction, associated with workflow improvements.

Chapter 45. AHRQ Quality Indicators

Marybeth Farquhar

What Are the AHRQ Quality Indicators?

The Quality Indicators (QIs) developed and maintained by the Agency for Healthcare Research and Quality (AHRQ) are one response to the need for multidimensional, accessible quality measures that can be used to gage performance in health care. The QIs are evidence based and can be used to identify variations in the quality of care provided on both an inpatient and outpatient basis. These measures are currently organized into four modules: the Prevention Quality Indicators (PQIs),[1] the Inpatient Quality Indicators (IQIs),[2] the Patient Safety Indicators (PSIs),[3] and the Pediatric Quality Indicators (PDIs).[4] A brief description of each module appears in Table 1.

Table 1. The AHRQ Quality Indicators modules

Prevention Quality Indicators (PQIs): These indicators identify ambulatory care sensitive conditions, defined as conditions for which good outpatient care can potentially prevent the need for hospitalization, or for which early intervention can prevent complications or more severe disease.
Inpatient Quality Indicators (IQIs): These indicators reflect quality of care inside hospitals and include inpatient mortality; utilization of procedures for which there are questions of overuse, underuse, or misuse; and volume of procedures for which there is evidence that a higher volume of procedures is associated with lower mortality.
Patient Safety Indicators (PSIs): These indicators focus on potentially preventable instances of complications and other iatrogenic events resulting from exposure to the health care system.
Pediatric Quality Indicators (PDIs): These indicators reflect the quality of care for children younger than 17 years of age and neonates inside hospitals (provider-level indicators) and identify potentially avoidable hospitalizations among children (area-level indicators).

Origins and History

In 1994, in response to requests for assistance from State-level data organizations and hospital associations with hospital inpatient data collection systems, the AHRQ developed a set of measures that used hospital administrative data provided by the Healthcare Cost and Utilization Project (HCUP), an ongoing Federal-State-private sector partnership that was established to develop uniform databases. As a result, these measures, called the HCUP Quality Indicators, were developed to take advantage of readily available administrative data and quality measures that had been previously reported in the literature.[5] The original HCUP Quality Indicators included 33 measures that could identify avoidable adverse outcomes such as in-hospital mortality and complications of procedures; the use of specific inpatient procedures thought to be overused, underused, or misused; and ambulatory care sensitive conditions. These

indicators identified potential quality-of-care problems and served as the starting point for further investigation.

In 1998, under contract with AHRQ, researchers at the University of California, San Francisco (UCSF) and the Stanford University Evidence-Based Practice Center (EPC) reviewed and revised the original set of measures.[5] This revision served to expand the HCUP Quality Indicators by (1) identifying quality indicators reported in the literature and in use by health care organizations, (2) evaluating both the HCUP Quality Indicators and other indicators using literature reviews and empirical methods, and (3) incorporating risk adjustment. The revised set, now known as the AHRQ QIs, originally included two modules: the PQIs released in April 2002, and the IQIs released in June 2002. Other modules were eventually added based on requests from the user community; specifically, the PSIs were released in May 2003, and the most recent set of measures, the PDIs, were added to the existing QI modules in February 2006. An additional module, the Neonatal Quality Indicators (NQIs), is currently under development and will be released in the near future.

Development of the AHRQ Quality Indicators

The AHRQ QIs were developed from an extensive, iterative process that included interviews from a broad spectrum of organizations that represented QI users and potential users, literature reviews that identified possible quality measures, evaluation of the candidate measures as well as evaluation of several risk-adjustment methods for use with the potential measures, empirical analysis, and validation. The process can be roughly divided into two phases: the first identifies candidate measures or indicators, and the second analyzes the potentially viable measures or indicators.

During development of the QIs, the UCSF-Stanford EPC used the Institute of Medicine's definition of care quality to guide the development process: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[6] Based on this definition, six key questions were developed to direct the selection of measures for further evaluation. They were:

- Which indicators currently in use or described in the literature could be defined using hospital discharge data?
- What are the quality relationships reported in the literature that could be used to define new indicators using hospital discharge data?
- What evidence exists for indicators not well represented in the current set of indicators—pediatric conditions, chronic disease, new technologies, and ambulatory care sensitive conditions?
- Which indicators have literature-based evidence to support face validity, precision of measurement, minimum bias, and construct validity of the indicator?
- What risk-adjustment method should be suggested for use with the recommended indicators, given the limits of administrative data and other practical concerns?
- Which indicators perform well on empirical tests of precision of measurement, minimum bias, and construct validity?

Identifying Candidate Indicators

In the first phase of development, the UCSF-Stanford EPC conducted interviews with individuals affiliated with hospital associations, business coalitions, State data groups, Federal agencies, and academia about topics related to quality measurement. The interviews provided background information on measure use, suggested new indicators for potential development, and provided the names of additional individuals within the field who could be contacted for an interview. The interviews also suggested new risk-adjustment methods and assisted in framing the evaluation of potential indicators. With this information and relevant literature, the team developed a framework in which to evaluate the performance of the candidate measure. Table 2 provides an overview of the criteria used to evaluate the potential measures as well as a brief description of each.

Table 2. Criteria used to evaluate potential Quality Indicators

Face validity: An adequate quality indicator must have sound clinical or empirical rationale for its use. It should measure an important aspect of quality that is subject to provider or health care system control.
Precision: An adequate quality indicator should have relatively large variation among providers or areas that is not due to random variation or patient characteristics. This criterion measures the impact of chance on apparent provider or community health system performance.
Minimum bias: The indicator should not be affected by systematic differences in patient case mix, including disease severity and comorbidity. In cases where such systematic differences exist, an adequate risk-adjustment system should be possible using available data.
Construct validity: The indicator should be related to other indicators or measures intended to measure the same or related aspects of quality. For example, improved performance on measures of inpatient care (such as adherence to specific evidence-based treatment guidelines) ought to be associated with reduced patient complication rates.
Fosters real quality improvement: The indicator should be robust to possible provider manipulation of the system. In other words, the indicator should be insulated from perverse incentives for providers to improve their reported performance by avoiding difficult or complex cases, or by other responses that do not improve quality of care.
Application: The indicator should have been used in the past or have high potential for working well with other indicators. Sometimes looking at groups of indicators together is likely to provide a more complete picture of quality.

Source: Agency for Healthcare Research and Quality. *Refinement of the HCUP Quality Indicators*[5] (p. 30).

The research team also undertook a literature review that was structured in two phases. The first phase identified potential measures within the literature that were applicable to comparisons among providers or among geographic areas. In addition, potential indicators were identified using the various established databases of measures such as those from the Joint Commission for the Accreditation of Healthcare Organizations, Healthy People 2010, and so on. In the second phase of the literature review, the team performed an initial screen of the candidate indicators for

relevance and accuracy. If an indicator met the criteria as described in Table 2, it received a comprehensive literature review and empirical evaluation.

The next phase of development was to identify potential risk-adjustment models for each of the selected candidate measures. Users of the QIs preferred a risk-adjustment system that was (1) open with published logic; 2) cost effective with data collection costs minimized and with any additional data collection being well justified; (3) designed using a multiple-use coding system, such as those used for reimbursement; and (4) officially recognized by government, hospital groups, or other organizations. In general, the All Patient Refined-Diagnosis Related Groups (APR-DRGs) tended to fit more of the user preferences than other alternatives considered. In addition, the APR-DRGs were reported to perform as well as or better than other risk-adjustment systems for several conditions.[7–9] The APR-DRGs are used in various AHRQ QIs; however, this method is not used with the PDIs, which use a novel and specialized risk-adjustment system that includes the data element Present on Admission (POA), the AHRQ Clinical Classification System, and stratification.

Analyzing Potential Indicators

The next step in the development process was empirical testing of all potential indicators. The primary datasets used were the HCUP Nationwide Inpatient Sample (NIS) and the State Inpatient Database (SID). The NIS is the largest all-payer inpatient care database in the United States, consisting of approximately 8 million hospital stays per year, specifically it consists of discharges of about a 20 percent stratified sample of community hospitals in the country. The SID consists of the universe of inpatient discharge abstracts in participating States, translated into a uniform format. This database encompasses about 90 percent of all community hospital discharges in the nation. More recently, the Kids' Inpatient Database was used to develop the AHRQ PDIs. This database, currently the only all-payer inpatient care database for children in the United States, contains 2–3 million hospital discharges. For more information about these databases, please go to the AHRQ website at www.ahrq.gov/data/hcup.

The data from these databases were used to test each evaluation criterion that was assessed empirically i.e., precision, bias, and construct validity. The results of the candidate indicators were compared, and those indicators that performed poorly were eliminated. Bias tests were conducted to determine the need for risk adjustment, and then finally, construct validity was evaluated to provide evidence of the nature of the relationship between potential indicators.

The next phase of indicator development used multi-disciplinary clinician panel reviews. The team solicited nominations from professional clinical organizations and hospital associations, that were selected based on the applicability of the specialty or subspecialty to the candidate indicators. Nominees were chosen based on meeting certain criteria. For example, nominees were required to spend at least 30 percent of their work time on patient care, including hospitalized patients. The panelists were selected so that each group had a diverse membership in terms of clinical practice characteristics and settings.

The members of the panel were given a number of documents to evaluate the candidate measures. The documents provided included information about administrative data; coding from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM); assignment of DRGs and Major Diagnostic Categories (MDCs); and specific definitions for adverse events or complications, preventability, and medical error. Candidate measure information incorporated exclusion and inclusion criteria, the clinical rationale for the indicator, and the specification criteria. A summary of literature-based evidence and empirical rates based

on the NIS were provided for reference as well. Finally the panelists were given a list of potential questions regarding indicator definitions that the team planned to explore. Each panelist completed a 10-item questionnaire that asked them to determine the candidate indicator's ability to screen out conditions present on admission, to identify conditions with high potential for preventability, to identify medical errors, or to evaluate access to high-quality outpatient care. Panelist were also asked to consider potential sources of bias, reporting or charting problems, potential ways of gaming the indicator, and possible adverse effects of implementing the measure. Finally, panelists were invited to suggest changes to the candidate indicator.

After the questionnaires were returned, the team convened a series of conference calls with the panelists to discuss their opinions regarding the candidate measures. Using a modified version of the RAND/UCLA method developed in the 1980s. The RAND/UCLA Appropriateness Method[10] is used to synthesize the best available scientific evidence and expert opinion on health care issues. This method is a way to reach formal agreement on how the current science is interpreted by care givers in the real world. For the development of the QIs, the primary goal of the interaction was to allow for and encourage varied opinions about the appropriateness of an indicator. For our purposes, consensus was not the goal of the discussion, and agreement and disagreement on every indicator under consideration was noted. Following each conference call, modifications were made to each indicator as suggested by the panelists. The revised indicators were then redistributed to the panelists, along with questionnaires, and instructions to reevaluate and again rate each indicator based on their current opinion after the conference call discussions. Once the final round of questionnaires was received, the team calculated median scores to determine the degree of agreement among panelists. In addition, the team calculated scores indicating the level of acceptability of the indicator and the dispersion of ratings across the panel. The following criteria covered in the questionnaire were used to summarize the panel's options on each indicator:

- Overall usefulness of the indicator, both for internal quality improvement purposes and comparisons between hospitals
- Likelihood that the indicator measures a complication and not a comorbidity (specifically, present on admission)
- Preventability of complication
- Extent to which a complication is due to medical error
- Likelihood that a complication that occurs is charted
- Extent that the indicator is subject to bias (systematic differences, such as case mix, that could affect the indicator in a way not related to quality of care)

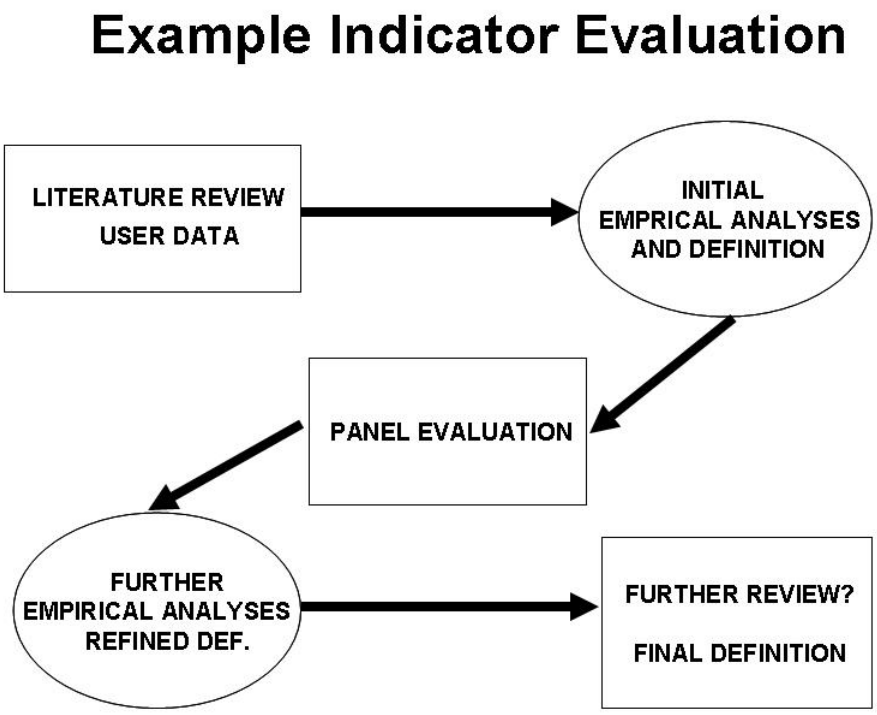
For area-level indicators, panelists provided feedback on the following areas:

- Overall usefulness of the indicator, both internally within an area and for comparisons between areas
- Extent to which an event reflects poor access to quality outpatient care
- Consistency in terminology for charting the principal diagnosis
- Extent that the indicator is subject to bias

The next step in the development process involved peer review of the candidate measures. Nominations were sought for clinicians, policy advisors, professors, researchers, and managers in quality improvement to participate on this panel. The group was instructed to provide comments on the indicators with constructive suggestions for content and presentation enhancements.

Once the panel reviews and evaluations were complete, the candidate indicators could go through further empirical testing to refine their definitions. After that, the indicator may undergo further clinical and peer review, which can occur over several rounds until the definition of the indicator is finalized. As with any measure of performance, the process of refinement is ongoing and becomes part of the measure maintenance activities of the measure developer. Figure 1 provides a graphic account of the basic development process.

Figure 1. The AHRQ Quality Indicator development and evaluation process



As a measure developer, AHRQ maintains these measures and on an annual basis, provides revisions to the measures, including ICD-9-CM and DRG code updates, an update to the reference population used in calculating the QIs, and refinement of the specifications based on additional evidence in the literature and user input. Literature reviews are completed on one QI module every year, which allows time for new research to be completed and subsequently published in peer reviewed journals.

What We Know About the AHRQ Quality Indicators

Measuring performance is central to improving the quality of health care. Performance measurement conveys the message of importance—that is, what is important is measured, while what is not measured is considered less important by many. The AHRQ QIs are measures of health care quality that make use of readily available hospital inpatient administrative data. The structure of the indicators consists of definitions based on ICD-9-CM diagnosis and procedure

codes. Inclusion and exclusion criteria are based upon DRGs: sex, age, procedure dates, and admission type. The numerator is equal to the number of cases flagged with the complication or situation of interest, for example, postoperative sepsis, avoidable hospitalization for asthma, and death. The denominator is equal to the number of patients considered to be at risk for that complication or situation, for example, elective surgical patients, county population from census data, and so on. The QI rate is equal to the numerator divided by the denominator. As with any type of performance measure, regardless of its data source, there are advantages to using certain measures as well as limitations associated with using them. What is presented below is a review of the data source used by the QIs as well as a review of the indicators by module. The strengths and limitations of the QIs are also discussed.

The AHRQ QIs and Their Data Sources

There are several sources of data that can be used to measure performance, and these data sources can be grouped into the following categories: administrative data (also known as billing or claims data), medical record information, patient-derived data (i.e., surveys);[11] confidential reports from providers, and direct observation. All categories of data have strengths and weaknesses and each data source should be evaluated for comprehensiveness or the completeness of data elements as they pertain to individuals, and inclusiveness or the extent to which populations are represented in a particular geographic area.[12] The AHRQ QIs use data derived from administrative databases, which is considered a "by-product" of care delivery, i.e., reimbursement to hospitals or physicians or determining insurance eligibility of patients.[9]

While administrative data were not originally intended to be used in research, these types of databases are often used by researchers in their studies and clearly offer some important advantages, such as the ability to track study subjects over time. Administrative data are also relatively inexpensive to collect and readily available to researchers, administrators, and others. Additional advantages include the large sample sizes associated with this type of data, the ease of collection without interference with the care of the patient, the population-based characteristic of administrative data, and identifiers associated with the data that permit observations across sites and settings of care. The AHRQ QIs can be used with any administrative data set and largely rely on the ICD-9-CM codes for diagnosis and procedures from individual hospitalization data, which are derived from the 2004 Uniform Bill (UB-04). Other information such as patient identifiers, hospitalization descriptors, admission types, insurance information, and charge data can be found on this form. Thus by putting together the range of ICD-9-CM codes and supplementary codes such as E codes* and V codes,† and from a creative and clinically informed use of these codes, a picture of a patient's clinical status and risk factors begins to form (see Table 3).

* These are external causes of injury and poisoning that capture how the injury or poisoning happened, the intent, and the place where the event occurred.

† These are supplementary classification codes that document factors influencing health status and contact with heath services, including such areas as health hazards related to communicable diseases, the need for isolation due to other potential health hazards and prophylactic measures, and persons with conditions influencing their health status, etc.

Table 3: Characteristics and Uses of Hospital Administrative Data

• Used to bill and pay for hospital services and contain information from the discharge claim.
• Standardized format, which is available electronically from all hospitals that bill for services.
• Used for health care quality research, evaluation, public reporting, and quality improvement.
• Typical data elements include patient gender, age, diagnoses, procedures, length of stay, admission source, discharge status, total charges, primary payer, and hospital identifier.
• Depending on the data source, other data elements that may be available include patient race, county or ZIP Code of residence, secondary payer, detailed charges, and identifier of primary physician or surgeon.
• Data format and quality may differ across hospitals or data organizations, such as the number of diagnosis and procedure codes available and the sequencing of the codes, the audits or edits applied to the data before and after submission, and the data values accepted.

The AHRQ QIs are valuable because they are based on widely available data that can be used to assess quality. Theses QI indicators also have uniform definitions and standardized algorithms that can be used with virtually any administrative data set, which allows for comparisons across States, regions, communities, and hospitals.

As with any data source used to assess performance, there are a number of drawbacks to using administrative data to examine the quality of care delivered by health care providers. Despite the large number of ICD-9-CM codes available and the implied detail they contain, these codes do not have operational clinical definitions assigned, which make assignment by coders somewhat variable. While coders are generally formally trained in coding methods and instructed to use the terminology in the medical record, clinicians seldom use a consistent lexicon in their charting. Thus, the meaning of codes without a clinical context, or without the considerations of disease progression, and the interaction of comorbidities can provide an inaccurate clinical picture—limiting the usefulness of the data. Yet despite this limitation, data availability, coding systems, and coding practices are improving, which enhance our ability to identify quality problems as well as success stories, which can be further identified and studied.

The AHRQ QI Modules

Prevention Quality Indicators (PQIs)

The AHRQ PQIs are one set of quality measures that can be used to identify potential problems; follow trends over time; and ascertain disparities across regions, communities, and providers. This module focuses on preventive care services—outpatient services that assist individuals with either staying healthy or managing chronic illness. In these instances, inpatient data can provide information on admissions for ambulatory sensitive conditions that evidence suggests could have been avoided, at least in part through better outpatient care. For example, patients with diabetes may be hospitalized due to complications for their disease if their conditions have not been adequately monitored or if they do not receive education that would allow them to self-manage the disease. There are currently 14 PQIs, listed in Table 4 that measure rates of admissions to the hospital.

Table 4: AHRQ Prevention Quality Indicators

- Diabetes short-term complication admission rate
- Perforated appendix admission rate
- Diabetes long-term complication admission rate
- Chronic obstructive pulmonary disease admission rate
- Hypertension admission rate
- Congestive heart failure admission rate
- Low birth weight rate
- Dehydration admission rate
- Bacterial pneumonia admission rate
- Urinary tract infection admission rate
- Angina admission without procedure
- Uncontrolled diabetes admission rate
- Adult asthma admission rate
- Rate of lower-extremity amputation among patients with diabetes

Factors such as poor environmental conditions or lack of patient adherence to treatment regimes can result in hospitalization. However, the PQIs provide a good starting point to assess quality of services within a community. The POIs can be used to provide a picture of health care in the community by identifying unmet needs, monitoring how well complications are being avoided in the outpatient setting, assessing access to health care, and comparing the performance of local health care systems across communities.

The PQIs represent the current state of the art in assessing the health care system as a whole, but particularly in the area of ambulatory care, for example, in preventing medical complications for both acute illness and chronic conditions. The PQIs are valuable when calculated at the population or area level and when used by organizations such as public health groups, State data organizations, health plans, large health systems, and other organizations concerned with the health of populations. The PQIs are risk adjusted for age and gender and provide information about potential problems in the community that may require further analysis. The PQIs help answer questions such as

- Does the admission rate for diabetes complications in my community suggest a problem in the provision of appropriate outpatient care to this population?
- How does the admission rate for congestive heart failure vary over time and from one region of the country to another?

These are just a few of the questions that the PQIs can address to assist those health care providers with responsibility for the health of a particular population. The PQIs allow for comparisons across States, regions, and local communities over time. The PQIs do not measure hospital quality, but reflect the care provided in the community.

Despite their strengths, there are several considerations when using these indicators. Differences in PQI rates can explain some of the variation across areas but not all. The complexity of the relationship between socioeconomic status and PQI rates makes it difficult to

delineate how much of the observed relationships are due to true access to care issues, difficulties in potentially underserved populations, or other patient characteristics unrelated to quality of care that vary systematically by socioeconomic status. Second, the evidence related to potentially avoidable hospital admissions is limited for each indicator because many of the indicators have been developed as parts of sets. Finally, despite the relationships demonstrated at the patient level between higher quality ambulatory care and lower rates of hospital admission, few studies have directly addressed the question of whether effective treatments in outpatient settings would reduce the overall incidence of hospitalizations.

The Inpatient Quality Indicators (IQIs)

The AHRQ IQIs provide information about the quality of medical care delivered in a hospital. This measure set represents the state of the art in measuring the quality of hospital care using inpatient administrative data. The IQIs include measures in the areas of inpatient mortality; utilization of procedures for which there are questions of overuse, underuse, or misuse; and volume of procedures for which there is evidence that a higher volume is associated with lower mortality.

The IQIs that focus on volume are proxy measures of quality and represent counts of admissions in which these procedures were performed. They are based on evidence suggesting that hospitals that perform more of certain procedures—for example, those that are intensive, high-technology, or highly complex—may have better outcomes for those procedures. The provider-level volume IQIs are:

- Esophageal resection volume
- Pancreatic resection volume
- Abdominal aortic aneurysm (AAA) repair volume
- Coronary artery bypass graft (CABG) volume
- Percutaneous transluminal coronary angioplasty (PTCA) volume
- Carotid endarterectomy (CEA) volume

The mortality indicators for inpatient procedures cover procedures for which mortality has been shown to vary across institutions and for which there is evidence that high mortality may be associated with poorer quality of care. The mortality indicators for inpatient surgical procedures are:

- Esophageal resection mortality rate
- Pancreatic resection mortality rate
- AAA repair mortality rate
- CABG mortality rate
- PTCA mortality rate
- CEA mortality rate
- Craniotomy mortality rate
- Hip replacement mortality rate

When evaluating mortality rates, the corresponding volumes should be examined in conjunction with the mortality rate because that provides more information about the care delivered. For example, esophageal resection is a complex surgery, and studies have noted that providers with higher volumes have lower mortality rates. These results suggest that providers with higher volumes have some characteristics, either structurally or with regard to processes that influence mortality.

The mortality indicators for inpatient conditions cover conditions for which mortality has been shown to vary substantially across institutions and for which evidence suggests that high mortality may be associated with deficiencies in the quality of care. The mortality indicators for inpatient medical conditions are:

- Acute myocardial infarction (AMI) mortality rate
- AMI mortality rate, without transfer cases
- Congestive heart failure mortality rate
- Acute stroke mortality rate
- Gastrointestinal hemorrhage mortality rate
- Hip fracture mortality rate
- Pneumonia mortality rate

Also included in the IQIs are utilization indicators that examine procedures whose use varies significantly across hospitals and for which questions have been raised about overuse, underuse, or misuse. High or low rates for these indicators are likely to represent inappropriate or inefficient delivery of care. The procedure utilization indicators are:

- Cesarean section delivery rate
- Primary cesarean delivery rate
- Vaginal birth after cesarean (VBAC) rate, all
- VBAC rate, uncomplicated
- Laparoscopic cholecystectomy rate
- Incidental appendectomy in the elderly rate
- Bilateral cardiac catheterization rate

There are currently 28 IQIs that are measured at the provider or hospital level, as well as 4 area-level indicators that are suited for use at the population or regional level. These 4 indicators, which are utilization measures, include:

- CABG area rate
- Hysterectomy area rate
- Laminectomy or spinal fusion area rate
- PTCA area rate

The IQIs can be used by a variety of stakeholders in the health care arena to improve quality of care at the level of individual hospitals, the community, the State, or the Nation. The IQIs represent advancement in assessing quality of care using hospital administrative data. While these data are relatively inexpensive and convenient to use and represent a rich data source that can provide valuable information, like other data sources that have various limitations, the data should be used carefully when assessing and interpreting the quality of health care within an institution.

The Patient Safety Indicators (PSIs)

The PSIs are a set of quality measures that use hospital inpatient discharge data to provide a perspective on patient safety.[13] Specifically, the PSIs identify problems that patients experience through contact with the health care system and that are likely amenable to prevention by implementing system level changes. The problems identified are referred to as complications or adverse events. There are currently 27 PSIs that are defined on two levels: the provider level and the area level. They are risk adjusted using a model that incorporates DRGs (with and without

complications aggregated); a modified comorbidity index based on a list developed by Elixhauser and colleagues;[14] and age, sex, and age-sex interactions.

At the provider level, the PSIs present a picture of patient safety within a hospital and provide information about the potentially preventable complication for patients who received their initial care and experienced the complication of care within the same hospitalization. The PSIs use secondary diagnosis ICD-9-CM codes to detect complications and adverse events. The measure set covers a variety of areas such as selected postoperative complications, selected technical adverse events, technical difficulty with procedures, and obstetric trauma and birth trauma. The 20 provider-level PSIs include:

- Postoperative pulmonary embolism or deep vein thrombosis
- Postoperative respiratory failure
- Postoperative sepsis
- Postoperative physiologic and metabolic derangements
- Postoperative abdominopelvic wound dehiscence
- Postoperative hip fracture
- Postoperative hemorrhage or hematoma
- Decubitus ulcer
- Selected infections due to medical care
- Iatrogenic pneumothorax
- Accidental puncture or laceration
- Foreign body left in during procedure
- Birth trauma—injury to neonate
- Obstetric trauma—vaginal delivery with instrument
- Obstetric trauma—vaginal delivery without instrument
- Obstetric trauma—cesarean section delivery
- Complications of anesthesia
- Death in low-mortality DRGs
- Death among surgical inpatients with treatable serious complications (previously known as Failure to rescue)
- Transfusion reaction (AB/Rh)

The area-level PSIs capture all cases of the potentially preventable complications that occur in a given area (e.g., metropolitan service areas or counties), either during hospitalization or resulting in subsequent hospitalizations. They are specified to include the principal diagnosis, as well as secondary diagnoses, for the complications of care. The measurement specifications add cases where a patient's risk of the complication occurred in a separate hospitalization. The seven area-level PSIs are:

- Foreign body left in during procedure
- Iatrogenic pneumothorax
- Selected infections due to medical care
- Postoperative wound dehiscence in abdominopelvic surgical patients
- Accidental puncture or laceration
- Transfusion reaction
- Postoperative hemorrhage or hematoma

Widespread consensus exists that health care organizations can reduce patient injuries by improving the environment for safety—from implementing technical changes, such as electronic

medical record systems, to improving staff awareness of patient safety risks. Clinical process interventions also present strong evidence for reducing the risk of adverse events related to a patient's exposure to hospital care. These PSIs can be used to better prioritize and evaluate local and national initiatives. Some potential actions, after an in-depth analysis of the system and process of care, include the following:

- Review and synthesize the evidence base and best practices from scientific literature.
- Work with the multiple disciplines and departments involved in care of surgical patients to redesign care based on best practices with an emphasis on coordination and collaboration.
- Evaluate information technology solutions.
- Implement performance measurements for improvement and accountability.

The ability to assess all patients at risk for a particular patient safety problem, along with the relative low cost of collecting the data, are particular strengths of the datasets that use administrative data. However, many important areas of interest, such as adverse drug events, cannot currently be monitored well using administrative data and using this data source to identify patient safety events tends to favor specific types of indicators. For example, the PSIs cited in this chapter contain a large proportion of surgical indicators, rather than medical or psychiatric measures, because medical or psychiatric complications are often difficult to distinguish from comorbidities that are present on admission. In addition, medical populations tend to be more heterogeneous than surgical populations, especially elective surgical populations, making it difficult to account for case mix.

While PSIs may be more applicable to patient safety when limited to elective surgical admissions, the careful use of administrative data holds promise to identify problems for further analysis and study. The limitations of this measure set include those inherent with the use of administrative data, clinical accuracy of the discharged-based diagnosis coding, and indicator discriminatory power. Specifically,

- Administrative data are unlikely to capture all cases of a complication, regardless of the preventability, without false positives and false negatives (sensitivity and specificity).
- When the codes are accurate in defining an event, the clinical vagueness inherent in the description of the code itself (e.g., hypotension) may lead to a highly heterogeneous pool of clinical states represented by that code.
- Incomplete reporting is an issue in the accuracy of any data source used for identifying patient safety problems, as medical providers might fear adverse consequences as a result of full disclosure in potentially public records such as discharge abstracts.
- The heterogeneity of clinical conditions included in some codes, lack of information about event timing available in these datasets, and limited clinical detail for risk adjustment all contribute to the difficulty in identifying complications that represent medical error or that may be at least in some part preventable. These factors may exist for other sources of patient safety data as well. For example, they have been raised in the context of the Joint Commission's implementation of a sentinel event program geared to identifying serious adverse events that may be related to underlying safety problems.

Yet, despite these issues, the PSIs are a useful tool to identify areas in patient safety that need monitoring and/or intervention for improved patient care.

The Pediatric Quality Indicators (PDIs)

The AHRQ PDIs are a set of quality measures that use hospital administrative data and involve many of the same challenges associated with measure development for the adult population. These challenges include the need to carefully define indicators, establish validity and reliability, detect bias, design appropriate risk adjustment, and overcome challenges of implementation and use. However, as a special population, children require special tailoring of quality measures and risk-adjustment methodologies. The AHRQ PDIs, developed through careful, ongoing research efforts, provide a risk-adjusted tool to identify quality problems for hospitalized children as well as assess the rate of potentially preventable hospitalizations. The AHRQ PDIs currently consist of 18 indicators defined as both provider- and area-level measures. The 13 provider-level PDIs are:

- Accidental puncture and laceration
- Decubitus ulcer
- Foreign body left in during procedure
- Iatrogenic pneumothorax in neonates
- Iatrogenic pneumothorax in non-neonates
- Pediatric heart surgery mortality
- Pediatric heart surgery volume
- Postoperative hemorrhage or hematoma
- Postoperative respiratory failure
- Postoperative sepsis
- Postoperative wound dehiscence
- Selected infections due to medical care
- Transfusion reaction

Existing risk-adjustment strategies for pediatric patients were not suitable for use with the AHRQ PDIs. Most available schemes apply to specific clinical groups and utilize clinical data not available in administrative databases. The APR-DRG methodology, used for risk adjustment in the adult population, was considered for use in the pediatric population. However, using the APR-DRGs could not adjust for complications in the pediatric population because it resulted in over-adjustment. As a result, different risk adjustment strategies were investigated for potential incorporation into the PDIs. Three important risk-adjustment factors of significance to the pediatric population were identified: (1) reason for admission (including principal procedure), (2) comorbidities, and (3) age and gender. Using a modified-DRG risk adjustment combined with comorbidity adjustment based on the AHRQ Clinical Classification System and age and gender adjustment, the AHRQ PDIs include a novel and specialized risk-adjustment system. They also include stratification, another approach to accounting for case mix. Stratification allows hospitals to identify which segment of the pediatric population accounts for any elevation in rates, creating more user-friendly measures. Tailored stratification schemes are available for six of the PDIs: accidental puncture and laceration, decubitus ulcer, iatrogenic pneumothorax, postoperative hemorrhage or hematoma, postoperative sepsis, and selected infections due to medical care. Despite these efforts to account for risk, it is anticipated that further research on pediatric risk adjustment will be important for assessing quality appropriately.

In addition to the provider-level indicators, the PDIs also include five area-level indicators:

- Asthma admission rate
- Diabetes short-term complication rate
- Gastroenteritis admission rate
- Perforated appendix admission rate
- Urinary tract infection admission rate

These indicators track potentially preventable hospitalizations and allow policymakers to target specific groups that appear to be developing more severe disease requiring hospitalization. Higher-than-anticipated rates may reflect poor access to care (e.g., from lack of insurance or too few primary care physicians), barriers to timely care (e.g., clinics that require daytime appointments), barriers to adherence to medical advice (e.g., language barriers), cultural influences that preclude seeking early treatment, or higher prevalence of poor health behaviors (e.g., smoking). Interventions may address any of these factors.

Area-level indicators are prone to bias due to cultural factors that may be outside of a health system's control. For instance, an area with a high number of illegal immigrants may have patients presenting with more advanced disease, because patients delay seeking care for fear of deportation. In addition, factors such as smoking or obesity may be more prevalent in certain areas. Risk adjustment should include these factors, and an adjustment for socioeconomic status, as a proxy, and has been included in these PDIs. However, risk adjustment for socioeconomic groups may mask true differences in access to good quality care. For this reason, risk-adjusted rates should be considered alongside raw, unadjusted rates.

Current Uses of the AHRQ Quality Indicators

There are a number of uses of the AHRQ QIs, ranging from internal quality improvement to pay-for-performance (P4P) initiatives. (See Table 5 for a list of organization types and associated uses of the QIs.) Each use has certain caveats associated with it, but the AHRQ QIs are one set of many performance measures that can be used for these purposes. Although the QIs were not originally developed for hospital-specific comparative quality reporting, they have been and are being used for public reporting and P4P initiatives. When various users began to apply the AHRQ QIs for public reporting and other initiatives, AHRQ undertook an analysis to determine their appropriateness for these new uses. The Agency concluded that these measures can be used for these purposes, with certain understandings. This analysis resulted in a document that provided detailed information about the use of the QIs for hospital comparative reporting and P4P—*Guidance for Using the AHRQ Quality Indicators for Hospital-Level Public Reporting or Payment,*[15] which is available on the Web at http://www.qualityindicators.ahrq.gov. This document is currently being updated to reflect the current state of the evidence of the AHRQ QIs in relation to public reporting and will include an evidence based reporting template that has been tested with the various stakeholder groups including consumers, providers, and others.

Decisions on how and whether to use the AHRQ QIs or any other measure set is a local matter and depends on various local issues such as data availability and data quality, legislative mandates, confidentiality issues and data use agreements, and resources, to name a few. AHRQ will continue to provide evidence that will inform and further clarify hospital-specific public reporting issues and other issues related to transparency.

Table 5. Users of AHRQ QIs

Type of Organization	Type of Use					
	Public Reporting	Quality Improvement/ Benchmarking	Pay-for-Performance	Research	Other/ Unknown	**Total**
Business group	2					**2**
Consulting firm				2		**2**
Employer		1				**1**
Federal Government		1	1	19		**21**
Health plan	1	1	3		4	**9**
Hospital association	1	8		2		**11**
Hospital or hospital network	2	3		1	9	**15**
Integrated delivery system		2			7	**9**
Other	2	4			1	**7**
Research organization		1		14	1	**16**
State or local government	12	2		5	2	**21**
Total	**20**	**23**	**4**	**43**	**24**	**114**

Source: Hussey PS, Mattke S, Morse L, et al. *Evaluation of the Use of AHRQ and Other Quality Indicators.* Santa Monica, CA: Rand Health; October 2006.

Quality Improvement

Originally, the AHRQ QIs were designed as an internal quality improvement tool to assist hospitals to identify and target potential areas for interventions. The ability to track quality of care for a wide range of patients is an important consideration for quality improvement. Hospitals, health care systems, and hospital associations use the AHRQ QIs for internal quality improvement, specifically to initiate case finding, root-cause analyses, and cluster identification, as well as to evaluate the impact of local interventions and to monitor performance over time.

Yet, as with any quality measures, these indicators must be used with care, because the administrative data on which the measures are based are not collected for research purposes or for measuring quality of care, but for billing purposes. While these data are relatively inexpensive to collect, convenient to use, and represent a rich source of information that provides valuable insights, they are one view of the multi-dimensional concept of quality. Our health care system currently uses a "hybrid" model derived from multiple sources, both electronic and paper records, to result in performance information. While not the only use of administrative data, it can as a sole data source, be used by individual hospitals to launch investigations into reasons for identified quality problems. Further study may:

- Reveal real quality problems for which quality improvement programs can be initiated.
- Uncover problems in data collection that can be remedied through stepped-up efforts to code more diligently.
- Determine that additional clinical information is required to understand the quality issues, beyond what can be obtained through billing data alone.

Overall, the AHRQ QIs are a valuable tool that takes advantage of readily available data to identify quality-of-care problems. Hospitals may use existing data to identify indicators with higher-than-expected rates, flagging potential quality concerns. These areas of concern may be investigated further to identify the underlying cause of the poorer-than-expected performance. In some cases, incorrect coding practices may be identified; in other cases, closer examination of system-level factors may be in order. Interventions may be devised to improve performance, and hospitals may track their own performance over time to identify areas for improvement.

Public Reporting and Pay for Performance

The AHRQ QIs are currently being used in several public reporting and pay for performance (P4P) initiatives at the national, State, and regional levels. At the national level, for example, they are used in tracking the quality of health care in the United States in the *National Healthcare Quality Report*[16] and *National Healthcare Disparities Report*[17] produced annually by AHRQ. These reports focus on four dimensions of quality—effectiveness, safety, timeliness, and patient centeredness—and are available on the AHRQ Web site. Other uses of the QIs include surveillance of trends over time at the State and community level as well as assistance in tracking disparities across areas, when the data are available.

Several organizations have incorporated the AHRQ QIs in reports on quality that allow for comparisons of individual hospitals. Organizations such as the Colorado Health and Hospital Association, the Texas Health Care Information Council, the Niagara Health Quality Coalition, and Norton Healthcare are a few. Many of these reports are Web based and are routinely updated. For a more complete list of organizations that use the AHRQ QIs for public reporting, see Table 6.

Table 6: Organizations Using the AHRQ QIs for Public Reporting

Organization Name	Type of Report	Description	QIs used
AFSCME Council 31[18]	One-time report	The union published a report on quality at Resurrection Health Care hospitals after complaints about quality from workers.	IQIs 15–20
California Office of Statewide Health Planning & Development[19]	Interactive tool and periodic written reports	A Web site includes an interactive tool for hospital comparison on selected IQIs and other risk-adjusted mortality indicators.	IQIs 1, 2, 4–7, 21–23, 33, 34; PDI 7
Chicago Department of Public Health[20]	Periodic report	Chicago runs a Web site providing a health profile, including PQIs, of community areas in the city.	PQIs (all except 2, 9)
Colorado Health and Hospital Association[21]	Periodic report	Hospital reports are shared among hospitals and published on a Web site.	IQIs 4–7, 12–20, 30, 31
Connecticut Office of Health Care Access[22]	One-time report	Databook on preventable hospitalizations.	PQIs (all)
Excellus Blue Cross/Blue Shield[23]	Interactive tool	Online hospital comparison tool for health plan members only.	Unspecified (members only)
Exempla Hospital System[24]	Periodic report	Exempla publishes quality information on its hospitals on its Web site. (The same results are also reported by the Colorado Health and Hospital Association.)	IQIs 12–20, 30, 31
Florida State Center for Health Statistics[25]	Interactive tool	Online hospital comparison tool.	PSIs 3, 6–8, 12, 13; IQIs 8–20, 32
Georgia Partnership for Health and Accountability[26]	Periodic report	A periodic report on health in Georgia includes a chapter on avoidable hospitalizations.	PQIs 3, 5, 8, 10, 11, 15
Massachusetts Dept. of Health and Human Services[27]	Interactive tool	Online hospital comparison tool.	IQIs 14, 16–21, 32–34
Missouri Department of Health and Senior Services[28]	Periodic report	Comparison of hospital surgery volume to help consumers choose a hospital.	IQIs 1, 2, 4–7; PDI 7
Niagara Health Quality Coalition and Alliance for Quality Health Care[29]	Interactive tool	Online hospital comparison tool.	IQIs 1–25
Norton Healthcare[30]	Interactive tool	Health system publishes quality data for its hospitals on its Web site.	PSIs 1–6, 8–16, 18–20; IQIs 1, 2, 4–9, 11–20, 22–24, 30, 31, 34; PDIs 2–9, 11, 13
Ohio Department of Health[31]	Periodic report	Online comparison of avoidable hospitalizations by county.	PQIs 1, 4, 5, 7, 8, 11, 14, 15
Oregon[32,33]	Interactive tool	Online hospital comparison tool and a report on Oregon's safety net by the Safety Net Advisory Council.	IQIs 11, 12, 15–17, 19, 20, 30; PQIs 3, 5, 8, 10, 11, 12, 15
Rhode Island[34]	One-time report	Report on hospital procedure volumes. Future reports on IQIs and PSIs in preparation.	IQIs 1–7
Texas Health Care Information Collection[35]	Interactive tool	Online hospital comparison tool.	IQIs 1–14, 16–20, 22–25, 30–33; PQIs (all)

Organization Name	Type of Report	Description	QIs used
The Alliance (Wisconsin)[36]	Periodic report	QualityCounts report on hospital safety performance. The report is based on AHRQ PSIs but modifies them for reporting.	PSIs 3, 6, 7, 8, 12, 17; IQI 33
Utah Department of Public Health[37, 38]	Periodic report	Web site providing health information for geographic areas. Three PQIs are included with numerous health status and other measures. State-level IQI results are presented on a one-page poster, available online.	PQIs 4, 11, 1+3+14 combined; IQIs (all)
Vermont Department of Banking, Insurance, Securities & Health Care Administration[39]	Periodic report	Online hospital comparison report.	IQIs 1, 2, 4–9, 11, 12, 30, 31; PDIs 6, 7

Note: Public reporting is defined as a publicly available report that compares AHRQ QI results between hospitals (IQIs and PSIs) or geographic areas such as counties (PQIs). No public reporting of the area-based IQIs or PSIs was identified. Not all of the public reports identified in this table are intended to influence consumers' choice of provider.
One-time reports are published comparisons that are not labeled as an ongoing activity.
Periodic reports are published comparisons, updated periodically, that are in static format (e.g., documents available as PDF files online).
Interactive tools are online comparisons that allow users to create customized reports (e.g., selection of providers or indicators of interest).

Source: Hussey PS, Mattke S, Morse L, et al. *Evaluation of the Use of AHRQ and Other Quality Indicators.* Santa Monica, CA: Rand Health; October 2006.

Organizations such as the Centers for Medicare & Medicaid Services and Anthem Blue Cross and Blue Shield of Virginia have incorporated selected AHRQ QIs into P4P demonstration projects or similar initiatives. These projects reward providers for superior performance based on a combination of performance measures, including the AHRQ QIs. Results from the Centers for Medicare & Medicaid Services demonstration project indicate that tying payment to performance may provide some incentive to improve the quality of care.

There are a number of factors to be considered when using the AHRQ QIs for public reporting and payment purposes. Factors related to data source and measurements raise important issues such as:

- Very low or low volume (small cell size) could impact patient confidentiality and also limit the ability to reliably identify quality differences.
- Measures may not be applicable to the majority of hospitals or applicable only to hospitals with specific services (e.g., cardiac surgery, obstetrics).
- Volume is a proxy measure; volume may be manipulated leading to concerns about appropriate utilization.
- Potential confounding bias or the impact may be impaired by skewed distribution not completely eliminated by risk adjustment or carefully constructed operational definitions.
- Benchmarking or the correct rate may not be clear.
- Many procedures are currently done on an outpatient basis or observation status.
- The indicator may require data not present in all administrative datasets, or risk adjustment may be inadequate when based only on data available from ICD-9-CM codes.
- Coding may vary across hospitals; some hospitals code more thoroughly than others, making fair comparisons across hospitals difficult.

However even with these limitations, codes, coding systems, and coding practices are improving and are often subject to auditing or monitoring for accuracy. Coders are becoming more aware of the importance of properly coding the data and how they are used in relation to quality improvement, public reporting, P4P and other initiatives.

Ideally, in public reporting and P4P initiatives, the results of the performance measures should be made available to those hospitals participating, along with information on averages for peer groups, for the State, and for the Nation.

It is important when using not only the AHRQ QIs but all measures used for purposes such as comparative reporting, purchasing, or payment to continually assess and evaluate them and provide feedback to the measure developer for measure refinement and improvement purposes. The process of measure development and maintenance is constant, and measure developer like AHRQ welcome input from uses in an effort to continue to refine and enhance the measures.

Research

A number of the AHRQ QIs have been used in health care research projects. On the whole, researchers use the indicators because of the quality and level of detail of the AHRQ documentation of the QIs as well as the fact that these measures capture important aspects of clinical care[40] (p. v). The AHRQ QIs, their documentation, and the related software reside in the public domain and are downloadable from the AHRQ Web site, free of charge. The QIs can be used with readily available administrative data, which researchers have ready access to in the

form of HCUP. Further, researchers appreciate the fact that they can dissect indicator results and relate them back to individual records, which helps to gain a better understanding of the logic used in the measures, which, in turn, assists in distinguishing data quality issues from actual quality problems[40] (p. vii). Topics of studies using the AHRQ QIs include an analysis examining the association between the Joint Commission accreditation scores and the AHRQ IQIs and PSIs,[41] the effect of resident physician work hour limits on surgical patient safety,[42] and the determination of whether persons with Alzheimer's disease were at greater risk for in-hospital mortality than non-Alzheimer's patients.[43]

Table 5, which is based on an environmental scan commissioned by AHRQ and completed by Hussey and colleagues,[40] indicates that the AHRQ QIs are frequently used by researchers in their projects.

What Nurses Need To Know

Measuring performance is central to quality improvement because it provides information on current and past performance that can help guide future improvement efforts. In particular, performance measures can distinguish between good and substandard performance. Accordingly, the development and application of performance measurement is essential to improving the quality of care. It is one of the "first steps in the improvement process and involves the selection, definition, and application of performance indicators…"[44] (p. 24). Performance measurement, while not the only influence, can act as a force to promote certain issues and agendas. Performance measurement conveys the message of importance. Specifically, what is important is measured, while what is not measured is considered less important.[45] By focusing people and resources on a particular aspect of an industry, performance measurement can be a driver of change and reform.

Nurses are an integral member of the health care team and are in a unique position to detect quality-of-care issues, often providing avenues for change in processes that improve quality and safety in health care.[46–48] The AHRQ QIs are one set of performance measures that provide information about the quality of care that nurses can use to plan and implement quality-improvement strategies. The climate for quality tracking, measurement, and reporting, and linking payment to quality, has changed dramatically in the past several years. The efforts by governments, accrediting bodies, large purchasers, employer coalitions, and others to track quality at the national, state-wide, and provider level; publish comparative quality reports; launch quality improvement efforts; and use public and private purchasing power to reward better quality have accelerated. Nurses not only are members of the quality team but often lead and coordinate efforts at the local levels that provide input into these efforts. Leaders of these quality efforts often consider using administrative data because they are readily available and inexpensive relative to other data sources. Data gleaned from the AHRQ QIs can be used to track trends, identify gaps in data measurements, and assist in redesigning organizational and workflow processes. Data provide a focus for improving health care quality, which can be used to make more informed decisions about policies within given facilities, communities, or regions. National and State benchmarks of the AHRQ QIs can be used to assess and compare an individual facility's progress in a certain area. Nurses are well positioned to review performance data, interpret the results, provided additional followup as warranted, and design interventions to improve the quality of care within an organization.

There are significant challenges associated with applying administrative or clinical data sources, no matter how "good" the measure is, for which nurses should be aware of. Selecting measures and the purposes for which to use them should depend upon organizational or program needs. Implementation issues, including data availability and data quality, need to be addressed during the measure-selection process because the immediate goal is to produce usable information for quality improvement, public reporting, planning, and care redesign.

Data availability is an issue that must be addressed. Typical data sources include clinical data (e.g., medical record abstraction, laboratory data, pharmacy data, electronic medical record), administrative data (UB-04, billing, or claims data), survey data (e.g., patient experience with care, employee satisfaction), and operational data (e.g., licensure, ownership, staffing levels, type of staff). Each data source has its strengths and limitations. While clinical data is usually preferred by providers, it requires medical abstraction that is usually costly to collect. The primary benefit associated with the use of clinical data is the greater number of data elements that can be abstracted, resulting in enhanced measure definition, risk adjustment, and linkage to care processes. While there are efforts underway to expand and automate access to clinical data, automated data are not yet a reality.

Administrative data, on the other hand, are the most widely available source of information about hospital services, patient care, and patient outcomes. All hospitals generate administrative data as part of billing operations, and all payers have access to administrative data. These types of data have been shown to be useful in quality assessment and medical research, as well as for other measurement tasks such as screening for complications, identifying mortality rates, and tracking health system utilization. Like clinical data, administrative data also have limitations. Because administrative data are collected principally for billing and related administrative purposes, these data lack the depth of clinical detail that can be helpful in quality measurement; variations in coding practices may create challenges for quality evaluations; and there can be data validity issues. Since the concept of quality is multidimensional, a combination of measures derived from clinical and administrative data sources would offer a more complete picture of quality, at least in the immediate future.

Regardless of the data source, nurses involved in the quality improvement enterprise should be aware of several factors and consider them when tasked with designing and using a performance measurement system. The purpose of the measurement project should be clearly specified. Is it to drive quality improvement or public accountability? Inform consumer decisions? Pay for performance? Subsequent decisions will depend on the purpose of the measurement effort. Once the purpose has been established, the stakeholders of the project should be identified to assess expectations and to determine to what extent the available data and measures can meet their interests. In the planning stages of the project, providers who will be affected by or measured should be given the opportunity to understand the purpose of the project, why certain measures were chosen, and what will be done with the results. There should also be an opportunity to understand the methodology, including measure definitions, any risk adjustment used, and the calculation of the measures.

Audits for quality or similar mechanisms should be in place to assure accuracy and completeness. Data explorations should be completed and should focus on overall data quality and content, beginning with simple frequency distributions on key variables. Nurses and other providers reviewing the data should ask the following questions: If the program includes the objective to evaluate access or outcome by patient race, is the data element present for each case? Are data missing in a consistent manner? Is a selected procedure performed so infrequently

in any single year that examining mortality rates would best be accomplished by combining data from several years? What comparative benchmarks are available? There are benchmarks at the national, regional, and peer-group levels from sources such as the *National Healthcare Quality Report*[16] and *National Healthcare Disparities Report*,[17] HCUPnet, and other State-level or hospital-system efforts. Finally, an evaluation component should be included as part of the initiative as it provides feedback, which can inform future decisions about the measurement project.

Nurses serve as an important member of the quality team, and often provide continuity from one phase of a project to another. Many nurses serve as part of leadership teams within their organizations and can provide valuable input into designing measurement strategies and quality improvement programs that improve the quality of care overall. Additionally, nurses are well positioned to not only analyze data from measures but also to design and implement strategies that impact care delivery. Many nurses coordinate activities among multidisciplinary teams, and organize interventions across departments which can ultimately result in improved quality of care for patients.

Enhancing the AHRQ Quality Indicators

Recently, the AHRQ QIs have undergone some changes based upon newly reported research, validation testing, the NQF endorsement process, input from several professional societies, and input from the QI user community. Based upon these activities, the AHRQ has revised the ICD-9-CM codes; incorporated the data element present on admission (POA) as a requirement for the calculation of selected measures; and added the ability to stratify certain measures such as delineating emergent cases from non-emergent cases for AAA Mortality Repair. In addition, the AHRQ has worked with other organizations to harmonize measures that are similar to the QIs, and as a result of these discussions, various coding changes have been incorporated into the numerator and denominator of selected measures.

The AHRQ also convened several expert panels to develop composite measures of the QIs. These discussions resulted in five composite measures: the PQI composite (PQI 17); Mortality for Selected Conditions (IQI 36); Mortality for Selected Procedures (IQI 35); Patient Safety for Selected Indicators (PSI 28); and Pediatric Patient Safety for Selected Indicators (PDI 19). The final report for each of these composites can be accessed from the AHRQ website.

AHRQ has also developed evidence-based reporting templates for the QIs. These templates were designed to report comparative performance data generated by the QIs to consumers and others. These templates are intended to report performance to consumers, but can be useful to other stakeholders in health care. The templates were tested by several focus groups that consisted of consumers, purchasers, providers and others. The first template uses the composite measures developed by AHRQ to report performance, while the second template groups the measures into health topics. Both templates are available, along with a sponsor guide are available on the AHRQ website.

Conclusion

The AHRQ QIs are one measure set, based on administrative data that can be used to evaluate the quality of clinical services. Most of the QIs focus on health care outcomes rather than rates of processes of care followed. The measures, their extensive documentation, and

associated codes for SAS® and Windows® reside in the public domain and are available for download at no cost to the user. Furthermore, the QIs are maintained by AHRQ, which continues to refine and enhance them. Updates to the modules are done on a yearly basis and are routinely released in the first quarter of the year. AHRQ also provides technical support to users on a wide range of issues, including questions about the software package, clarifications of indicator definitions, theoretical questions on the indicators, and interpretation of performance results. The QI support team can be reached via e-mail at support@qualityindicators.ahrq.gov.

Future enhancements to the AHRQ QIs are underway and include the development of indicators specific to neonates, the development of additional indicators in areas such as hospital outpatient care, day surgery, diagnostic procedures, and emergency department care. Other planned improvements include incorporating additional clinical data elements such as lab values and do-not-resuscitate-order flag. Additional research is needed to develop evidence-based outcome measures that are sensitive to nursing practice.

"Quality of care is highly variable and delivered by a system that is too often poorly coordinated, driving up costs, and putting patients at risk."[49] (p. 1). Improving the access to and the performance of our health care system is a matter of national urgency.[50] Yet, defining what quality is in health care is not easy. Quality is a complex, multidimensional concept that suggests different things to different people.[47, 51] Consequently, competing views of quality should be balanced among patients, purchasers, managers, and health care professionals. A widely used definition of quality in health care is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[6]

Regardless of how quality is defined, the only way to know whether the quality of health care is improving is to measure the performance of those that deliver it. Performance measures and performance measurement systems provide a tool to determine if quality exists. Currently there is a proliferation of performance measures, and development of these measures shows no sign of abating. While there is a plethora of measures in areas such as cardiac care, there is a dearth or complete lack of measures in other areas such as mental health and cancer care. Better coordination among measure developers is key to reducing the measurement burden of health care organizations. With the adoption of the electronic health record, performance measurement has the potential to become a by-product of care, instead of a distinct data-gathering activity.

The AHRQ QIs are one set of performance measures that cover a broad array of conditions and that use an inexpensive, readily available data source. While these measures do have certain limitations, these measures have been and are being used in a variety of initiatives that have contributed to improved quality of care within the United States.

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Chapter 46. Magnet Environments for Professional Nursing Practice

Vicki A. Lundmark

Background

In hospital settings, nurses fulfill two roles. Based upon expert knowledge, nurses provide care to the ill or prevent illness. Nurses also maintain and manage the environment surrounding the delivery of care, which has increasingly involved coordinating the care activities provided by other health care providers. Of three reports published since the year 2000 by the Institute of Medicine,[1–3] the 2004 report on patient safety was the first to emphasize the connection between nursing, patient safety, and quality of care. The report specifically noted the importance of organizational management practices, strong nursing leadership, and adequate nurse staffing for providing a safe care environment. The report also noted how frequently the patient safety practices identified by the literature "were the same as those recommended by organizations studying the nursing shortage, worker safety, and patient satisfaction"[3] (p. 317).

While it seems logical to assume that safe and effective patient care depends on the presence of "an organizational context that enables the best performance from each health professional"[4] (p. 186), remarkably little knowledge has accumulated about how the organization and delivery of nursing services influences patient outcomes. One explanation for this situation is that health services research so firmly turned its focus to organization/environment and organization/market questions following the rise of health economics and health maintenance organizations (HMOs) in the 1970s that it was caught somewhat unprepared when quality issues began to emerge in the latter part of the 1990s. As a result, few conceptual tools exist "to address the heart of quality concerns: the internal work processes and arrangements inside health care organizations . . . that contribute to variations in quality"[5] (p. 318).

Another limiting factor has been the inherent challenges of measuring organizational practice environments and the complexity of nursing's effects on patient outcomes. Improved theoretical frameworks and greater methodological rigor will be needed to guide and advance the nursing research on patient outcomes.[6, 7] Nursing research has already been leading the way in this effort, which may not be surprising given the deep knowledge nurses have of the internal workings of health care organizations.[5]

The magnet hospital concept, originating from a groundbreaking study in the early 1980s[8] that sought to explain instances of successful nurse recruitment and retention during a severe nurse shortage, provides one framework for specifying the organizational and practice environment conditions that support and facilitate nursing excellence. The purpose of this chapter is to summarize the magnet research evidence related to nurse or patient outcomes.

Magnet Hospitals and the Attraction and Retention of Professional Nurses

The original magnet study began in 1981 when the American Academy of Nursing appointed a task force to investigate the factors impeding or facilitating professional nursing practice in

hospitals. The four researchers on the task force were working from the knowledge that despite a nursing shortage for a large number of hospitals, a certain number "had succeeded in creating nursing practice organizations that serve as 'magnets' for professional nurses; that is, they are able to attract and retain a staff of well-qualified nurses and are therefore consistently able to provide quality care"[8] (p. 2). Therefore, the research goal was set to explore the factors associated with success in attracting and retaining professional nurses.

Through an extensive nominating process, 41 hospitals from across the country were selected to participate in the study based upon their known reputations as being good places for nurses to work and the evidence they submitted to document a relatively low nurse turnover rate.[9] Subsequently, a series of group interviews was held with representatives from each hospital. Two interviews were conducted in each of eight geographically dispersed locations. In the morning, one of the task force researchers interviewed the chief nurse executives from the participating hospitals in that area. Then, in the afternoon, a second group interview session was held with staff nurses. Each staff nurse who participated in the interviews was selected by his or her chief nurse executive.

Based upon their analysis of this interview data, the task force researchers identified and defined a set of characteristics that seemed to account for the success the 41 reputational magnet hospitals had enjoyed in attracting and keeping a staff of well-qualified nurses at a time when other hospitals around them were not able to do so. The labels given to these characteristics, which have come to be known as the forces of magnetism, are listed below in Table 1. Many of the insights they embody have a long history of study within the sociological literature related to organizational performance, leadership, worker autonomy and motivation, decentralized or participative management, work design, coordination and communication, effective groups and teams, and organizational innovation and change.[10]

Table 1. The Magnet Characteristics of a Professional Practice Environment

Forces of Magnetism 1983 (McClure)[8]	Forces of Magnetism 2005 (ANCC)[11]
Administration	
Quality of leadership	1. Quality of nursing leadership
Organizational structure	2. Organizational structure
Management style	3. Management style
Staffing	4. Personnel policies and programs
Personnel policies and programs	[staffing embedded in #4]
Professional practice	
Professional practice models	5. Professional models of care
Quality of care	6. Quality of care
Quality assurance	7. Quality improvement
Consultation and resources	8. Consultation and resources
Autonomy	9. Autonomy
Community and the hospital	10. Community and the hospital
Nurses as teachers	11. Nurses as teachers
Image of nursing	12. Image of nursing
Nurse-physician relationships	13. Interdisciplinary relationships
Professional development	
Orientation	14. Professional development [original
In-service and continuing education	subgroups embedded]
Formal education	
Career development	

Note: Order shown in the left column has been slightly rearranged for ease of comparison.

The relationship of a magnet environment to quality was recently described by one of the original task force researchers. Looking back on the original magnet study more than 20 years later, McClure wrote[12] (p. 199),

> We found that all these settings had a commonality: their corporate cultures were totally supportive of nursing and of quality patient care. What we learned was that this culture permeated the entire institution. It was palpable and it seemed to be almost a part of the bricks and mortar. Simply stated, these were good places for all employees to work (not just nurses) and these were good places for patients to receive care. The goal of quality was not only stated in the mission of these institutions but it was lived on a daily basis.

The Magnet Recognition Program® of the American Nurses Credentialing Center (ANCC)*

In the early 1990s, the American Nurses Association (ANA) initiated a pilot project to develop an evaluation program based upon the conceptual framework identified by the 1983 magnet research. The program's infrastructure was established within the newly incorporated American Nurses Credentialing Center of the ANA, and the first facility to receive Magnet recognition was named in 1994.[11] Interest in Magnet™ has been increasingly accelerating. While only about 225 organizations have achieved Magnet recognition since the program's inception, nearly two-thirds of them did so within the last 3 years, and the applicant list continues to expand.

Applicants for Magnet recognition undergo a lengthy and comprehensive appraisal process[13] to demonstrate that they have met the criteria for all of the forces of magnetism shown in the right column of Table 1. Currently, documentation or sources of evidence are required in support of 164 topics.[11] Organizations that receive high scores on written documentation move to the site-visit stage of the appraisal and a period of public comment. The philosophy of the program is that nurses function at their peak when a Magnet environment is fully expressed and embedded throughout the health care organization, wherever nursing is practiced. Magnet organizations submit annual reports and must reapply every 4 years to maintain their recognition.

In the context of a rapidly evolving health care system, ANCC has the responsibility as a credentialing body to continuously refine and improve the criteria it uses for Magnet recognition in order to "separate true magnets from those that simply want to achieve the recognition"[14] (p. 123). ANCC does so by evaluating new information from multiple sources, the scholarly research literature, expert groups convened to deliberate specific issues, and feedback from Magnet facilities and appraisers, particularly in relation to identifying effective and innovative practices.

Continuity between the original magnet research and ANCC's Magnet program is provided by the conceptual framework for the forces of magnetism. Little has changed in the essential definitions for the forces except that ANCC has revised them to reflect contemporary hospital settings and elaborated under each force a set of required documentation for applicants to submit and appraisers to evaluate. Beginning in 2005, however, an important change appeared in the

* The Magnet Recognition Program® and ANCC Magnet Recognition® names and logos are registered trademarks of the American Nurses Credentialing Center. Magnet™ is a trademark of the American Nurses Credentialing Center. Magnet is capitalized in this chapter when it refers to the ANCC Magnet Recognition Program or to organizations that have been designated Magnet by the Magnet Recognition Program.

Magnet application process. Whereas previous application manuals had itemized evidence requirements according to ANA's *Scope and Standards for Nurse Administrators*,[15] the new manual version[11] reorganized the criteria into the framework of the forces of magnetism. This transition should help to clarify the correspondence between the elements ANCC's Magnet program evaluates in its appraisal process and the magnet characteristics that nursing and health services researchers study.

Reviewing the Evidence

Research studies were retrieved for this review by searching PubMed® and CINAHL® for articles referencing magnet or magnetism in the title or abstract. Two inclusion criteria were used. (More details can be found below, in "Search Strategy.") The articles had to (a) report findings from analyses of primary or secondary data, and (b) investigate relationships between magnet variables and nurse or patient outcomes. Nurse outcomes of interest were job satisfaction, burnout, and intention to leave[16, 17] or similar variables such as mental health. Nurse perceptions of patient care quality has been a frequently used measure in the magnet-related survey research, and one study used nurse perceptions of safety climate as the dependent variable. But studies that included patient outcome variables measured from other sources were seldom found, although patient mortality and patient satisfaction are represented in the evidence tables.

Limitations of the Research

Overwhelmingly, the magnet research has been dominated by cross-sectional survey studies with convenience samples of organizations and staff nurse respondents. The basic approaches used to capture magnet environments in the research have been to include organizations from the 1983 magnet study or with ANCC Magnet recognition in the hospital sample or to administer survey scales believed to measure magnet characteristics, traits, or factors. Usually, but not always, these approaches have been used in combination. Analyses have typically been limited to simple comparisons of survey items or subscale results between two groups.

With few exceptions, the majority of this research has suffered from two major limitations: biased sampling at both the organizational and respondent level; and a scarcity of comprehensive, valid, and reliable measures for assessing the level of magnet characteristics present in any setting. Unless magnet characteristics are measured adequately across the organizations participating in a study, the degree to which their presence differs between the comparison groups cannot be assessed. Because the organizations that have attained ANCC Magnet recognition constitute a voluntary sample, it is possible that high levels of some or many magnet characteristics may also exist in other organizations that have not chosen to apply for the recognition.

Overwhelmingly, the survey scales most frequently used to measure magnet characteristics have all derived from the Nursing Work Index (NWI). Because these scales have dominated the magnet research, it is important to understand how they are constituted and how they have evolved over time. The first version of the NWI was designed to inclusively and comprehensively reflect the findings of the 1983 magnet research study.[18] It was intended to measure four variables: work values related to staff nurse job satisfaction, work values related to perceived productivity, staff nurse job satisfaction, and perceived productivity (the perception of

an environment conducive to quality nursing care). Content validity for the instrument was assured by having three of the four original magnet researchers review it for inclusiveness.[19] The NWI consisted of 65 items and asked respondents to make three Likert-scale judgments on each item.

Aiken[20] subsequently adapted the NWI to measure only organizational features by dropping the judgment statements related to job satisfaction and perceived productivity. Compared to the NWI, the NWI-Revised (NWI-R) contained fewer items, but otherwise remained the same except that one item was modified and two more were added. Four NWI-R subscales were conceptually derived from an item subset.[21]

Two of the NWI-R subscale domains, nurse autonomy and nurse-physician relationships, are readily recognizable in comparison to the forces of magnetism listed in Table 1. The other two domains, organizational support and control over nursing practice, are represented by sets of items that could be classified across several forces of magnetism. Control over nursing practice is defined as organizational autonomy or the freedom to take the initiative in shaping unit and institutional policies for patient care. Hinshaw[22] described clinical autonomy and organizational autonomy as interactive concepts. Both types of autonomy were evident in the findings from the original magnet study.[8, 23]

Since the NWI-R was developed nearly a decade before any subsequent NWI-derived scale versions appeared, the NWI-R has been the most frequently used measure of magnet characteristics in magnet research. An advantage of this fact has been the ability to compare findings across studies. A disadvantage may have been the formation of a wide impression that the magnet hospital concept is more circumscribed than it actually is. In the literature reviewed here, the phrase most frequently used to introduce the magnet concept to readers directly cites the NWI-R subscales; magnet is said to describe hospitals where nurses have greater autonomy, control over nursing practice, and good nurse-physician relationships. Given nursing's history as a subordinated profession,[24] one can understand that these three dimensions of the magnet concept attracted the most initial attention.

In the last 5 years, three additional versions of the NWI have appeared. Except for minor changes in wording, all use items from the NWI or the NWI-R as originally written. However, each version consists of different, empirically derived scale or subscale formations. Lake[25] created the 31-item Practice Environment Scale of the NWI (PES/NWI) with five subscales and an overarching composite scale. Estabrooks and colleagues[26] created a single-factor, 26-item scale called the Practice Environment Index (PEI). Choi and colleagues[27] created the Perceived Nursing Work Environment scale (PNWE)[†] with 42 items and 7 subscales. Neither the PEI nor the PNWE measures appear in the studies reviewed here.

Research Evidence

The evidence tables in this chapter are divided into three parts. Evidence Table 1 covers the early research period and itemizes studies conducted with hospitals from the group of 41 reputational magnets that participated in the 1983 study. Evidence Table 2 includes studies that compared health care organizations with and without designation as ANCC-recognized Magnets. Finally, Evidence Table 3 itemizes studies that investigated the relationship of various magnet

[†] Subscales for the PNWE are labeled professional practice, staffing and resource adequacy, nurse management, nursing process, nurse-physician collaboration, nurse competence, and positive scheduling climate.

characteristics to outcomes. Insofar as possible, the evidence tables are arranged in chronological order to illustrate how magnet research has progressed since the concept of a magnet environment first appeared in the literature in the 1980s. In addition, each row or panel in the tables represents a single data collection event. If multiple articles were generated from a single data collection effort, they are cited together in the same panel of the table. The purpose of this arrangement is to present a clearer picture of the body of evidence as a whole, revealing that the total number of data sources (with their associated measures and methods) that have constituted the magnet research since 1983 is relatively small. In addition, this arrangement draws attention to which articles are better read as a set by anyone wishing to understand the research in detail. Methodological information related to a single data collection effort can sometimes be scattered across multiple publications.

Evidence Table 1 includes two of the most compelling studies to have come out of the magnet literature, those initiated by Aiken and her colleagues[28-35] within a decade of the publication of the original magnet study. For the Medicare mortality study[28], magnet characteristics were not directly measured. However, the use of risk adjustment techniques for predicted mortality and multivariate matched sampling methods to control for factors that might affect mortality provided strong support for concluding that the set of reputational magnet hospitals was uniquely different as a group. As Aiken has summarized it, these "findings suggest that the same factors that lead hospitals to be identified as effective from the standpoint of the organization of nursing care are associated with lower mortality"[20] (p. 72).

Guided by a conceptual framework originating in the sociology of organizations and professions,[20] the second compelling study[29-35] was formulated to examine how certain modifications to the organization of nursing in hospitals introduced by the AIDS epidemic affected patient and nurse outcomes. The AIDS epidemic in combination with high nurse vacancy rates caused a number of urban hospitals to grant "unusual discretion to nurses to redesign general medical units into dedicated AIDS units"[20] (p. 63). Since the comparison group of hospitals for this study included two reputational magnet hospitals and a third hospital believed to be magnet-comparable, the researchers were able to discern that many of the same positive results achieved in dedicated AIDS units could apparently be attained by making changes at the organizational level. Magnet characteristics (as measured by the NWI-R subscales) were associated with significantly better outcomes for nurse safety, job burnout, patient satisfaction, and mortality 30 days from admission.

The studies shown in Evidence Table 2 consistently display positive results relating magnet characteristics (as measured by the NWI-R or PES/NWI subscales) to nurse job satisfaction, burnout, intention to leave, and perceived quality of care. The exception to this finding is the mixed results shown for the nurse-physician relationship subscale. Havens's[36] study with chief nurse executives found higher levels on the NWI-R subscales to be associated with reports of higher patient care quality, less recruitment difficulty, and fewer patient/family complaints. The studies shown in the first two rows of Evidence Table 2, which demonstrated more favorable results for the ANCC Magnet group compared to the reputational magnet group, also supported the view expressed by McClure and Hinshaw that magnet status "is not a permanent institutional characteristic but rather one that requires constant nurturing"[14] (p. 119).

Evidence Table 3 lists three studies that explored the degree to which magnet characteristics could be found in hospitals outside the United States or in nonhospital settings. Thomas-Hawkins and colleagues[37] and Smith, Tallman, and Kelly[38] found that some magnet characteristics linked significantly to intentions to leave in freestanding dialysis units and to job satisfaction in rural

Canadian hospitals, respectively. Rondeau and Wagar[39] found significant associations between magnet characteristics and resident satisfaction and nurse satisfaction, turnover, and vacancy rates in long-term care organizations in western Canada.

The remaining studies shown in Evidence Table 3 are important for a number of reasons. Using multiple measures, a variety of samples and respondent groups, and more powerful analyses, Laschinger and her colleagues[40-44] have been testing a theoretical model linking structural empowerment and magnet characteristics (as measured by the NWI-R or PES/NWI) to nurse and patient outcomes with variables such as trust and burnout posited as mediators. The empowerment dimensions being measured—perceptions of formal and informal power and access to opportunity, information, support, and resources—also appear to overlay some descriptions of magnet characteristics from the original 1983 research. By testing relationships with a set of theoretically selected variables and multivariate statistical methods, the studies of Laschinger and colleagues have been progressively building knowledge about how factors in the complex nursing practice environment interact with each other to affect outcomes.

The work that will be required to explicate how the organization and delivery of nursing services functions as a mechanism to improve patient safety and the quality of care has only just begun. The literature review conducted by Lundstrom and colleagues[45] found a number of studies that start to suggest the mechanisms by which organizational and work environment factors influence worker performance and ultimately patient outcomes. However, the authors also noted, "What we do know about changes in organization and structure of hospitals and the potential for those changes to affect patient outcomes pales by comparison to what we do not know"[45] (p. 103).

Reviewing the magnet research presented in this chapter leads to similar conclusions. The evidence almost uniformly shows consistent positive relations between job satisfaction or nurse-assessed quality of care and the magnet characteristics measured by subscales of the NWI-R or PES/NWI. But the connections from those results based on staff nurse surveys to patient outcomes measured objectively by other means have seldom been studied.

In a recent systematic review of the hospital nursing environment's effect on patient mortality, Kazanjian and colleagues[6] found associations between unfavorable environment attributes and higher patient mortality rates in 19 of 27 studies. However, other studies of the same attributes showed contrary or neutral results. Too much variability existed in measures, settings, and methodological rigor across studies to permit any pooling of results. The authors concluded it would be difficult to determine "how to design optimal practice settings until mechanisms linking practice environment to outcomes are better understood"[6] (p. 111).

Evidence-Based Practice Implications

The magnet framework outlined in Table 1 specifies a set of factors important for establishing positive work environments that support professional nursing practice. As the evidence reviewed in this chapter shows, few studies have explored the relationship of magnet characteristics to patient outcomes. Since the associations found were consistently positive, this constitutes a promising body of work, but one that is just beginning to emerge. In contrast, more evidence has accumulated to demonstrate links between magnet characteristics or Magnet recognition and favorable outcomes for nurses such as lower burnout, higher satisfaction, and fewer reports of intentions to leave. The practice implications suggested by these findings have been delineated in detail by the Institute of Medicine's 2004 report on patient safety, which

included a comprehensive review of the research that clarifies how nurse outcomes reflect and interact with working conditions to affect patient safety and quality.[3]

Keeping Patients Safe: Transforming the Work Environment of Nurses cited conditions in the work environments of nurses as "the primary sources" of threats to patient safety that "must be addressed if patient safety is to be improved"[3] (p. 47). The report presented a series of recommendations for improving leadership, management, and organizational support practices that emphasizes the increased participation of employees in work design, problem-solving, and organizational decisionmaking as a "key ingredient to successful organizational change"[3] (p. 260). The report noted that high involvement in decisionmaking for nurses "has been studied under a number of constructs, including shared governance, nursing empowerment, control over nursing practice, and clinical autonomy"[3] (p. 122).

In keeping with the realization that threats to patient safety result from complex causes,[2] *Keeping Patients Safe* identified a multifactor approach to creating favorable work environments for nurses. Many of the strategies and goals described in the report correspond to the descriptions of magnet environments initially provided by McClure and colleagues[8] and currently elaborated for contemporary settings in the appraisal criteria for Magnet recognition.[11] For example, of the 27 goals the report listed as "Necessary Patient Safeguards in the Work Environment of Nurses"[3] (p. 16–17), 20 are addressed by the current evidence requirements for Magnet recognition.[11] The multidimensionality of the magnet framework reflects the highly complex, variable, multilevel, and multifaceted nature of nursing practice environments, but it also poses measurement challenges for researchers interested in studying the influence of magnet environments on outcomes.

Research Implications

Mick and Mark[5] have argued that while nursing research has contributed substantially to the knowledge about how internal structures and work processes relate to patient safety and quality outcomes in health care organizations, there is a compelling need to improve the methodological sophistication of the research and to expand the theoretical frameworks that guide it. Many of the suggestions they make for doing so are echoed in the research implications generated by this review. Greater attention needs to be paid to addressing sampling bias issues, improving critical measures, collecting objective data from sources other than nurse self-reports, and designing multilevel and longitudinal studies. As Table 1 reveals, the conceptual definition of a magnet environment encompasses many fields and disciplines from which theoretical insights may be borrowed and tested.

Taking better account of multiple organizational perspectives and hierarchical levels in the research will build knowledge about how the relationships between magnet characteristics and patient outcomes differ by role or practice location. For example, Laschinger, Almost, and Tuer-Hodes[41] found that magnet characteristics and empowerment related differently to each other and to job satisfaction for nurse practitioners than for staff nurses, and Friese's[46] results differed significantly on some magnet characteristics only for oncology nurses. Distinguishing unit locations may be particularly important. Mick and Mark have claimed that "it is the exploration of work structures and processes at the nursing unit level that is contributing to the lion's share of advancing knowledge about what does and does not have an impact on patient and organizational outcomes"[5] (p. 319).

Finally, while the NWI-R and later versions of the NWI have yielded a wealth of useful data, questions have also been raised as to the measurement adequacy of at least three of them.[47] Variable, unpredictable, contextually sensitive, and multifaceted,[25, 47] "the nursing practice environment is a complex construct to conceptualize and measure"[25] (p. 177). Yet developing, improving, and refining measures to reliably capture all of the factors of a magnet environment may be the most important next step.

Conclusion

The magnet concept defines a framework for facilitating the professional practice of nursing that has demonstrated effectiveness in attracting nurses and shows promise for contributing to optimal patient outcomes. There is a compelling need to improve the measures and methods used to research magnet characteristics and environments before the links that connect organizational context to nurse and patient outcomes can be sufficiently understood.

Search Strategy

A series of searches was carried out in October 2006 using the National Library of Medicine's PubMed database and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database. Several search terms and phrases including the word "magnet" or "magnetism" were tested in both cases. The most effective were "magnet[Title/abstract] and nursing[Title/abstract]" in PubMed and "magnet" in [TI Title] OR "magnet" in [AB Abstract or Author-Supplied Abstract] with advanced search in CINAHL. Supplementary backup searches were also performed substituting the word "magnetism" for "magnet" in CINAHL and the word "hospitals" for "nursing" in PubMed. The PubMed searches yielded 134 unique titles to review. Cross-checking the CINAHL results against the PubMed lists yielded two additional titles.

The overwhelming majority of articles identified by these searches fell into editorial, interpretive, or narrative categories—especially narratives describing how an individual organization prepared for or achieved ANCC Magnet recognition. If an abstract was ambiguous about whether the article reported results from a primary or secondary data analysis, the article itself was retrieved in order to make a determination. The article by Laschinger and Leiter[44] was previously known and not identified by the search strategy.

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Evidence Table 1.[‡] Studies With Reputational Magnet Hospitals

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Kramer and Hafner 1989[19] Kramer and Schmalenberg 1987[48-51] Kramer, Schmalenberg, and Hafner 1988[52]	Nursing Work Index (NWI), 65 items designed to measure work values representing the findings from the 1983 original magnet study Other measures: • culture of excellence, 8 items suggested by Peters and Waterman[53] • locus of control • autonomy-patient advocacy • self-concept/self-esteem • role behavior scales	Cross-sectional studies	Cross-sectional survey, interviews, observations, document review Outcomes: from NWI: • job satisfaction • perceived productivity of quality patient care	1985–86 data collection 16 reputational magnets proportionate by region, 8 comparison county, community, and medical center hospitals in Virginia Survey n = 2,236 staff nurses, 1,634 in reputational magnet and 702 in comparison group; interview n = 800+ staff nurses, 632 nurse managers/executives	Staff nurses in magnet hospitals had significantly higher scores on • job satisfaction • perceived productivity of quality care Causal model testing to predict outcomes with 31 variables produced no findings.
Kramer and Schmalenberg 1991[54, 55]	Magnet factors: • perceived adequacy of staffing • image of nurses • how nursing is valued (how important, how active, how powerful) Other measures: • culture of excellence, 39 items to represent 7 attributes	Cross-sectional studies	Cross-sectional survey Outcome: Overall job satisfaction: • organizational structure (7 items) • professional practice (5 items) • management style (5 items) • quality of leadership (4 items) • professional development (3 items)	1989–90 data collection Survey n = 939 nurses in 14 reputational magnets (from 1985–86 sample), 808 nurses in comparison "panel" sampled from 5,000 *Nursing89* subscribers	Nurses in magnet hospitals had significantly more positive scores on • job satisfaction Nurses in magnet hospitals reported higher levels for • a culture of excellence • perceived adequacy of staffing • image of nursing • value of nursing

[‡] To illustrate how this research has developed and expanded over time, the evidence tables in this chapter are arranged in chronological order by the data collection date for each study, when available, or publication date.

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Aiken, Smith, and Lake 1994[28]	Status as a reputational magnet hospital	Cross-sectional studies	Cross-sectional; multivariate matched sampling procedure to control for relevant hospital characteristics (e.g., teaching status, technology availability, board certification of physicians, emergency room presence), adjusting for differences in predicted mortality for Medicare patients Outcome: Medicare mortality rate (within 30 days of admission)	1988 Medicare data 39 reputational magnet hospitals (census of all available or eligible), 195 control hospitals (5 matches for each magnet) from all nonmagnet U.S. hospitals with >100 Medicare discharges	Magnet hospitals had a 4.5% lower mortality rate (95% CI (confidence interval) = 0.9 to 9.4 fewer deaths per 1,000 discharges).
Aiken and Sloane 1997[29, 30] Aiken, Sochalski, and Lake 1997[31] Aiken, Sloane and Lake 1997[32] Aiken, Lake, Sochalski 1997[33] Aiken, Sloane, and Klocinski 1997[34] Aiken, Sloane, Lake 1999[35]	Nursing Work Index-Revised (NWI-R), 57 items, with subscales for • nurse autonomy (5 items) • control over nursing practice setting (7 items) • nurse relations with physicians (2 items) • organizational support (10 items from previous 3 subscales)	Cross-sectional studies	Cross-sectional survey, needlestick reports for a 30-day period, patient interviews, patient chart abstraction Outcomes: Nurse — • job burnout • safety (needlesticks) Patient — • satisfaction with care (multi-item scale and a single-item overall rating) • mortality 30 days from admission	1991 data collection 40 medical units, 2 in each of 20 urban hospitals located throughout U.S., 10 hospitals with dedicated AIDS units, 10 matched comparable hospitals without AIDS units (scattered-bed), 2 comparison hospitals were reputational magnets, 1 more was considered magnet based on researcher knowledge of facility Survey n = 820 RNs from all employed on units ≥16 hours per week (86% response rate); interview n = 594 patients; chart outcomes for 1,205 AIDS patients	Patients with AIDS in magnet scattered-bed units had lower odds of dying than in any other setting; higher nurse-to-patient ratios were determined to be the major explanatory factor. Patient satisfaction was highest in magnet hospitals; control over nursing practice setting was determined to be the single most important explanatory factor. Nurses in magnet hospitals sustained significantly fewer needlestick injuries. Nurses in magnet hospitals and dedicated AIDS units had significantly more positive scores for emotional exhaustion, autonomy, nurse control over resources, and nurse-physician relations.

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Scott, Sochalski, and Aiken 1999[23]		Literature review, narrative	Search method unstated.		Summarizes findings cited in this table and synthesizes insights from these and additional magnet studies to illuminate the leadership characteristics and professional practice attributes found within reputational magnet hospitals.

Evidence Table 2. Studies Comparing Health Care Organizations With and Without ANCC Magnet Recognition

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Aiken, Havens, and Sloane 2000[56] Friese 2005[46]	NWI-R single items and subscales, Aiken et al.: • nurses' autonomy • nurses' control over the practice setting • nurse relations with physicians Practice Environment Scale/Nursing Work Index (PES/NWI), Friese: • nurse participation in hospital affairs (9 items) • nursing foundations for quality of care (10 items) • nurse manager ability, leadership, and support of nurses (5 items) • staffing and resource adequacy (4 items) • collegial nurse-physician relations (3 items) Other measures: • job characteristics (hours worked, workload, supervisory responsibilities, nonnursing duties)	Cross-sectional studies	Cross-sectional, comparative multisite observational Outcomes: • perceived quality of care • job satisfaction • intent to leave • burnout (Maslach Burnout Inventory)	1998 data collection 7 ANCC Magnets (census as of study date), 13 reputational magnets (12 from Kramer et al.'s 1985–86 sample) with 2 additional teaching hospitals included in Friese's secondary analysis Aiken et al. survey n = 2,045 RNs in medical or surgical units, 1,064 in ANCC Magnet and 981 in reputational magnet group Friese analysis n = 1,956 of which 305 = oncology nurses (155 in ANCC Magnet and 150 in comparison group) and 1,651 = nononcology nurses (755 in ANCC Magnet and 896 in comparison group)	Nurses in ANCC Magnets were significantly more likely to report • higher ratings of care quality • higher job satisfaction • less frequently feeling burned out, emotionally drained, and frustrated by their job Oncology nurses in ANCC Magnets reported nearly half the exhaustion levels of oncology nurses in the 13 reputational magnets and 2 teaching hospitals. In both analyses, most NWI-related subscale scores were significantly higher for nurses in the ANCC Magnet group; exceptions were that scores for nurse-physician relations and nurse manager ability, leadership, and support differed significantly, favoring ANCC Magnets only for oncology nurses.
Havens 2001[36]	NWI-R subscale: • organizational support Other measures: • degree restructuring implemented, 9 items	Cross-sectional studies	Cross-sectional survey; comparative Outcomes: • difficulty recruiting staff RNs (1 item) • quality of patient care (global ratings and reports of complaints)	1999–2000 data collection 21 ANCC Magnets, 35 reputational magnet hospitals (census samples of both groups) Survey n = 43 chief nurse executives, 19 in ANCC Magnet and 24 in reputational magnet group	Chief nurse executives in the ANCC Magnet group reported less difficulty recruiting RNs and were significantly more likely to report • high quality patient care • fewer patient/family complaints • organizational support for autonomy, control over practice, and nurse-physician collaboration

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Upenieks 2002, 2003[57, 58]	Power and empowerment – Conditions of Work Effectiveness Questionnaire-II (CWEQ-II) 20 items: • 2 global items • 4 subscales to measure perceived access to opportunity, information, support, and resources	Cross-sectional studies	Cross-sectional survey Outcome: Job satisfaction - NWI-R subscales: • autonomy • nurse control over practice setting • relations between nurses and physicians Plus 3 researcher-designed subscales: • self-governance (7 items) • organizational structure (6 items) • education opportunities (6 items)	Convenience sample of 2 ANCC Magnets, 2 comparable comparison hospitals Survey n = 305 medical-surgical nurses	Nurses in the ANCC Magnet group had significantly higher scores on • job satisfaction • power and empowerment
Brady-Schwartz 2005[59]	Status as ANCC-recognized Magnet	Cross-sectional studies	Cross-sectional survey; quantitative, descriptive correlational Outcome: • overall job satisfaction (total McCloskey Mueller Satisfaction Scale score; subscales: extrinsic rewards, scheduling, family/ work balance, coworkers, interaction, professional opportunities, praise and recognition, control/ responsibility) • intention to leave (Anticipated Turnover Scale)	3 ANCC Magnets, 3 comparison hospitals Survey n = 470 RNs, 173 in ANCC Magnet and 297 in comparison group	Nurses in ANCC Magnet group had significantly higher overall job satisfaction, including significant subscale differences for professional opportunities, control/responsibility, and extrinsic rewards. Higher overall job satisfaction correlated with stronger perceptions of voluntarily remaining in current position.

Evidence Table 3. Studies of Magnet Characteristics

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Laschinger, Shamian, and Thomson 2001[40]	Magnet characteristics—NWI-R subscales: • nurse autonomy • nurse control over practice setting • nurses' relations with physicians Other measures: • trust and confidence in management — Interpersonal Trust at Work Scale • burnout—The Human Services Survey, 3 components (emotional exhaustion, depersonalization, decreased personal accomplishments)	Cross-sectional studies	Cross-sectional survey Outcomes: • job satisfaction • perceived quality of care • perceived quality of unit	Ontario, Canada Survey n = 3,016 staff nurses from medical-surgical settings (subsample from a stratified random sample) in 135 hospitals	Model testing with these variables explained 39–40% of the variance with either job satisfaction or nurse-assessed quality as the outcome. Magnet characteristics influenced job satisfaction and perceptions of care quality with trust in management and emotional exhaustion as important mediators. Higher levels of magnet characteristics were associated with higher levels of trust in management and lower levels of burnout.
Thomas-Hawkins, Denno, Currier 2003[37]	Magnet characteristics – PES/NWI subscales (some items adapted to reflect setting): • nurse participation in hospital affairs • nursing foundations for quality of care • nurse manager ability, leadership, and support of nurses • staffing and resource adequacy • collegial nurse-physician relations	Cross-sectional studies	Cross-sectional survey Outcome: intentions to leave job in next year (1 item)	United States 1,000 staff nurses working in freestanding hemodialysis facilities (random sample from American Nephrology Nurses' Association members)	Nurses who intended to leave their jobs reported significantly lower levels of magnet characteristics represented by all of the PES/NWI subscales except for collegial relations between nurses and physicians.

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Laschinger, Almost, and Tuer-Hodes 2003[41]	Magnet characteristics—NWI-R subscales: • nurse autonomy • nurse control over practice setting • nurses' relations with physicians Other measures: Empowerment • CWEQ-II, 4 subscales: access to opportunity, information, support, and resources • Job Activities Scale-II, 3 items: perceptions of formal power • Organizational Relationships Scale-II, 4 items: perceptions of informal power	Cross-sectional studies	Cross-sectional survey data from 3 independent studies; predictive, nonexperimental Outcomes: • Global Job Satisfaction Questionnaire (Studies 1, 3) • Nurse Job Satisfaction Questionnaire (Study 2)	Ontario, Canada Study 1: survey n = 233 randomly selected staff nurses from urban tertiary care hospitals throughout Ontario Study 2: survey n = 263 randomly selected staff nurses from 3 rural community hospitals in a western Ontario network of 8 Study 3: survey n = 55 acute care nurse practitioners from urban tertiary care hospitals throughout Ontario	For staff nurses, empowerment and magnet characteristics were significant independent predictors of job satisfaction; for nurse practitioners, the combination of empowerment and magnet characteristics significantly predicted job satisfaction. Average ratings on empowerment and magnet characteristics were moderate for staff nurses and higher for nurse practitioners. Total scores on empowerment and magnet characteristics were strongly correlated for all three samples; the most strongly related empowerment features were access to resources for staff nurses and access to information for nurse practitioners. All empowerment dimensions related significantly to perceptions of autonomy; access to resources related most strongly to control over practice environment; and informal power related most strongly to nurse-physician relationships.

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Tigert and Laschinger 2004[42]	Magnet characteristics – NWI-R subscales: • nurse autonomy • nurse control over practice setting • nurses' relations with physicians Other measures: Empowerment • CWEQ-II, 4 subscales: access to opportunity, information, support, and resources • Job Activities Scale-II, 3 items: perceptions of formal power • Organizational Relationships Scale-II, 4 items: perceptions of informal power	Cross-sectional studies	Cross-sectional, correlational survey design Outcomes: mental health • State of Mind subscale (5 items) from the Pressure Management Indicator • Emotional Exhaustion subscale (6 items) from the Maslach Burnout Inventory	Ontario, Canada; Data collected 2001 Survey n = 75 critical care nurses, a subsample of 239 nurses working in teaching hospitals (randomly selected from College of Nurses of Ontario)	The combined effects of empowerment and magnet characteristics explained 19% of the variance in burnout and 12% of the variance in state of mind. Empowerment related significantly and positively to perceptions of magnet characteristics; however, only empowerment was a significant independent predictor of emotional exhaustion, and only magnet characteristics were a significant predictor of state of mind.
Rondeau and Wagar 2006[39]	Magnet similarity represented by employer-of-choice strength (7 items, e.g., how establishment views, values, treats its nursing personnel; how staff and community view its treatment of nurses) Other magnet characteristics measures: • high involvement (high commitment) work practices (10 items) • progressive, participatory decisionmaking workplace culture (3 items) • training support (10 items)	Cross-sectional studies	Cross-sectional survey Outcomes: • resident satisfaction (3 items) • nurse turnover and vacancy rates • nurse satisfaction (3 items)	Canada Data collected 2003 Survey n = 114 nurse executives sampled from all long-term care organizations (nursing homes) in western Canada with ≥35 beds	Higher scores on magnet employer-of-choice strength were significantly associated with • higher resident satisfaction • lower turnover and vacancy rates • higher nurse satisfaction • high involvement work practices • progressive decisionmaking • nurse training opportunities and assistance

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Smith, Tallman, and Kelly 2006[38]	Magnet characteristics categories: • supportive management (5 items) • professional autonomy and responsibility (4 items) • nurse-physician working relationship (2 items) • nurse-manager working relationship (2 items)	Cross-sectional studies	Cross-sectional survey, interviews Outcome: job satisfaction (3 items from Job Diagnostic Survey)	Canada Survey n = 123 nurses in diverse clinical areas from 13 rural northwestern hospitals recruited via circulating letter/flyer	All magnet characteristics items were significantly but modestly correlated with job satisfaction except for the 2 items measuring nurse-physician relationship and 1 of the 4 autonomy items.
Armstrong and Laschinger 2006[43]	Magnet characteristics – PES-NWI subscales: • nurse participation in hospital affairs • nursing foundations for quality of care • nurse manager ability, leadership, and support of nurses • staffing and resource adequacy • collegial nurse-physician relations Other measures: Structural empowerment – CWEQ-II, 2 global items and 6 components: access to opportunity, information, support, resources, formal power, and informal power	Cross-sectional studies	Cross-sectional survey; exploratory; predictive, nonexperimental Outcome measure*:* Safety Climate Survey	Canada 40 staff nurses working in a small community hospital in central Canada	The combination of structural empowerment and magnet characteristics was a significant predictor of perceptions of patient safety climate. Overall empowerment significantly positively related to all magnet characteristics, with total empowerment most strongly related to use of a nursing model of care and good nursing leadership on the unit.

Source	Environment Issue/Attribute Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Laschinger and Leiter 2006[44]	Magnet characteristics – PES-NWI subscales: • nurse participation in hospital affairs • nursing foundations for quality of care • nurse manager ability, leadership, and support of nurses • staffing and resource adequacy • collegial nurse-physician relations Other measures: Maslach Burnout Inventory–Human Service Scale, 3 subscales: • emotional exhaustion (9 items) • depersonalization (5 items) • personal accomplishment (8 items)	Cross-sectional studies	Cross-sectional survey Outcome measure: adverse events (nurse-reported frequency of occurrence of negative patient events in past year: • falls • nosocomial infections • medication errors • patient complaints)	Canada Survey n = 8,597 nurses (4,606 from a stratified random sample of licensing registry lists in Ontario and 3,991 from a census sample of acute care nurses in Alberta), a subset of participants in the *International Survey of Hospital Staffing and Organization of Patient Outcomes* conducted in 5 countries	With all measured components included in the model, structural equation modeling analysis showed direct and indirect effects of all environment factors on patient safety outcomes partially mediated by burnout. Both staffing adequacy and use of a nursing model of care directly affected patient safety outcomes. Staffing adequacy directly affected emotional exhaustion, and use of a nursing care model directly affected personal accomplishment. Nursing leadership played a fundamental role in relation to policy involvement, staffing adequacy, RN-MD relationships, and support for a nursing (vs. medical) model of care.

Chapter 47. Patient Safety and Health Information Technology: Role of the Electronic Health Record

Nancy Staggers, Charlene Weir, and Shobha Phansalkar

Background

An electronic health record (EHR) is a real-time, point-of-care, patient-centric information resource for clinicians[1] that represents a major domain of health information technology (HIT). More recently, an EHR has been defined as "a longitudinal electronic record of patient health information, produced by encounters in one or more care settings."[2] It includes patient information such as a problem list, orders, medications, vital signs, past medical history, notes, laboratory results, and radiology reports, among other things. The EHR generates a complete record of a clinical patient encounter or episode of care and underpins care-related activities such as decisionmaking, quality management, and clinical reporting. Some distinguish between the terms EHR and electronic medical record (EMR), with EMR focusing on ambulatory care systems. However, in practice, the terms are interchangeable. In this chapter, the term EHR relates to computerized patient health records stored within and among institutions.

This chapter first presents a review of the literature about orders management—also called computerized provider (or physician or practitioner) order entry. The next section addresses barcoding, an area closely related to orders management. Third, the chapter synthesizes the literature about the impact of orders-related clinical decision-support systems on nursing practice.

Ordering and associated functions in EHRs is a salient focus for several reasons. First, EHRs are a current centerpiece in contemporary health informatics. A nationwide emphasis exists to install these clinical systems over the next decade, largely because of a 2004 statement by President Bush that most Americans would have an EHR in 10 years.[3] Second, the benefits of EHRs are becoming more well known. For instance, a 2006 systematic review of the literature concluded that overall use of HIT increased adherence to guidelines for care, increased surveillance and monitoring of patients, yet had mixed effects for medication errors and time utilization.[4] Third, nurses in the United States are now or will be using EHRs in the near future. Understanding orders management through the EHR is imperative because the effect on nursing practice promises to be great.

Orders management is an interdisciplinary activity crossing organizational boundaries; therefore, the literature review for this topic was broad, including all care settings and providers other than nurses. The ordering process inherently involves nurses, especially in acute care settings, as recipients of medical orders and initiators of nursing orders. However, this relationship may not be acknowledged in the design of empirical studies.

The Institute of Medicine (IOM) recommended computerized orders and decision-support applications as main HIT mechanisms for increasing patient safety in the future.[5] Existing research about the nursing impact of orders, barcoding, and decision support within EHRs needs to be examined and then expanded in near-future research. This chapter reviews EHR ordering and the associated, more researched areas, and suggests EHR areas for future research. The authors chose to concentrate this section on information-intense versus technology-focused impacts.

Orders Management in EHRs

Orders for patients are the connective tissue in any EHR. They are necessarily complex, integrating patient-specific interventions across departments. Orders are written by members of the health care team, primarily physicians and nurses. Orders management crosses customary boundaries, and it is just as likely to integrate computerized applications and functions as it is to disintegrate traditions. For example, information once the purview of one department becomes shared across many disciplines. Who owns data, such as a patient's allergies or weight, becomes a topic of vigorous discussion. New work processes are crafted. Because of the complexity of orders management, computerized provider (physician) order entry (CPOE) has been a topic of research.

The genesis for the recent increase in publications in this area was the IOM's *To Err Is Human: Building a Safer Health System* report on errors in medicine. The IOM recommended information technology as a major mechanism to reduce errors.[6] Likewise, the IOM's *Crossing the Quality Chasm: A New Health System for the 21st Century*[5] had a profound message for the information technology community and recommended, among other things, the installation of CPOE and decision support to improve patient safety. In its most recent publication, *Preventing Medication Errors: Quality Chasm Series*,[7] the IOM recommends that clinicians make greater use of information technology for prescribing and dispensing medications. Thus, it is imperative to understand the practice impacts of CPOE and its related functions of barcoding and clinical decision support.

Research Evidence—CPOE

The CPOE studies were analyzed using a quality instrument specific to informatics called QUASII.[8] This instrument assesses informatics study qualities across construct, internal, external, and statistical conclusion validity areas. The CPOE studies may be divided by QUASII scores into two tiers: Tier 1 (with QUASII scores at or above 61) and Tier 2 (with scores at or below 54). No scores between 54 and 61 were observed, and studies with QUASII scores below 30 were excluded from consideration. Tier 1 includes studies that have more reported rigor in study design and controls with fewer possible threats to construct, internal, external, and statistical conclusion validity. Tier 2 includes studies with less reported rigor and increased possible threats to validity. Studies with less rigor are included here because they are often widely cited and have even dominated the literature.

The studies were sorted by dependent variables into medication errors, efficiency impacts (time and length of stay), and quality care. The studies are summarized in Tables 1 and 2. In Table 3 a sample of qualitative studies is listed to show the contrast in the types of variables examined in these studies compared to quantitative CPOE studies.

Varying Definitions of CPOE

The term CPOE is used imprecisely. Researchers have used the same term to mean orders with these differing capabilities:

- Electronic orders, including electronic transmission to appropriate ancillary departments[9]
- Electronic orders without an interface to one or more ancillary departments, requiring either order transcription to paper or order entry by others into systems with different functional capabilities[10–12]
- Orders including order sets[13]
- Orders with no order sets[14]
- Orders without capability for complex medications, such as intravenous (IV) orders, total parenteral nutrition (TPN), or complex functions such as oncology protocols
- Orders with integrated alerts, reminders, and decision support to assure order completeness and accuracy, especially for medications[15]
- Orders with no checks, alerts, reminders, or decision-support capabilities[16, 17]
- Orders without a pharmacy interface or any decision-support capabilities[18]
- Orders with or without associated clinical documentation
- Orders with full capabilities, complete decision support, documentation (especially an electronic medication administration record, or eMAR), and complete support for all orders, including complex protocols
- No description of existing capabilities

Researchers report conclusions as if the CPOE capabilities were equivalent, when these varying instantiations, in effect, amount to very different strengths of CPOE as an independent variable. In particular, the lack of appropriate departmental interfaces and integration in one study, such as a pharmacy interface in a study tracking medication error rates, is very much in contrast to a study examining medication errors using a system with an existing pharmacy interface. CPOE requiring order transcription of any kind—to a medication administration record (MAR) or foreign pharmacy system—necessarily increases errors, and these very transcription errors are typically included in the count of overall medication errors rates.

The same notion can be applied to the presence or absence of computerized decision support in its most basic form. Basic decision support can allow checking for order completeness and accuracy. If medications errors are being examined, a CPOE study of an application with no basic order checking is not equivalent to studying one with any decision support integrated into CPOE. More advanced decision support for drug-drug or drug-allergy interactions, and checks for other interactions or dosing accuracy, add yet another level to CPOE applications. Researchers are led to conflicting conclusions if this variability of functions is not taken into consideration. At best, the broad scope of CPOE systems (and lack of specific descriptions in the studies of the features of systems) leads to confusion in the interpretation of results. These differing capabilities are noted when reported by researchers.

CPOE Impacts and Variables Studied: Quantitative Studies

Sites and CPOE applications. CPOE evaluations have been concentrated at large academic medical centers, particularly at Brigham & Women's Hospital in Boston and the Ohio State University medical center in Columbus. The unique, "homegrown" systems at Brigham, Vanderbilt University in Nashville, and the Regenstrief Institute at the Indiana University School of Medicine (Indianapolis) populated earlier literature—although, more recently, vendor systems have been studied. Studies of vendor systems include the Siemens, Eclipsys, General Electric (GE), and Cerner CPOE applications, in descending order of frequency.

Medication errors and adverse drug events. The relationship of CPOE to medication errors, adverse drug events (ADEs), and subsets of those categories is reported in 12 studies (see Table 1). Of these, three systematic reviews addressed the effect of CPOE on medication errors and/or ADEs. The systematic reviews concluded that CPOE (and isolated clinical decision-support systems) can reduce medication errors.[19–21] However, since these reviews were published, researchers have published conflicting conclusions about the topic.[22, 23]

Studies on inpatient units in five different settings reported significant decreases in medication errors after CPOE implementation.[11] More specifically, all medication errors and non-missed-dose errors decreased in two sites,[10, 18] and potential and nonintercepted ADEs significantly decreased with the homegrown application at Brigham and Women's Hospital.[15] Shulman and colleagues[11] reported a lower proportion of medication errors with CPOE, and King and colleagues[18] reported a 40 percent reduction in errors. Transcription errors were reduced or entirely eliminated.[17, 20, 24]

In contrast, two researchers found no differences in rates for ADEs with CPOE.[16, 18] In the outpatient arena, no differences were found in total errors, ADEs, or rules violations,[16] although the system in this one setting lacked any order checking for completeness or accuracy and lacked basic decision support. The differences in ADE detection may be due to underpowered studies[19] and also to the differences in functionality discussed earlier and the differing definitions for ADEs. Moreover, studies used varying scales to rate errors and ADEs ranging from self-developed categorical scales of minor/major/serious to the American System of Health-Systems Pharmacists classification.

Increases in medication error rates after implementation of CPOE have also been reported. In 2005, Spencer and colleagues[12] reported an increase in one type of error (i.e., pharmacy processing) on two inpatient medicine units, while other medication errors were unchanged from pre-CPOE implementation. Unfortunately, this site had no system interface to pharmacy, and the researchers acknowledge that the increased error rate may have been related to the need to transcribe orders in the pharmacy. Without the interface or a method to ensure orders were complete and accurate, the only seeming advantage of CPOE at this site was the speed of communication to the pharmacy for transcription. Researchers in Portugal[17] concluded that CPOE eliminated their transcription errors, but other errors continued—such as right class/wrong drug, and other errors likely solvable by the basic decision support they lacked (e.g., unclear orders, missing frequency, incorrect dosages, drug interactions, and duplicative therapies).

Life-threatening errors and serious ADEs were higher in the early years at Brigham and Women's, when no decision support was installed. For example, a screen for potassium orders allowed new, potentially very serious errors to occur.[15] These potential errors were intercepted by either nursing or pharmacy before the drugs were administered. Likewise, CPOE at one institution in London created three major errors that could have resulted in harm or death of a patient had they not been intercepted.[11] Again, this site had no decision support in place to prevent a reported error of 7 mg/kg of morphine being ordered instead of 7 mg, a potential overdose of 70 times the normal range. This site also saw an increase in minor, nonintercepted errors with CPOE, from 43 for handwritten orders to 93 with CPOE. That said, with all errors combined, the overall rate of errors was lower with CPOE. However, the details behind that overall rate show increases in potential major errors if decision-support capabilities are not available. This statement is in contrast to the conclusion by Chaudhry and colleagues,[4] perhaps

because his literature review concentrated on the years before these newer studies were published.

In all studies, the researchers did not include external forces, contextual variables, or organizational forces that may have contributed to changes in medication errors. For example, several studies extended over multiple years, through changes in chief information officers, national changes about patient safety, and increased emphasis on medication errors. Especially with the more recent studies, changes in error rates could have been due to these factors as well as information technology implementations.

The variability in conclusions may also be explained by the differences in available functions, particularly the lack of pharmacy interfaces and basic decision support. Therefore, the previous researchers' conclusions about CPOE decreasing medication errors must be modified: CPOE can reduce medication errors if appropriate functions are available to prevent new errors. Transcription errors can be eliminated with electronic communication and interfaces together with structured order entry. CPOE can substantially reduce overall (and many serious) medication errors if (1) electronic communication and automatic order interfaces are in place, (2) basic order checks for completeness are present, and (3) decision support at its most basic level is available—checking for drug–drug and drug–allergy interactions and for dosing ranges.

Clinical efficiency measures—time and length of stay. Eleven studies examined the effects of CPOE on efficiency measures of time and/or hospital length of stay (LOS) (see Table 2). CPOE offers clear benefits in processing efficiency for orders management and availability of electronic laboratory and radiology results. CPOE reduced the time from order entry to results availability for laboratory and radiology orders in four sites.[13, 25–27] Another clear benefit is that CPOE decreased the time from pharmacy ordering to medication administration time.[13, 25, 26, 28]

Likely because of timely availability of results and faster order processing, patients' hospital LOS was shorter.[26, 29] One systematic review concluded that one of the benefits of CPOE is reduced LOS.[20] Other clinical efficiencies are related to use of CPOE. For example, Ohio State University hospital saw a significant improvement in the number of patients whose abnormal potassium levels were normalized within 24 hours.[24]

On the other hand, order entry itself takes longer using CPOE than with paper. A systematic review of the impact of computers on time efficiency concluded that the use of central desktops for CPOE was not efficient, consuming 98.1 percent to 328.6 percent more time per working shift.[30] CPOE took 2.2 minutes longer per patient, but after duplicative tasks were removed, the extra time per patient was shortened to an average of 0.43 min.[31] At Brigham and Women's, CPOE took 44–73 minutes longer per day, especially for entering one-time orders.[32] However, this study was done before order sets were widely used. At Regenstrief, an early CPOE application took interns 33 minutes longer during a 10-hour period.[29] Interns entered orders on microcomputers and then printed them, using them as traditional paper documents afterwards. Likewise, a more recent study at Massachusetts General Hospital[33] demonstrated an increase in medical interns' ordering time, among other time-related variables. Prior to CPOE, interns spent 2.1 percent of their time ordering; after CPOE, they spent 9 percent of their time ordering. Two of these studies were published about early CPOE applications in the 1990s, and all four measured homegrown systems. None of the studies examined time for order sets or vendor-based solutions. Of note, CPOE may take providers somewhat longer to enter orders, but efficiencies are obtained later in the orders management cycle—in nursing, ancillary departments' order processing, and in reduced time for results availability and administrative tasks.[33]

Quality care variables. Three studies examined variables not reported by others, namely the quality of documentation and one particular patient outcome (see Table 3). In one study, a significant increase occurred in the number of documented consents for do-not-resuscitate orders.[34] In another study, researchers conducted a randomized controlled trial to examine the effect of medical students' rotations in a CPOE site versus traditional sites on the quality of orders written on a fictitious patient[50] They found that the quality scores for orders during an academic examination were significantly higher for students using CPOE.

A third study produced alarming results that conflict with other, more promising benefits of CPOE. A recent article reported an increased mortality coincident to a CPOE implementation at a pediatric hospital.[14] The researchers reported a direct association between CPOE and increased mortality among pediatric patients admitted through interfacility transport. However, this facility experienced substantial workflow changes in conjunction with CPOE installation. For example, no preregistration was available, delaying order entry until full registration was completed after the patient physically arrived. This process change delayed therapies and diagnostic testing.

Important human–computer interaction issues impacted treatment times. The new ordering system required substantially more order entry time during a critical period of patient care, and the wireless bandwidth capacity was often exceeded during peak periods. Crucial aspects of work organization changed with all medications being centralized, meaning that nurses were unable to access medications locally and the pharmacy could not process medication orders until they had been activated. Sadly, when the pharmacy accessed CPOE to process an order, other clinicians were locked out of the application. The researchers also reported a decrease in face-to-face communications that provided relevant information for patient care management post-CPOE.

In this study, CPOE was likely a proxy variable for significant, but untoward, process changes in that particular institution. The lesson from this article is that work processes must be thoroughly examined before CPOE "goes live," and projected, substantial treatment delays are an excellent reason to delay going live until work design is safe for patient care. For critically ill patients in emergency departments (EDs), intensive care units (ICUs), and pediatric units, new processes cannot delay treatment. Workflow and usability analyses can preclude the kinds of impacts seen in this article.

CPOE and a Sampling of Qualitative Studies

A sampling of qualitative studies shows a contrast in variables addressed by these researchers versus the researchers of quantitative studies (see Table 4). While not usual to include as evidence, these qualitative studies provide insights for future studies and as well as interesting aspects of CPOE. Koppel and colleagues[23] interviewed 261 clinicians, including nurses, about CPOE and its perceived role in medication errors. Clinicians reported new errors with CPOE because of fragmented data and processes, lack of integration among systems, and human–computer interaction issues. For example, obtaining a summary view of all the medications a patient was receiving was difficult because providers had to scroll through multiple screens to view medications. In another example, the fit between computer and workflow processes was a problem because nurses typically charted medications at the end of a shift using global commands instead of charting at the time medications were actually given. And in another study of CPOE, Sittig and colleagues[35] found that negative emotions about CPOE prevailed for both nurses and physicians.

One study concluded that communication was broadly affected by CPOE, from interpersonal to intrainstitutional.[36] Significant impacts on team and physician-nurse communication occurred with CPOE. Nurses felt that CPOE degraded communication among the dyad of doctor and nurse, and thought that it took more effort post-CPOE to get residents to come see patients needing attention. A multisite study of the Veterans Affairs' (VA's) early CPOE application showed that nurses thought the quality of care had improved with CPOE, but the control over their jobs and roles decreased.[37]

Quantitative studies examined more easily definable and, perhaps, more simplistic variables, such as measurable medication errors and ADEs, timed processes of order entry to results posted, and mortality. The qualitative studies, on the other hand, examined richer aspects of processes and interdependent variables, such as types of errors created by CPOE, interdependent communication patterns, and perceptions of role changes. With the complexity created by orders management, both methods are needed in the future research.

Evidence-Based Practice Implications

Silence about nursing impacts cuts across the CPOE quantitative studies. Only one quantitative study mentions nursing impacts with CPOE: changes associated with CPOE resulted in medications not being available on patient units in a timely manner, resulting in missed doses.[10] Bates and colleagues acknowledged the increase in missed doses but deemed these minor, and the missed-dose errors were excluded from summary findings of the study.

Impacts of CPOE on nursing were examined in the sample of qualitative studies. The sample of qualitative studies indicated that (1) nurses at three sites in one study had negative emotional perceptions of CPOE, (2) interpersonal communication between nurses and physicians was disrupted by CPOE, and (3) nurses perceived that the quality of care improved with CPOE.

Even with few studies specifically addressing nursing issues, implications are evident. Nurses can expect improved speed for results availability with CPOE. The elapsed time from writing an order to available results is a clear and expected benefit. Although not surprising, this is a benefit to the care team and the patient. Obviously, legibility of orders and improved availability of information occurs as well, by virtue of orders being typed and available electronically. Nurses can expect more efficient treatment related to results availability and decreases in hospital LOS for patients post-CPOE.

Whether medication errors and ADEs are impacted by CPOE depends upon available application functionality. Thus, all nurses will want to be aware of available functional and technical support and their implications. If, for example, the CPOE system has no pharmacy interface or integrated decision-support capabilities, aggressive monitoring systems will need to be in place to intercept medication errors ranging from transcription errors and interaction issues (drug-drug, drug-allergy interactions) to dosage issues (dose range, right class/wrong drug, frequency) and more serious errors. If no eMAR exists, then errors associated with transcription will be present because transcription to a paper medication administration record is required. Serious medication errors can increase with CPOE if no decision support is available. As functionality increases with computerized applications and electronic transmission, provider-based error-monitoring mechanisms can be tailored down in scope. Medication errors can decrease if interfaces and appropriate documentation using an eMAR are available, along with decision-support capabilities for order accuracy, dosing issues, and interaction checking. In fact,

given the implications of CPOE without interfaces and decision support, nurses should actively support a CPOE installation only if adequate functionality will be installed.

That said, no health information technology is a panacea. When lower-level errors are solved, such as results availability and transcription errors, a new level of issues will emerge, some beneficial and some prompting concern. CPOE creates professional interdependence and slices across departmental boundaries. Thus, changes in work design, roles, and communication will occur. Work processes need to be carefully analyzed for potential detrimental changes before going live, and either the work design or the EHR design must be tailored for patient safety and quality. Nurses can expect to feel the impact of more electronic and less face-to-face communication, especially from physicians. Knowing this, alternative communication channels and opportunities can be constructed. Roles will need to be renegotiated among medicine, pharmacy, and nursing for order activation, allergy entry, weight documentation, and other interdependent issues.

Research Implications

Study descriptions and designs. Identifying and specifying the capabilities of CPOE is imperative. Future studies should indicate the exact functions in the article and abstract as well, and in the title, if at all possible. Chaudhry and colleagues.[4] noted this same issue with general HIT studies. Careful conclusions are necessary when CPOE does not provide basic functionality such as pharmacy, laboratory, or eMAR interfaces. CPOE capabilities are not equivalent, so they should be treated like the different independent variables they are. Adequate descriptions of these study characteristics are needed, at minimum.

Broadening the definition of CPOE would allow researchers to conceptualize future studies differently. The term “order entry” misrepresents the concept by implying that only the entry portion of the whole process is important. Ordering is a process starting with entry, to communication, to processing by various recipients, and then to documenting actions against specific orders. By conceptualizing ordering in this way, future studies can be designed to measure impacts across the health team.

Potential external influences need to be taken into account in study design as potential confounding variables. Studying CPOE in a natural environment is challenging research. However, rather than ignore these variables, as has been done in the past, future researchers should want to identify and control, or at least measure, these variables. This notion is stressed by Snyder and colleagues.[38] External forces outside the institution should also be considered in study conclusions—for example, the influence of national trends for increasing patient safety with concomitant information technology installations.

Future research themes. Three major themes for future research emerged: (1) nursing impacts from computerized orders management, (2) human-computer interaction issues, and (3) implementation science. The concept of CPOE needs to be expanded to encompass an orders management cycle. To date, the concept has been studied primarily as order entry in quantitative studies. The ordering process is a complex, interdependent, and interactive process composed of at least these multiple, intersecting elements: systems design, interpersonal and intersystems communication, implementation processes, and organizational structures. Thus, orders management needs to be examined in the future as the interdependent, interdisciplinary, and interactive process that it is. A few authors of qualitative studies have started that process.

Because orders management is a complex process, identifying only simple outcomes variables does not do the phenomenon justice. Multiphased studies with multiple process and outcome variables are needed to begin to understand orders management and its impact.

Nursing impacts of computerized orders management. From the nursing perspective, nearly any study of orders management with nursing impacts will be novel. Ideally, an interdisciplinary study of orders management should be crafted using both quantitative and qualitative methods. Crucial variables include the impact on workflow, cognitive processes for information synthesis across disparate systems, and patient safety issues with various vendors' CPOE applications. A standardized method for medication error reporting is needed to facilitate reporting across institutions and vendor applications. In concert with recommendations from Kaushal, Shojania, and Bates,[19] commercial products should be compared and key implementation factors identified. Mixed methods in future studies are very desirable since quantitative and qualitative methods would provide a powerful mechanism to uncover information about orders management as a complex process.

Human–computer interaction issues. A second theme of future research relates to usability and human–computer interaction impacts of orders management and clinical decisionmaking. Human-computer interaction within EHRs is a critical area to explore in HIT. For at least a decade, health informatics experts have stated that user interface design and other related areas of human–computer interaction are understudied and, in fact, an area in desperate need of attention.[39, 40] Yet, research in this area has moved at a glacial speed. In some recent literature, serious user interface issues have surfaced related to CPOE.[14, 41] In particular, the rigid, linear, structured computing processes reflected in user interfaces did not adequately address clinicians' work processes, which are nonlinear, interruptive, and flexible. These findings accentuate the need for research in user interface design.

Research in human–computer interaction is beginning in health informatics, but more is immediately needed. Two researchers outlined detrimental effects of the usability aspects of order applications.[14, 42] Patel[40] studied issues surrounding physicians' cognitive structures and stressed the importance of cognitive science to informatics. Ash and colleagues examined aspects of CPOE, such as unintended consequences of CPOE and other human-systems issues.[41, 43, 44] Staggers[45–48] studied effective screen designs as they related to the efficiency (response time) and effectiveness (accuracy) of various EHR designs. Future research needs to focus on systems usability to understand what designs facilitate safer orders management; what vendors offer safe, usable, and accurate orders management applications; how vendor applications compare in efficient and effective designs for interdisciplinary applications, such as orders management; what designs facilitate effective clinical decisionmaking; and what work design needs to be in place for successful implementation of CPOE.

Implementation science. Clinical systems implementation in health settings should be a third focus of future research. Anecdotal guidelines exist for systems implementation, but little evidence is available to guide institutions across the nation as they implement EHRs. As of late 2005, only about 20 percent of U.S. institutions had installed EHRs, HIMSS Analytics reported only 3 percent of institutions had CPOE by 2007 and none had a full EHR; therefore, research into the science of implementation can be of benefit in the future.[49] At the very least, we should uncover factors crucial for implementation success in health settings, especially from the organization and system design perspective. Funding should be made available for implementation studies outside academic medical centers and urban areas.

Evidence Table 1. CPOE Effects on Medication Errors

Source	Setting	CPOE	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Bates 1998[15]	Brigham & Women's (medical and surgical units)	Homegrown	Pretest, post-test	CPOE plus team effect on nonintercepted, potential, and all adverse drug events (ADEs).	Nonintercepted serious ADEs decreased by 55%. Preventable ADEs declined 17% (not significant). Nonintercepted potential ADEs decreased 84%. CPOE plus team offer no additional benefit over CPOE only. No differences seen for all ADEs.	48	CPOE and a "team effect" were intertwined in effects.
Bates 1999[10]	Brigham & Women's (3 medical units)	Homegrown: Transcription to a paper medication administration record required	Time series (1 pretest and 3 post-tests over 4 years)	Medication errors for pre- and post-CPOE x 3.	All errors decreased. Nonmissed dose errors decreased by 81%. Nonintercepted serious errors fell 86%. Nursing workflow impacted negatively and missed-dose errors increased.	43	Study spanned 4 years, during which national trends for patient safety changed. System design changed substantially.
Cordero 2004[25]	Ohio State Univ. neonatal ICU Inpatient	Vendor (Siemens)	Pretest, post-test with controls	CPOE effect on accuracy of Gentamicin doses.	Reduced medication errors for selected NICU drugs.	77	Results for select orders only.
Gandhi 2005[16]	Brigham & Women's 4 outpatient clinics	Homegrown: CPOE without checks or decision support	Cross-sectional	Prescribing errors, potential ADEs, and rule violations.	No differences in total errors, ADEs, or rules.	74	CPOE design had no checks for missing data, dosing, frequency, interactions.

Source	Setting	CPOE	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Kaushal 2003[19]	N/A	Various forms	Systematic review	Effect of CPOE and clinical decision support on medication safety.	CPOE and isolated clinical decision-support systems (CDSS) can reduce medication errors. Studies under-powered to detect differences in ADEs and have studied "homegrown" systems.	N/A	
King 2003[18]	Children's Hospital, Toronto, Inpatient	Vendor (Eclipsys). No interface with pharmacy. No decision support.	Retrospective cohort study over 6 years	Rate of medication errors on 2 CPOE medical units versus 1 medical and 2 surgical units over 3 years post-implementation.	Medication errors were 40% lower on CPOE units, but no difference for ADEs.	90	Medication study but no EHR interface to pharmacy. No decision support.
Kuperman 2003 [20]	N/A	Various forms	Systematic review	CPOE impact on LOS and medication errors.	CPOE reduces medication errors (incorrect dosing, interactions), transcription errors.	N/A	
Mirco 2005[17]	Portugal, internal medicine units, institution not named	Application not stated. Unit dose available, but no decision support or interaction checking.	Pretest, post-test, no controls reported	CPOE effect on medication errors.	CPOE eliminates transcription and patient identification errors. Errors were right class/wrong drug and unclear orders. Smaller % of errors due to frequency, incorrect dose, drug interaction, duplicative therapy, length of therapy.	37	No interaction checks or decision support available. Study spanned 2 years.
Papshev 2001[21]	Electronic prescribing in ambulatory practice	N/A	Systematic review	Electronic prescribing (including CPOE) effect on medication errors.	Reduces medication errors.	N/A	

Source	Setting	CPOE	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Potts 2004[9]	Vanderbilt	Homegrown "Wiz" order system	Pre/post with controls	CPOE effect on potential ADEs, medication prescribing errors (MPE), and rules violations (RV).	Reduced ADEs, MPEs, and RVs.	60	Unique homegrown CPOE design.
Shulman 2005[11]	Univ. College in London, ICUs	Vendor (GE systems)	Time series (1 pre and 4 post over 37 weeks)	CPOE without decision support and handwritten orders effect on medication errors and type of error.	Lower proportion of errors with CPOE. Reduced major/moderate outcomes for nonintercepted and intercepted errors combined. Two errors with CPOE resulted in patient harm. Increase in minor intercepted errors with CPOE (43 versus 93).	44	Errors tracked by one ICU pharmacist. No decision support in place.
Spencer 2005[12]	U. North Carolina, Chapel Hill, 2 medicine units	Vendor (Siemens). No pharmacy interface.	Pretest, post-test with controls	Effect of CPOE without decision support and handwritten orders on medication error rates.	Increase in reported errors for pharmacy processing. Other errors unchanged. Errors include drug allergy, duplicate orders.	50	Medication errors voluntarily reported. No pharmacy interface. Errors attributed to the lack of the pharmacy interface.

Evidence Table 2. Computerized Physician Order Entry (CPOE) Effects on Process Efficiency (Time and Length of Stay)

Source	Setting	CPOE	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Bates 1994[32]	Brigham & Women's (medicine and surgery house staff)	Homegrown	Pretest, post-test with no reported controls	Pre/post CPOE medicine and surgery house staff time spent in order entry activities.	CPOE takes more time (44–73 min/day), especially for one-time orders.	50	Unknown % of order sets, which speed CPOE times.
Cordero 2004[25]	Ohio State Univ. neonatal intensive care unit (NICU), inpatient	Vendor (Siemens)	Pretest, post-test with controls	CPOE effect on radiology result times for abdominal, chest films, medication turnaround times for caffeine loading doses, accuracy of Gentamicin doses.	Reduced medication and radiology turnaround times, medication errors for selected NICU drugs.	77	Results for select orders only.
Kuperman 2003[20]	N/A	Various	Systematic review	CPOE impact on length of stay (LOS).	CPOE reduces LOS.	N/A	
Lehman 2001[28]	Rush Presbyterian	Vendor (Siemens). No pharmacy interface.	Pretest, post-test with no controls	CPOE impact on pharmacy order turnaround time (order to medication delivery on unit).	Over 60% faster with CPOE.	74	Orders were printed in pharmacy and transcribed into pharmacy system.
Mekhjian 2002[26]	Ohio State Univ, transplant unit, medical intensive care unit, and surgical ICUs	Vendor (Siemens). CPOE plus eMAR.	Pretest, post-test with no controls	CPOE impact on medication turnaround times, radiology procedures, lab results.	Reductions in medication turnaround times, transcription errors. More timely results reporting for radiology and lab. Severity adjusted LOS decreased in 1 hospital but not another.	65	For selected medication orders only.
Ostbye 1997[27]	Univ. Western Ontario	Vendor (Siemens from Norway)	Quasi-experimental parallel comparison, descriptive	CPOE effects on results reporting on 2 similar surgical units.	Average time to complete and transmit lab tests decreased from 7 to 1.5 minutes. Results availability decreased by about 3 hours.	76	Good study design, but elected to not analyze data.

Source	Setting	CPOE	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Overhage 2001[31]	Regenstrief Institute	Homegrown. Used in 11 primary care clinics.	Randomized controlled trial. Time-motion study.	Time for CPOE compared to paper. Perceptions about order entry.	CPOE is 2.2 min per patient longer, but when duplicative tasks are removed, only 0.43 min per patient longer. Perceptions that work is done faster, quality of care and documentation is improved.	108	Unique homegrown CPOE application.
Papshev 2001[21]	N/A	N/A	Systematic review	Electronic prescribing (including CPOE) effect on time	Can eliminate the time gap between point of care and point of service.	N/A	
Shu 2001[33]	Massachusetts General Hospital	Homegrown	Pre/post with pager reminders for time recording	CPOE impact on physician time.	Interns spent 9% of their time ordering vs. 2.1% pre-CPOE. Counterbalanced by less time spent for nursing, pharmacy and quality and efficiency changes.	54	
Tierney 1993[29]	Regenstrief (Wishard Memorial Hospital) 6 inpatient internal medicine services	Homegrown. Orders printed and not sent electronically to departments.	Randomized controlled trial with time-motion study	Effects of orders entered by interns into a computer workstation compared to paper.	Mean LOS was 0.89 day shorter. CPOE interns spent 33 minutes longer per 10-hour period (5.5 min/pt/day).	110	Orders routed to printers in pharmacy. Otherwise printed and treated like paper records.
Thompson 2004[13]	St. Paul's Hospital, Vancouver, 11-bed ICU	Vendor (Eclipsys)	Pretest, post-test	Effect of CPOE on the timeliness of urgent lab and imaging test results.	Improved test turnaround time for stat lab and radiology orders.	54	Used order sets.

Evidence Table 3: Quality Care Variables

Source	Setting	CPOE	Study Design	Study Intervention	Key Findings	Quality Score	Considerations
Han 2005[14]	Univ. Pittsburgh, inpatient pediatrics	Vendor (Cerner)	Pretest, post-test with controls	Effect of CPOE on pediatric mortality rates.	Mortality rate increased from 2.8% to 6.57%.	61	New workflows substantially delayed treatment for critically ill patients. ICU order sets not available. Unclear how CPOE was measured. Possible colinearity between CPOE and severity of illness, shock.
Salmasy & Marx 1997[34]	Urban academic center	Not stated	Pretest, post-test with controls (over 4 years)	CPOE effect on documented consents.	Increased from 75% to 90%.	74	Significant differences in patients' severity of illness. Increased national emphasis on DNR orders during the study duration.
Stair & Howell 1995[50]	Georgetown Univ. medical students on emergency medicine rotations	Not stated	Randomized controlled trial. Students randomly assigned to 4 different locations.	CPOE effect on quality of orders for an imaginary patient.	Quality scores for medical students at CPOE sites better than manual.	94	

Evidence Table 4: Qualitative and Descriptive Studies

Author(s)	Site	CPOE	Study Design	Study Intervention	Key Finding(s)
Ash 2004[41]	Sites in the Netherlands, Australia, and 4 hospitals in the United States	Various applications	Qualitative description of unintended errors	Unintended effects of patient care information systems.	Unsuitable human–computer interfaces for interrupted tasks, cognitive overloads with structured or complete information entry, work fragmentation, overcompleteness; misrepresentation of workflows as linear, clearcut and predictable, inflexibility, rigid requirements for medication orders, work-arounds, loss of communication & feedback, decision support overload, and a decrease in redundancies for error catching.
Dykstra 2002[36]	Univ. of Virginia, El Camino Hospital, Puget Sound and American Lake VA Hospitals	Various systems	Qualitative	CPOE's role on communication patterns.	Impacts on physician–nurse communication without a physical presence, availability of information for the care-team and patient increases, "black box" may mask errors.
Koppel 2005[42]	Urban tertiary care teaching hospital	Vendor (Eclipsys)	Qualitative – interviews, focus groups, observations on 261 physicians, nurses, and pharmacy leaders	CPOE's role in medication errors.	CPOE facilitated 22 medication error sources due to fragmentation of data, lack of systems integration, and human-machine interface flaws.
Sittig 2005[35]	U. Virginia, VA Hospital, El Camino hospitals with recent and long-standing CPOE installations	Various systems	Qualitative – interviews with 50 people (physicians, physician assistants, and nurse practitioners)	Emotional responses to CPOE installations.	Prevalent negative emotions. Implications for CPOE design (irrelevant alerts, slow systems, focusing making "the right thing the easiest to do").
Weir 1995[37]	VA	Homegrown	Descriptive survey	Nurses' perceptions of work, quality of care, and physician–nurse communication.	Positive impact on the quality of care, less job control.

Barcode Medication Administration in EHRs

Background

To Err Is Human focused attention on the frequency of medical errors occurring in U.S. hospitals.[6] In response, the health care industry has been counting upon the strengths of technological innovations to improve patient safety and decrease medical errors. Before the IOM report, the Harvard Medical Practice Study revealed that medication errors most frequently occurred in hospitals.[51] Medication errors can occur at any stage of the medication administration process—starting at the ordering of the drug by the physician, followed by dispensing of the drug by the pharmacist, and ultimately ending in the actual administration of the drug by the nurse to the patient. However, a 1995 study showed that 38 percent of potential and preventable ADEs occurred at the time of administration by nursing personnel.[52] Further evaluation of these errors found that wrong dose, followed by wrong route and wrong drug, were the most common administration errors.[53]

As discussed in the previous section of this chapter, the implementation of CPOE systems is targeted to eliminate errors occurring at the ordering phase. On the other hand, barcode medication administration (BCMA) systems work toward decreasing errors that arise further into the medication administration process. Integration of the two technologies, that is, BCMA systems with CPOE systems, can lead to significant improvements in patient safety and efficiency of medication administration.

National organizations leading the patient safety efforts have recognized the improvements brought about by the implementation of barcode technology in hospitals. The IOM, National Patient Safety Foundation, and the American Society of Health-System Pharmacists have recommended the implementation of BCMA systems as a means for improving patient safety. In 2004, the U.S. Food and Drug Administration (FDA) mandated the barcoding of all medications and blood components to decrease adverse events.[54] This rule requires pharmaceutical companies to provide a National Drug Code (NDC) on most prescription medications and some over-the-counter medications. Additionally, in compliance with the Joint Commission's (formerly the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO) patient safety goals, all hospitals are required to implement barcoding technology for patient identification and for matching patients to their medications by 2007.[55]

Thus, BCMA systems are strongly associated with efforts to bring about a culture of safety in health care. BCMA systems particularly impact the role of nursing in the administration of medications at the bedside. In this section, the empirical evidence surrounding the use of BCMA systems is evaluated, describing the integral role it has come to play in nursing care, and suggesting future directions for research.

Use of BCMA for Medication Administration

Barcoding technology has a variety of applications in health care. It has been used previously for a broad array of applications, such as transfusion and blood bag matching,[56–59] tracking laboratory specimens,[60] and inventory control,[61–63] etc. However, the application of barcoding to medication administration is newer.

Barcode technology can be used as a stand-alone application or linked to the CPOE or EHR system in the hospital. If the BCMA system is not integrated into the EHR, there would be

limited capability to have real-time alerts to detect discrepancies of the medications administered against the orders entered by the physician or to maintain an accurate documentation of medications administered.

In an integrated EHR environment, there is a seamless flow of information following every stage of the medication administration cycle, making it possible for BCMA systems to become part of the medication process workflow. Upon admission, every patient receives a barcoded wristband. These bands identify patients as they are steered through various tests and procedures at the hospital. After examining the patient, the provider enters medications electronically into the CPOE system. Following verification, the pharmacist packages unit doses of the ordered medications into barcoded containers and sends these to the nursing floor. The barcoding on the medication containers has information regarding type of medication, recommended dosage, and the frequency of administration.

The unit doses sent by the pharmacy are stored in a medication cart, which also carries a wireless laptop computer and a hand-held scanner. In an integrated EHR environment, the barcode scanning is linked to the clinical databases via a wireless network. At the patient's bedside, nurses scan their badges, or log into the BCMA system, scan the patient's wristband, and scan the medication. The BCMA system validates whether the "five rights" of medication administration—right patient, right drug, right dose, right frequency, and right route[64]—match the order entered in the CPOE system. If there is a discrepancy, an alert is displayed on the computer screen. Once a medication is scanned it is automatically documented in the medication administration record (MAR) as having been administered to the patient. In most BCMA systems, the nurse has the capability to record missed medications or changes in the time that the medication was administered. Thus, the BCMA system not only offers real-time validation at the point of care, it can also reduce nurses' workloads by creating an automatic and accurate log of the medications administered to the patient.

Research Evidence for BCMA

The research evidence on the use of BCMA systems is limited. The majority of the studies reporting outcomes related to implementation of BCMA technology were conducted in Veterans Health Administration (VHA) facilities; the VHA is a pioneer in the implementation of barcode technology for medication administration. The BCMA system currently used at the VHA is a homegrown system that has undergone several modifications. BCMA technology was first prototyped at a Topeka, Kansas, facility in 1996. In 1999, the BCMA system was integrated with the Computerized Patient Record System (CPRS), which is the CPOE system used at the VHA.[65] By 2000, the system and the associated hardware were implemented in 92 percent of the VHA inpatient wards. The following section discusses the evidence related to key variables associated with BCMA.

Decrease in medication errors. The most commonly measured variable was the change in medication error rate. Four studies described the measurement of this variable: three showed a decrease, and one study recorded an increase in medication error rate post-BCMA implementation. Coyle and colleagues[66] described the implementation of a BCMA system at one VHA facility—some of the refinements and upgrades that the system had undergone based on nursing recommendations. The changes were made to address specific workflow issues to increase acceptance of BCMA in routine practice. A survey administered to the nursing staff evaluated the acceptance of BCMA technology after 3 years of implementation. Results showed

that 97 percent of the nursing staff agreed that BCMA had decreased the risk of medication errors. Additionally, in the first year, the medication errors decreased by 23 percent, and, by the fifth year, by 66 percent. Consistent with these results, another VHA study by Johnson and colleagues[65] compared the overall medication error rates in 1993 and 2001 and found an 86 percent decrease over this period. Anderson and Wittwer[67] conducted a similar study in a non-governmental setting and found that the medication error rate decreased to less than 50 percent of its baseline value within 6 months of implementation of the BCMA system.

Another study measuring medication error rates was conducted in the medical-surgical units of a Midwest government hospital.[68] This study examined whether there was a difference in the medication error rate 1 year before and after implementation of BCMA. The error rates at the administering and dispensing stages were specifically examined. The study showed an 18 percent increase in the medication error rate. However, this increase was explained by the ability of the BCMA system to record any discrepancies in the medication administration, such as late or missed doses, which were previously underreported or went undocumented.

Discrepancies in documentation. The documentation functionality of BCMA systems enables the creation of an accurate and complete MAR, which can then become part of the patient's EHR. However, large discrepancies exist in medication documentation, even in an electronic environment. Only one study compared the discrepancies in documentation that arise upon implementation of a BCMA system. An examination of the discrepancies between MAR and patient billing records for large-volume intravenous solutions identified three types of discrepancies.[69] Failure to document administration to a patient occurred 38 percent of the time, the rate of failure to credit the patient for returned solution was 37 percent, and the rate of administration of solution to a patient other than for whom it was dispensed was 25 percent. This study also examined the potential for BCMA technology to decrease these discrepancies in documentation. A 19-percent improvement in the consistency of documentation was observed after introducing BCMA technology.

Impact on nursing workflow. A supplementary finding of the study by Barry and colleagues[69] was that the lowest scanning rates for items were achieved by the nursing personnel, largely because BCMA has such a huge impact on the workflow of nurses. In this study, the scanning capability was available only at the nursing station, requiring nurses to return to the station each time they wanted to scan an item. Lack of consideration of nursing workflow processes can result in low rates of adoption of BCMA technology. Another study of the medication administration process from the perspective of nurses found ways to make the technology less disruptive to nurses' workflow.[70] The researchers described strategies to improve acceptance of the technology among nurses and hypothesized that a tangible measurement of this acceptance would be seen in the increase in scanning rates. Patient armband scans went up by 7 percent, and medication label scanning showed a 15-percent increase over a 5-month period. The increase in scanning rates was small, but the study lacked a clear description of what the exact intervention was, and hence it is difficult to make conclusions about why it failed to have a larger impact on the scanning rates.

Using human factors theories to guide an ethnographic evaluation, before and after implementation of a BCMA system, the analysis and process-tracing protocols derived five negative, unintended effects of introducing this technology.[71] The investigators found that BCMA technology can lead to the creation of work-arounds that might result in new paths to occurrence of ADEs. This study is the first of its kind to conduct an in-depth analysis of the

design modifications, organizational policies, and elements of training that need to be in place for BCMA technology to fit seamlessly into the nurses' workflow.

Thus, the range of variables assessing the impact of BCMA technology on the workflow of nurses is broad and complex. An example of a simplistic variable is the measurement of the nurses' acceptance of BCMA technology by number of medication and patient identification scans.[70] Complex variables surrounding nurses' workflow have been measured using conceptual frameworks derived from the human factors engineering domain, such as recognition-primed decisionmaking (RPD), human-automation interaction, workload, authority-responsibility double-binds, and mutual awareness among members of the clinical team.[71]

Use of BCMA in the outpatient setting. Only one study described the use of BCMA in the outpatient pharmacy setting.[72] This was a small feasibility study evaluating whether BCMA could be used for automatic verification of medications during dispensing. The study suggested that manual checks could be replaced by barcode technology to improve pharmacist productivity and increase cost savings; however, empirical evidence supporting these conclusions was absent.

Beyond medication error rates. Unlike CPOE systems, there is a fair amount of uniformity when describing a BCMA system. Also, contrary to CPOE interventions—which were conducted largely at urban, academic institutions—BCMA studies are primarily conducted in VA settings. However, the slow penetration of this technology has resulted in very few evaluation studies. In general, there is a paucity of empirical evidence supporting the implementation of BCMA systems. The BCMA technology is advocated as an important safeguard for reducing ADEs, but sufficient evaluation of how this technology affects the dynamics of a complex hospital setting, in ways other than the reduction of medication error rate, is lacking.

Evidence-Based Practice Implications

The implementation and adoption of BCMA systems is slow, perhaps due to disruptions in nurses' workflow. Ease of use is directly linked to technology adoption. Inpatient environments are extremely busy and require technology that can easily adapt to the needs of nurses, enabling them to adopt the new technology readily into routine care.[73] Coyle and Heinen[66] provide a good description of how nursing staff are involved in the design and modification of BCMA software at the VHA. These recommendations helped the information technology team design software to align with workflow needs. Also, there is an effort by vendors to constantly upgrade and update the equipment to make it more user-friendly. The VHA environment has reaped the benefits of involving its nursing staff in the development process and implementing staff recommendations.[71, 74] Other hospitals need to consider this strategy to improve acceptance of BCMA technology by nurses. The VHA also has a national BCMA development team that is entrusted with the responsibility of continuously evaluating and revising the technology.[71]

Impact on nursing workflow. One of the efforts recently suggested was the replacement of the laptop computer with hand-held devices. A field evaluation of usability of this technique with nurses revealed that, while this might be useful for the administration of pain medication and hanging IV fluids, it was not ideal for use with medications in general.[66] Such determinations made from actual field studies serve two purposes. First, they enable nurses to be involved in the process of development and deployment, thus fostering ownership of the technology. Second, evaluation of the technology in a naturalistic setting can help us understand the far-reaching

impact that the introduction of a new technology can have on the workflow patterns—and prevent any new threats to safety that might be introduced by the technology itself.

Changing nurses' perceptions about technology. Adoption of BCMA technology calls for a behavioral change. According to the Technology Acceptance Model,[75] such a change can be brought about by improving perceptions regarding the system, specifically perception of the ease of system use and its usability in routine practice. Tailoring interventions that are geared toward understanding nurses' perceptions will promote adoption. System training should focus on educating nurses about how BCMA serves as a safety net and aids them in preventing errors. Also, organizational policies that support a transparent environment for the reporting of errors—rather than a culture of blame—can improve nurses' perception of BCMA technology. As the nursing shortage increases in hospitals across the nation, nurses need to view safety checks, such as BCMA technology, as aids rather than impediments in their practice.

Enhancing interdisciplinary communication. A seamless integration between the CPOE and BCMA systems can enhance workflow and also build interdisciplinary communication. Information systems have the capability to serve as the common thread linking an interdisciplinary clinical team with the therapeutic decisions driving patient care. Expansion of BCMA into institutions will strengthen nurses' relationship with other members on the clinical team and help other clinical staff to better appreciate nurses' contribution to patient safety.

Research Implications

Nursing practice has undergone a dramatic transformation with the implementation of BCMA systems. BCMA increases the visibility of the nurse's role in the medication administration process and contributes to the organization's commitment to patient safety efforts. Strategies that can be employed to enhance future research efforts in this domain are discussed below.

Medication error rate. A deeper examination is needed for the most commonly evaluated variable characterizing the medication error rate. No study reports an analysis regarding the type of ADEs, such as preventable and potential (often called near misses), that occurred while a BCMA system is in use. Such an evaluation would give us a deeper understanding of the ADEs that are being missed by the system and allow us to create modifications to better capture them.

Need for evaluation of economic outcomes. The policies of the FDA mandating barcoding of medications and the regulatory efforts of other patient safety organizations will, hopefully, encourage adoption of barcode technology. Research in this domain is limited and needs to be expanded to include examination of some core outcomes related to BCMA implementation. Quantitative estimations of return on investment following BCMA implementation and economic outcomes resulting from prevention of medication errors will expedite the adoption of this technology in more hospitals.

Outcomes such as reduced length of stay, decreased number of nursing full-time equivalents needed to perform medication administration, and decreased litigation following administration of incorrect medications are important economic considerations that hospital administrators evaluate when deciding in which technology to invest their health care technology dollars. These outcomes need examination with respect to BCMA technology.

Need for nurse involvement in BCMA implementation and design. As BCMA technology gets deployed in the medication administration process, it will have serious implications for nursing practice. Several issues surrounding the nursing workflow environment

need to be examined when implementing a BCMA system. Issues ranging from the usability of the hardware and software to pragmatic issues, such as the ease of use of the barcode reader and availability of the portable computer, will determine nurses' acceptance of BCMA in their patient care routine. This offers nurse researchers unique opportunities to provide leadership in the development and design of BCMA systems. Active collaboration of nurses with information technology personnel—to provide input on the display of alerts for urgent orders, reports of missing medications, or on recording the missed medications during a shift—can be invaluable to the deployment of BCMA systems.

Sociotechnical evaluation. Evaluation of BCMA technology from a sociotechnical perspective would help gain a deeper understanding of nurses' use of BCMA systems. There is a paucity of literature measuring the sociotechnical issues of compliance with alerts, cognitive load, efficiency, productivity, and emotional aspects of using the technology.

Documentation discrepancies. Besides serving as a safety check for nurses in the medication administration process, BCMA systems also play a key role in creating electronic MARs. Discrepancies in the documentation process have also been evaluated. Such discrepancies arise when medications that have been dispensed by the pharmacy fail to be administered by nurses. The returned medications are not credited back into the patient's billing account. Thus, discrepancies arise between what is dispensed, what is administered, and ultimately what the patient is billed for. Even though documentation discrepancies have been examined, there is no evaluation of the economic impacts of these discrepancies. Such discrepancies could lead to undesirable fiscal outcomes for the hospital, which might affect adoption of these systems. A systems analysis of how these discrepancies arise and what organizational policies can be put in place to inhibit them needs to be conducted.

The implementation of barcode technology can prevent the potential or near-miss errors that would not have been detected otherwise. Nurses must take an active and visible role in the development and deployment of BCMA technology. Participation is the key solution to implementing BCMA technology.

Evidence Table 5. Studies Evaluating Barcode Medication Administration (BCMA)

Source	Setting	BCMA	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Anderson 2004[67]	St. Mary's Hospital Medical Center	Vendor	Pretest, post-test	Decrease in medication error rate.	The goal of 50% decrease in medication errors in the pilot unit was exceeded within 6 months of implementation. A 44% decrease in medication errors was reported for the entire hospital.	46	Lacks description of implementation process and how medication error rate was measured.
Barry 1989[69]	2 nursing units and 2 controls in a private, not-for-profit hospital	Homegrown	Pretest, post-test with controls	Potential for using barcode technology to reduce documentation errors of IV solution administration.	Errors were traced to three primary sources: (1) failure to document administration of solution (38%), (2) failure to credit patient for IV solutions returned to the pharmacy (37%), and (3) administration of solution to the wrong patient (25%).	48	BCMA was tested specifically on IV solutions. In-service training sessions were conducted.
Coyle 2005 [66]	Various Veterans Affairs Medical Center (VAMC) hospitals	Homegrown	Time series	Survey of nursing staff perceptions about BCMA decreasing risk for medication errors. Decrease in medication errors.	After 3 years, 97% of the nursing staff agreed that BCMA could decrease the risk for medication errors, potential and actual. Medication errors decreased by 23% in the first year and by 66% after 5 years.	44	Description of nursing staff involvement in the design and modification of BCMA system to resolve workflow and software issues. Good description of BCMA functionality. Lacks description of study methodology and study subjects.
Englebright 2005[70]	85 facilities of Hospital Corporation of America	Unknown	Pretest, post-test	Frequency of scanning patient armbands and medication labels.	Patient armband scanning increased by 7%, and medication label scanning increased by 13%.	31	Lacks description of implementation process and a description of how acceptance among nurses was improved.

Source	Setting	BCMA	Study Design	Study Intervention	Key Finding(s)	Quality Score	Considerations
Hokanson 1984[72]	1 outpatient pharmacy service in an ambulatory clinic	Homegrown	Cross-sectional	Feasibility study of using BCMA in the pharmacy setting.	No dispensing errors were made.	39	The study was conducted for a limited time (36 hours) and a single clinic session.
Johnson 2002[65]	VAMC	Homegrown	Time series	Number of medication errors prevented.	Prevented 549,000 medication errors while dispensing 8 million doses, in 6 years.	57	Compared medication rates from the manual medication administration system and the electronic BCMA system.
Low 2002[68]	2 medical surgical units at a Midwest government hospital	Vendor (Tremont BCMA)	Pretest, post-test	Medication error rate 12 months pre- and postimplementation of a BCMA system.	Medication error rate increased by 18% after BCMA implementation due to enhanced reporting by BCMA system.	62	The measurement of medication error rate prior to implementation was using the incident report system, while post-BCMA implementation the system would create automatic logs if any discrepancies arose in the medication administration.
Patterson 2002[71]	Acute care and nursing home wards of three VA hospitals	Homegrown	Cross-sectional, observational study before and after implementation	To identify the negative, unintended side effects resulting from the implementation of BCMA systems that can create new paths to ADE occurrence.	Five negative side effects after BCMA implementation were identified.	98	The outcomes of this study serve as recommendations for design modification of the BCMA system in the VA.

Decision-Support Systems for Nursing

Background

Patient safety researchers view decision-support systems (DSS) as a solution to high rates of medical errors and inappropriate care. Many researchers view embedding DSS systems into well-developed, comprehensive CPOE systems as the only method to significantly impact clinical decisionmaking. Order entry with DSS harnesses the full potential of the computer to provide relevant information, guide decisions, and structure data entry.[6, 76, 77] For this section of the chapter, the main focus is on decision-support interventions for nursing that are embodied within a CPOE system that is linked to a comprehensive electronic health record (EHR). DSS interventions were considered if they were implemented in the context of an existing CPOE system or could easily be integrated into a CPOE system. Decision-support systems are software designed to support or enhance clinical decisions. This is a broad definition and includes changes in information displays, alerts, reminders, or fully developed algorithmic computerized protocols.

Research Evidence

There were two published studies on nursing-specific DSS studies conducted in a CPOE environment.[78, 79] There were many other published studies that reported early development work and validation results for DSS related directly to nursing. However, because so few were implemented, they were not eligible for inclusion here. Overall, there were 31 studies where the DSS intervention either was embedded in an EHR with CPOE or could reasonably be expected to have that capacity (see Table 6). This set of studies could be divided into two groups. The first group includes those studies targeting nursing decisionmaking directly (e.g., prevention of pressure ulcers, incontinence, triage). There were 13 studies in this group; however, only one was actually implemented in a CPOE system. The second group includes those studies largely targeting physicians, but the clinical focus could reasonably be associated with nursing. This judgment is, of course, subjective, as nursing is involved in almost all aspects of care. However, some activities have substantial nursing involvement. There were 18 studies in this second group, covering three broad areas: (1) acute care guidelines for selected topics, (2) critical care, and (3) preventive care. There were many other studies where the role of nursing might be significant, such as coagulation therapy or diabetes management. Because the nursing role was not explicated and would likely vary, these studies could not be included.

Direct decision support for nursing. Out of the 31 studies identified as relevant, 13 focused directly on nursing. Three studies concerned consultant systems for the prevention of pressure ulcers. All three were essentially qualitative or descriptive, presenting very little patient outcome data.[80–82] Decision support for the management of urinary incontinence has been studied as well. Petrucci and colleagues[83] found large increases in knowledge and decreases in episodes of urinary incontinence in a patient care unit where a consultation system was implemented, as compared to a unit in the same hospital where it had not been implemented. Three studies examined the performance of staff conducting telephone triage with the help of algorithmic decision-support systems. All found improved performance, although all three used the weakest design, a pretest, post-test evaluation.[84–86] Two other studies directly addressed alerts and reminders to nursing staff for preventive care. Both of these showed strong results, including

one study that compared standing orders with alerts directed at nursing staff to alerts directed toward physicians.[79, 87]

In another study, the effects of different forms of physiologic data displays in a neonatal ICU were examined in a CPOE environment.[78] In this study, all infants were randomly assigned during an 18-month period to one of four groups: (1) no display of trend data, (2) continuous display of trend data, (3) alternating 24-hour display of trend data starting in the first 24 hours, or (4) the same as the third group starting after the first 24 hours. The number of orders for colloid, blood gases, and ultrasound were measured, as were longer-range variables, such as total time on ventilation, total time on supplemental oxygen, length of stay, and death. No differences in patient outcomes were noted, although surveys found increased knowledge regarding neonatal physiology on the part of the staff. Because patients rather than clinicians were assigned randomly, it is highly likely that there was dispersion of the effects of the independent variable.

Finally, several studies on a clinical decision-support system (CDSS) that guides nurses in identifying patient preferences consistently found improvement in the degree that nurses were able to act in accordance with patient preferences. These studies employed a high-quality design, and although the program was never embodied in an EHR, it is conceivable that one day it might implemented with resultant, improvement in the continuity of care.[88–90]

Indirect decision support for nursing. The remaining 18 studies were selected because they used a computerized intervention that either was instituted in a CPOE environment or used a well-established EMR. In addition, these studies focused in areas where nursing would likely be highly involved. One study[79] contrasted standing orders (to the nursing staff) versus computerized reminders for preventive care for inpatients, finding nearly twice the improvement with standing orders. Three studies focused on the use of guidelines to prevent deep venous thrombi in post-surgical patients, involving both nursing and physician activities. In two of the studies, significant results were found for provider compliance using the guidelines, but no difference was found regarding patient outcomes.[91, 92] In the third study,[93] both compliance with guidelines and patient outcomes were improved.

Four other studies were conducted in critical care settings, involving mostly complex guidelines (e.g., ventilator support). In two other studies, the effects of a computerized guideline for the treatment of adult respiratory distress syndrome were the focus of the investigation. Both were conducted by investigators from the LDS hospital in Salt Lake City, which had an extensive EHR at the time, but not full-scale provider order entry. East and colleagues[94] examined the impact of the computerized guideline in a prospective multi-center randomized trial for 200 patients. No significant differences were found in survival or ICU length of stay between treatment groups. There was a significant reduction in morbidity as measured by a standard scoring system, as well as a lower incidence of over-distension lung injury. In a similar study, a pilot of the study published above at Memorial Hermann Shock Trauma ICU, McKinley and colleagues[95] randomized 67 trauma patients to either being cared for by the protocol or not. No difference was found between patients in terms of survival, length of stay, or morbidity.

In another study conducted in the outpatient setting in the VA, with a complete CPOE system, computerized guidelines for mental health screening resulted in significantly higher compliance than paper guidelines. It was not clear in the description how nurses (not including the advance practice nurses) were involved in the implementation, but they might have been the individuals actually receiving the alerts.[96]

Several studies using qualitative techniques found similar issues. Karfonta[97] used grounded theory to examine the experiences of 23 nurses and 10 physicians using DSS systems in the ICU.

Overall, all interviewees mentioned the role of DSS in assisting in forecasting the outcomes of decisions. Difficulties in learning the system, trusting the output, and understanding the technology were additional themes.[97] Lyons and colleagues[98] examined VA employees' perceptions of guideline implementation and utilization in the VA's CPOE system. Information technology issues were perceived as major barriers to effective guideline implementation. Patterson and colleagues[99] conducted a human factors qualitative analysis of the VHA clinical reminder system and noted that increased workload, training, time, and role divisions were key barriers to success.

The remaining studies all focused on preventive care reminders or hypertension followup, with only two focused mainly on nursing.[87, 100] In most cases, but not all, the studies found improved compliance. Because the studies took place in the outpatient setting, the role of the nursing staff likely varied greatly, but is not elucidated. Further analysis would have to be done to determine if an increased role of nursing in providing followup and initiating immunization was a determinant contributor of success.

Challenges with research evidence. Three main themes can be extracted from the results. First, for the most part, nursing activity is simply not addressed in these studies. Nurses make decisions every day about pain and wound management, whether a patient's symptoms are severe enough to notify a physician. Nurses often have to decide if a patient's symptom is drug related, or if a drug might interact with other drugs before they give them. In many cases, nurses have primary responsibility for patient education and family support. Few decision-support interventions have been developed for any of these high-level, decision-based actions. It is as if nursing decisionmaking is invisible and nurses are viewed as data collectors, rather than decisionmakers. In addition, one of the main roles that nurses fill in an inpatient setting is that of an intermediary between the patient and other providers. This communication role is a crucial function in ensuring quality of care. However, communication has been significantly neglected in EHR designs, as was noted earlier in this chapter and by many other authors.[101, 102] Most of the work to create DSS has focused on structured documentation, order review, or systems designed to force or track nursing actions. For example, one study examined the effectiveness of putting a signal on a nurse and tracking where they were at all times to ensure efficiency.[103] Another study examined the impact of opening locked medicine cabinets (in the room) only when medications were due, to ensure that nurses would give them on time.[104]

Second, the mechanics of providing DSS for nursing in a regular CPOE inpatient setting has not been well explicated. In many settings, the computers are located at the nursing stations, making them unavailable at the time of care. The model of having decision-support software located on computers situated at the nursing station fails to support a nurse who is constantly on the move. Development and exploratory work has been published, examining the use of portable laptops or hand-held computers, but no high-quality studies have reported on an actual implementation directed at nursing.

Third, none of the studies have examined the mechanism of action for DSS interventions. This is true of the DSS literature in general. Because DSS interventions can range from alerting a clinician about something they already know (e.g., a reminder), to alerting the staff to where a patient is in a process (tracking), to providing new information that educates and informs, it is important to measure the intended psychological effect as well as the outcome.[105, 106] Although most studies show significant increases in provider compliance, the effect is small, and the upper limits are in the low 40- or 50-percent levels.

Evidence-Based Practice Implications

The above three themes provide a framework for discussing how to link this work to practice. Because the large body of nursing activity is simply not addressed in these studies, it is difficult to identify the important practice implications. Many clinical interventions are likely designed by nursing for quality improvement purposes using the EHR, and these are not being captured in the formal research literature. In the VHA, there are substantial local initiatives led by nursing to improve patient care using the functionalities provided by the CPOE. Few, if any, are published. If they are published, the focus is on "lessons learned" rather than to provide scientific evidence of efficacy. Nurses in practice can inform themselves of the functionalities of their EHR and volunteer to serve on hospital informatics committees that make strategic decisions. Adapting the system to nursing's needs and adapting to the system is a process of whole-system transformation.[107–109]

The second issue regarding the improvement of practice is how to improve the mechanics of providing DSS for nursing in the inpatient setting, given the fact that nurses are often on the move. Some of the more effective decision support can be arrangements of lists, printouts, and other easy-to-carry tools to simplify and organize data. Most EHRs have the capacity to be customized to individual clinical needs. Nurse managers are in a unique position to evaluate their system and participate in the development of low-resource-impact, decision-support tools. Nurse managers could also be involved in technology planning, to ensure that computers are available at the bedside. In addition, interventions, such as BCMA, structure nursing documentation. But because it is linked to an information system, imbedded DSS could easily be implemented to alert nurses about possible ADEs.

Because DSS is likely to be implemented by administration, it is important that the nurse managers argue for evaluation of the system. Evaluation should focus on measuring the implementation itself, the work process changes, and the outcomes. The evaluation should be started at the same time as the implementation so that the information gleaned will not only minimize any negative impact on patient safety, but also will provide for maximum input by nursing staff during the change process. Ongoing evaluation is essentially a quality management activity and is a practical approach to clarifying the mechanisms of action—and to ensuring that the impact of DSS on nursing practice is formally addressed.

Research Implications

The three themes identified above also provide a framework for discussing future research implications. The work that needs to be addressed immediately is clarification of nursing roles in the implementation and success of DSS systems, especially those implemented in the context of CPOE systems. Most of these interventions are multidisciplinary and involve substantial process reengineering that goes largely unreported. Nurses are in a position to fully comprehend the depth of this reprocessing, and expanding our understanding in this area would be a contribution to the field as a whole. Implementation as a science is expanding, and nursing expertise is crucial.

Secondly, much more work needs to be done to delineate and clarify the actual decisions made by nursing in order to develop effective decision-support systems. This goal can be accomplished in two ways. More qualitative work is needed to describe and analyze nursing decisionmaking using recent theoretical advances in the cognitive sciences. Activity theory,[110]

goal theories,[111] and adaptive rationality[112] are areas that would be very useful as approaches to understanding nursing practice. In addition, although many studies have been published that explore decisionmaking and nursing expertise, some of which have been developed and validated, very few have been actually implemented. Nursing needs to examine the barriers that prevent the outcome of these research projects from reaching higher levels of adoption.

Finally, because the mechanism of action for DSS interventions is not examined, future advancement in the field of decision support is constrained. As described above, mechanisms are likely to be either psychological (e.g., directing attention, decreasing memory loads, or educational) and/or organizational (e.g., changing work processes and role behaviors). Designing studies that measure memory load, manipulate and test the role of attention, and directly assess learning effects as part of a DSS design would greatly advance the science.

Evidence Table 6. Decision-Support Systems Within an Electronic Health Record Related to Nursing

Source	Setting	Study Design	Study Intervention	Key Finding(s)	Quality Score
Barnett 1983[113]	Outpatient	Randomized controlled trial	Reminders for followup for hypertensive patients.	Followup was significantly improved in the group receiving the reminders, in rate of followup attempted or achieved by the responsible physician and in the repeated recording of blood pressure.	90
Barton 1990[114]	Outpatient health maintenance organization	Pretest, post-test	Postcards compared to simple reminders compared to feedback and reminders.	No changes in vaccination rates until computerized reminders were supplemented with feedback to individual providers.	48
Cannon 2000[96]	Outpatient mental health VA	Randomized controlled trial with patients randomized within providers	Computerized vs. paper reminders for screening and documentation of mood disorders using CaseWalker.	The computerized screening reminders resulted in a higher screening rates for mood disorder (86.5 vs. 61 percent, *P* = 0.008) and improved documentation.	90
Clark 2005[80]	Multilevel care in Canadian Health Region	Qualitative, descriptive	Computerized advisory management system to prevent pressure ulcers.	Evaluation indicated an increase in knowledge relating to pressure ulcer prevention, treatment strategies, resources required. Lack of visible senior nurse leadership; time required to acquire computer skills and to implement new guidelines; and difficulties with the computer system were identified as barriers.	N/A
Coe 1977[115]	Outpatient	Cluster case cohort	Blood pressure management in outpatients using computerized reminders.	No significant difference in patient outcomes.	64
Cunningham 1998[78]	Critical care	Randomized control trial	Continuous trend display vs. summative aggregated displays.	None of the short-, medium-, or long-term patient outcomes demonstrated any significant benefit from the provision of computerized physiologic trend monitoring.	102
Dale 2003[116]	Emergency services	Pretest, post-test	Consultant support for nurse triage.	More patients requiring an ambulance were seen in the emergency department for the intervention group as compared to the control (odds ratio = 2.62; 95% CI = 1.78–3.85).	90
Davidson 1984[87]	Outpatient	Pretest, post-test	Specific nurse-targeted reminders.	Significant increases in stool examination for occult blood (32% to 47%), breast examination (29% to 46%), and influenza immunization (18% to 40%).	78

Source	Setting	Study Design	Study Intervention	Key Finding(s)	Quality Score
Dexter 2004[79]	Inpatient	Randomized controlled trial	Compared standing orders to computerized reminders in a CPOE environment.	Patients with standing orders received an influenza vaccine significantly more often (42%) than those patients with reminders (30%) ($P < 0.001$). Patients with standing orders received a pneumococcal vaccine significantly more often (51%) than those with reminders (31%) ($P < 0.001$).	110
East 1999[94]	Critical care	Randomized controlled trial	Computerized guidelines for management of ventilated patients.	No significant difference in survival or ICU length of stay between the two treatment groups ($X^2 = 0.49$, $P = 0.49$) and ($F(1) = 0.88$, $P = 0.37$). There was a significant reduction in morbidity ($F(1) = 4.1$, $P = 0.04$) and severity of over-distension lung injury ($F(1) = 45.2$, $P < 0.001$).	102
Hutchison 1989[100]	Outpatient clinic	Pretest, post-test repeated measures	Printed reminders attached to charts taken from EMR.	Vaccination rate increased from 10.1% to 26.8% and no increase in influenza immunization in the comparison practice.	64
Karfonta 1999[97]	Critical care	Qualitative analysis of nurses and physicians	DSS in general.	DSS was seen to be important for forecasting decisional outcomes. Included four sub-areas: DSS learning, understanding DSS technology, creating DSS inferences, and trusting DSS-derived data. UK.	N/A
Kucher 2005[93]	Inpatient in a CPOE environment	Randomized controlled trial	Alerts given to physicians.	The rate of prophylaxis increased from 14% in the control to 33% in the intervention group. Those receiving prophylaxis had 41% less incidence of DVT than those who did not.	84

Source	Setting	Study Design	Study Intervention	Key Finding(s)	Quality Score
Lyons 2005[98]	Inpatient VA	Qualitative	Perceptions of VA clinicians regarding the role of information technology in implementing guidelines.	Eighteen themes clustered into four domains. Workplace factors were more often discussed by administrators, system design issues discussed most by nurses, and personal concerns discussed by physicians and nurses. Facilitators included guideline maintenance and charting formats. Barriers included resources, attitudes, time and workload, computer glitches, computer complaints, data retrieval, and order entry. Themes with dual designations included documentation, patient records, decision support, performance evaluation, clinical practice guidelines (CPG) implementation, computer literacy, essential data, and computer accessibility.	N/A
McKinley 2001[95]	Critical care	Randomized controlled trial	Computerized guideline to manage ventilated patients.	Outcome measures (i.e., survival, ICU length of stay, morbidity, and barotrauma) were not significantly different between groups. Fio2 > or = 0.6 and Plateau > or = 35 cm H2O exposures were less for the protocol group.	102
Mosen 2004[92]	In patient post-op in highly developed EMR system, but not complete CPOE	Pretest, post-test	Guideline to prevent post-surgical DVT (deep vein thrombosis).	The overall prophylaxis rate increased from 89.9% before implementation of the computerized reminder system to 95.0% after implementation ($P < 0.0001$). The combined 90-day rate of symptomatic DVT, pulmonary embolism (PE), and death attributable to PE remained the same (pre-1.0%; post-1.2%; odds ratio = 1.21; 95% CI = 0.67–2.20).	52
Murray 2004[116]	Outpatient in a CPOE environment	Randomized controlled trial	Computerized suggestions given to (1) physicians, (2) pharmacists, (3) both, or (4) none.	No significant differences found between groups in terms of quality of life, hospitalizations, ER visits, cost, or blood pressure (BP).	110
Patterson 1998[91]	Inpatient in a CPOE environment	Pretest, post-test	Computerized algorithm with protocols for prevention of DVTs.	The preintervention rate of DVT prophylaxis over a 3-month period was 85.2% (785 of 921 eligible cases). For the 3 months following the introduction of the computerized reminder, compliance with DVT prophylaxis increased to 99.3%.	64

Source	Setting	Study Design	Study Intervention	Key Finding(s)	Quality Score
Patterson 2004[99]	Outpatient use of clinical reminders in the VA CPOE system	Qualitative	Human factors analyses were conducted on users across multiple settings and roles.	Significant barriers and issues were identified, including time, workload, nonrelevance, ease of use, training, complicated procedures for refusal, etc.	N/A
Petrucci 1991[83]	Nursing home in a non-CPOE environment	Case control	Disease management consultation for urinary incontinence.	The number of wet occurrences of patients residing on units where nurses consulted UNIS decreased significantly; F (2,9) = 34.67. The knowledge of urinary incontinence also improved significantly when nurses consulted UNIS; F (2,157) = 19.46.	54
Rogers 1982[117]	Outpatient in a non-CPOE environment	Randomized controlled trial	Alerts to manage hypertension, obesity, and renal disease, using printouts only.	Decreased BP, decreases in hospitalization and length of stay.	84
Ruland 1999[88]	Inpatient unit for the elderly	Quasi-experimental nonrandom assignment; groups selected in tandem.	Use of a systematic protocol for eliciting patient preferences given to nurses in experimental group.	Patients whose nurse was given their personal preferences reported care more congruent with their preferences.	68
Ruland 2002[89]	Inpatient	Randomized controlled trial	Use of a hand-held computerized decision support.	Nurses' use of CHOICE made nursing care more consistent with patient preferences (F = 11.4; $P < 0.001$) and improved patients' preference achievement (F = 4.9; $P < 0.05$).	78
Ruland 2003[90]	Outpatient	Randomized controlled trial	Use of a computerized system that collects patient preferences.	Patient reports of topics addressed during the consultations showed greater congruence in the experimental group as compared to control group.	108
Schriger 1997[118]	Emergency services	Time series	Guidelines for treatment of occupational body fluid exposures.	Mean % documentation of essential items increased from 57% to 98% in the intervention phase, and aftercare instruction increased from 31% at baseline to 93% during the intervention phase, but both decreased to baseline when the computer system was removed. Compliance with guidelines increased from 63% to 96% during the intervention phase. Percentage of charges increased from 44% to 81% during the intervention phase and decreased to 36% following the intervention.	78

Source	Setting	Study Design	Study Intervention	Key Finding(s)	Quality Score
Schriger 2000[119]	Emergency services	Time series	Guidelines for care of febrile children.	Percentage of 21 essential history and physical examination items increased from 80% during the baseline period to 92% in the intervention phase (13% increase; 95% CI = 10–15%). Mean percentage documentation of 10 items in the aftercare instructions increased from 48% at baseline to 81% during the intervention phase (33% increase; 95% CI = 28–38%). All decreased to baseline when the computer system was removed.	68
Slovis 1985[85]	Emergency services	Pretest, post-test	Triage DSS using flip charts; users were not clinicians.	The DSS system shortened the average response time from 14.2 minutes to 10.4 minutes for the most urgent cases ($P < 0.05$); resulted in a significant increase in the use of advanced life support units for this group ($P < 0.02$).	44
Strachan 2001[86]	Emergency services	Pretest, post-test	Triage	Effective triage went from 20% to 32%.	44
Tang 1999[120]	Outpatient CPOE environment.	2-yr prospective case control	Reminders for immunization.	Used physician volunteers for CPOE. Compliance rates for the computer-based patient record system (CPR) user group increased 78% from baseline ($P < 0.001$), whereas rates for the paper records (PR) user group did not change significantly ($P = 0.18$).	64
Willson 1995[81]	Inpatient	Pretest, post-test	Implementation of AHCPR guideline on pressure ulcers.	Comparison of computerized protocol with a previously implemented paper protocol. Very little data.	N/A
Zielstorff 1997[82]	Inpatient unit	Case control	Pressure ulcer DSS for nurses used by nurse volunteers; no data on usage.	Dependent variables were knowledge and decisionmaking results from simulations. No patient data provided.	N/A

Conclusion

Across the sections in this chapter, several themes are apparent. First, nursing and nursing impacts are nearly absent in the current empirical studies of work on EHR orders and clinical decision support within ordering systems. Future research is needed to understand the impact of that technology on the role of nurses and workflow methods that are effective for nurses in a computerized orders environment. Nursing clearly participates in the orders process; yet, the assessment of that role is missing to date. More important, nurses and pharmacists serve in roles as protectors against errors in patient care. The counts of intercepted errors speak to this role in a simplistic way. More complex variables and expanded research is needed on this topic. With CDSS, nurses are studied as invisible partners in the care process rather than as decisionmakers themselves. Yet, nurses make thousands of care decisions a day. Borrowing methods from psychology, future researchers could expand the cognitive work in this area.

BCMA is the exception to the absent nursing voice. In BCMA, nurses are integral to the success of the application. Medication error reduction with BCMA is apparent. Additionally, the VHA has effectively included nurses in the design and implementation of technology-assisted medication administration. However, technology assistance in medication administration represents a lower-level cognitive process than, say, decisionmaking about symptom assessment or an independent care intervention. Thus, future research on decision support for higher cognitive processes and the nurse as a full-fledged decisionmaker is warranted.

There are several limitations to this work. A strong effort was made to have well-defined inclusion criteria to make the studies as homogeneous as possible and to allow valid comparisons. However, the inclusion criteria have limited this analysis to implemented solutions, narrowing the possible CDSS applications in particular. Likewise, studies were excluded from areas such as imaging and psychiatry; in the future these areas could be examined. Our results included some qualitative work, not usually considered as evidence, but included here to better describe the phenomena at hand. An analysis without qualitative studies would perhaps come to different conclusions.

Studies in sociotechnical and human-computer interaction are needed in each of these areas. This would help us understand the complex processes inherent in technology design and adoption. Interdisciplinary examinations are needed in future research to understand interdependent roles. With technology becoming an omnipresent participant on today's health care teams, traditional roles on a health care team have been altered. For example, computerized orders management changes roles, and role renegotiation must take place. New process and new issues emerge with complex technologies like CPOE; this interdependence needs to be systematically evaluated in the future. The research in HIT integrative functions is just beginning. Future opportunities are many for areas of great impact to nursing.

Search Strategies

CPOE Search Strategies

A broad search of the literature from 1976 through the end of 2005 was undertaken as part of a larger study to locate articles dealing with the practice impacts of clinical computing applications. Searches were conducted in PubMed®, CINAHL, Cochrane, PsychInfo, DARE, INSPEC, CENTRAL, and HTA databases. The search strategy is located in appendix A. The

search yielded 63,731 references with 1,023 abstracts rated as having empirical data. Abstracts were coded for relevancy and sorted into categories (e.g., clinical decision support, CPOE, EHR adoption). CPOE-coded articles were retrieved as a subset from the larger search results. Search terms were

> online order entry OR computer-based physician workstation OR practitioner order entry OR physician order entry OR electronic health record OR computerized physician documentation OR computer medical records OR medication order entry OR computer based order entry OR CPOE OR POE

The CPOE search yielded 178 potentially eligible articles.

CPOE articles were rated for eligibility with empirical studies of any design and systematic reviews being considered relevant. The relevant studies examined implemented solutions with a concentration on any practice implications of CPOE. Letters, opinions, and editorials were excluded, as were articles dealing with models or theoretical discussions about systems. Further, studies were excluded if they (a) provided only verbal summaries of CPOE impacts or satisfaction with CPOE; (b) focused solely on CPOE costs or ordering volumes; (c) primarily focused on imaging, dentistry, simulations, psychiatry, data mining, or genetics; or (d) focused solely on CPOE or EHR adoption methods. The authors separated studies with a major focus on guidelines and order-related decision support into a separate section of this chapter. This first section targets clinical impacts of paper-based ordering compared to CPOE.

BCMA Search Strategy

A review of studies published in peer-reviewed journals and meeting abstracts was undertaken. The search criteria used for PubMed® was as follows:

> barcode point-of-care technology OR bar code medication administration OR BCMA OR medication bar coding OR barcode medication administration OR barcode point-of-care technology OR eMAR OR electronic medication record

The search was limited to studies with abstracts that were published in the English language and spanning the years 1976 to 2005. This search retrieved 205 abstracts, out of which 29 were relevant. A second search was conducted to look for studies that focused on the nursing domain by combining the above search strategy with "AND nursing." The same limits were applied to this search as well. A total of 33 abstracts were retrieved, out of which 10 were considered relevant for this review. In all, 39 abstracts were considered relevant in our first evaluation.

A second evaluation was conducted by retrieving and reading the full text articles. The inclusion criteria used to determine whether a study was relevant or not were the same as those used for CPOE, as described above. Eight studies provided evidence of actual implementation of a BCMA system and its evaluation; the remaining 31 articles were discarded. Further, quality assessment of the studies was conducted using the QUASII instrument. Table 5 presents a summary of the key findings and variables measured in the nine studies that were finally evaluated.

Decision Support Search Strategy and Methods

The broader search strategy used for this review is described at the beginning of the chapter. The results retrieved from this larger search were further analyzed for relevance to DSS interventions for nursing. To be included in the final round, a study had to be reporting an actual

evaluation or research study conducted with real patients cared for with the intervention in place. Although the focus was on those studies associated with CPOE and an EHR, few have been conducted (especially for nursing). Therefore, studies were included where the intervention could easily be implemented *in the context* of CPOE with an EHR. Studies whose main focus was on nursing interventions designed to improve documentation, care planning, or administration were *not* included. Simulations, early reports of development findings, or validation of DSS software were also not included, nor were studies that were simply descriptive or had a "lessons learned" perspective. However, studies that used methods close to a traditional qualitative methodology or formal human factors analysis were included when appropriate, for example, the focus was on a system implemented in real time.

Inclusionary terms:

Online order entry OR computer-based physician workstation OR practitioner order entry OR computer-based medical record OR electronic health record OR computerized physician documentation OR computer medical records OR decision support computer program OR health maintenance reminder OR CDSS OR computer-aided OR computerized decision making support OR clinical decision support system OR computerized feedback OR computer-assisted dosing OR computer feedback OR predictive instrument OR computer-aided quality assurance OR computer alert OR clinician order entry OR provider order entry OR computerized reminder OR computer reminder OR computer-based monitoring system OR expert system OR computer-based medical decision support OR decision support system OR computer based order entry OR event reporting system OR electronic healthcare record OR electronic monitoring OR electronic health record OR electronic medical record OR electronic incident reporting OR electronic record OR electronic patient record OR electronic record keeping OR medical information system OR computer-predicted OR computer-based monitoring OR computer-based prompt system OR CPOE OR POE OR electronic journal OR medical reminders OR electronic reminders OR medical record alert.

Inclusionary Mesh® terms (for PubMed® only):

"Decision Support Systems, Clinical"[MeSH] OR "Hospital Information Systems"[MeSH] OR "Medical Records Systems, Computerized"[MeSH]

Exclusionary terms:

NOT (X-ray OR biochemistry OR DNA OR RNA OR genome OR tomography OR dentistry OR dental OR simulation OR molecular OR animal OR psychiatric OR biofeedback OR HIPAA OR in-home OR data mining OR algorithm)

Exclusionary Mesh® terms (for PubMed® only):

NOT ("Validation Studies"[Publication Type] OR "Editorial"[Publication Type] OR "Letter"[Publication Type] OR "News"[Publication Type] OR "Comment"[Publication Type] OR "legislation and jurisprudence"[Subheading] OR "Libraries, Medical"[MeSH])

Limits

Articles considered were those published in English during the time period January 1, 1976 to August 1, 2004.

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Chapter 48. Patient Safety, Telenursing, and Telehealth

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Background

Tele is a prefix meaning "at a distance," and it is used in terms such as telescope, or telemetry. The prefix *tele,* when combined with the term *scope,* has the single clear following meaning: an instrument to view phenomena at a distance.[1] However, in health care, as in other arenas, the prefix *tele* often takes on several meanings. For example, the term *telemetry* is described as a process,[2] data,[3] and an electronic device[4] related to the task of remote measuring and reporting of information of interest. There is inconsistent and emerging nomenclature related to *tele* in health care.

The inconsistent use of language associated with the delivery and management of health care at a distance has made it even more difficult to distinguish the ontology of terms and describe their related safety and quality issues. Specifically, previous literature has used the terms *telehealth, telemedicine,* and *telenursing* somewhat interchangeably, and the few articles reporting safety concerns were difficult to cluster for further analysis.

Telenursing is the use of "technology to deliver nursing care and conduct nursing practice"[5] (p.558). Although the use of technology changes the delivery medium of nursing care and may necessitate competencies related to its use to deliver nursing care, the nursing process and scope of practice does not differ with telenursing. Nurses engaged in telenursing practice continue to assess, plan, intervene, and evaluate the outcomes of nursing care, but they do so using technologies such as the Internet, computers, telephones, digital assessment tools, and telemonitoring equipment. Bearing in mind that health services now provided via teletechnologies have expanded, the term telehealth is used to capture the breadth of services. For the purposes of this review, the Health Resources and Services Administration defines telehealth as "the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration."[6] Telemedicine, the original term, is defined as the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data, and education using interactive audio, visual, and data communications.[7] The American Nurses Association has defined telenursing as a subset of telehealth in which the focus is on the specific profession's practice (i.e., nursing).[8]

The delivery of telehealth care is not limited to physicians and nurses; it includes other health disciplines such as radiology, pharmacy, and psychology. These disciplines also deliver care using electronic information and telecommunications technologies and are accordingly called *teleradiology, telepharmacy, telepsychology,* and so forth. Although they are not the focus of this review, these disciplines are selectively included here for two reasons: (1) the safety issues associated with care delivered using electronic and telecommunications technologies are more similar than they are different among the various health disciplines, and (2) the dearth of research on safety and quality in the telenursing literature led the authors to include important research in other health disciplines. By including the research findings on safety and quality from varied health disciplines, the body of telenursing knowledge is expected to expand.

Research Evidence

Although the summary for the AHRQ evidence report, *Telemedicine for the Medicare Population*,[9] specifically mentions safety related to telemedicine and how evidence could be presented and researched, it is ironic to note that in all the evidence tables of all the AHRQ reports there are no studies that mention safety or specifically research patient safety in telehealth. Indirect evidence such as monitoring, prevention of acute care events or complications, testing the technology for comparison with in-person care, and outcomes research all allude to safety but do not address it specifically. It is clear that there is a gap in the literature and research evidence for telehealth specifically related to safety. However, telenurses and other health care professionals are continually struggling to increase the safety of their patients, increase the quality of health care, and decrease adverse events, although the evidence of the impact of these concepts is not apparent in the research.

The four themes that emerged upon review of the literature offer insight into the field of telehealth and the practice of telenursing. Although not noted or researched specifically, patient safety is an important part of the diagnosis, monitoring, outcomes, and technical tools used in telehealth practice.

Diagnosis and Teleconsultation

A great deal of research has been done on the use of telehealth for diagnosing disease. It has been shown that diagnosis of disease using telehealth is successful (Evidence Table 1). For example, Schwabb and colleagues[10] found that the remote interpretation and diagnosis with electrocardiogram results was just as good as interpretation in person. Additionally, telehealth has successfully been used as a tool for diagnosing acute leukemia.[11]

In addition to diagnosis, educational sessions for providers, as well as patient education and psychosocial counseling, have been researched. Telehealth has been shown to be a successful endeavor for education and counseling through two-way audio and video technology.[12–14] Providers of care also have seen great benefits from consultations through telehealth equipment. Similar to education and counseling, two-way audio and video technology has been researched and shown to be beneficial for consults between providers.[15] For instance, home health nurses may use telehealth equipment to consult with specialists, or physicians may consult with each other regarding a particular patient.

Monitoring and Surveillance

Compliance and adherence problems are among the many issues that are important to achieving patient safety. After a patient leaves a provider's office or a hospital, the patient is responsible for his or her own health care at home. Patients often do not follow a treatment plan as directed by a physician or provider due to several factors, including: miscommunication or faulty understanding of the treatment plan, lack of access to facilities needed for the treatment plan, and a complex treatment regimen that the patient cannot comprehend without additional guidance.[16] This can cause negative outcomes and creates safety issues for the patient. Therefore, inventive and efficient telehealth-based methods of caring for patients are increasingly being used to improve compliance or adherence to the prescribed regimen of care, as well as for symptom management. Telehealth is one strategy for monitoring and communicating with

patients beyond the acute care setting. It has also had an impact upon health care utilization rates for acute care services (such as decreasing visits to the Emergency Department) in studies with limited sample sizes, although large randomized trials have not yet been reported (Evidence Table 2).

Adding to the problem of adherence in patients is a lack of access to quality health care, specialists, or nurses. With the current trend in outpatient care management, monitoring, and surveillance of patients, additional nurses are needed for the increasing number of home care patients and the increasing acuity of illnesses in these patients.[17] Further, patients who live in rural areas or in medically underserved areas may not be receiving the expert care that is needed.[18, 19] Traveling far distances to a treatment facility, time lost from work for treatment, and other responsibilities also contribute to the compliance issue.

To meet the patients' needs, and with the additional burden on nursing because of the current nursing shortage, many home care agencies are looking for innovative ways to care for a large number of patients. Telehealth technology offers increased productivity for nurses by decreasing travel time to remote areas, thereby increasing the average daily census.[20] Especially in rural areas, where driving time to patients' homes can take up the majority of a nurse's day, new time-saving and patient safety initiatives are imperative, leading to further adoption of telehealth in home care. Audio and video technology can facilitate remote home health monitoring between patients and caregivers.[17, 20] Often, peripheral devices placed in patients' homes—such as thermometers, sphygmomanometers, and stethoscopes—are connected to the telehealth equipment so telenurses can monitor clinical signs remotely. Nurses are able to spend more time on direct patient care rather than indirect care, resulting in better use of their time and education. Hence, telehealth and telenursing address barriers to quality health care that are created by geographic location and costs associated with lost time.

Clinical and Health Services Outcomes

The majority of research completed on outcomes after implementing telehealth has been related to chronic conditions such as diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD). Often, morbidity and mortality are measured outcomes for these patients, and telehealth use shows better outcomes in these areas (Evidence Table 3).

More specifically, telehealth technology has been shown to be a successful method of telehealth intervention, inducing communication that has helped patients' HbA1c levels to decrease, as well as offering assistance to traumatic brain injury patients in transitioning from the hospital to the community.[16, 21]

In addition to the more widely used telehealth technologies, there are a number of devices and applications with specific functionalities that are making a difference in patient health care and safety as related to health outcomes. Glucoboy and Digiscope are two examples of these new technologies. The former is a diabetic tool in a video game cartridge format. The cartridge is inserted into Nintendo's Game Boy and has been shown to help children with the management of type 1 diabetes mellitus.[22] The Digiscope is a telehealth technology that allows for screening of diabetic retinopathy in a primary care physician's office rather than under the specialized care of an ophthalmologist.[23] These telehealth technologies have been shown to be practical alternatives to traditional care.

Technical Issues

Telehealth technology differs in every situation and can range from telephone calls postoperatively to preventing diabetic complications in children by using a popular video game system, to live, interactive voice and video patient education, to downloadable data devices used by patients with data interpreted by telenurses. Studies report various technology approaches used by various types of providers in different settings with diverse disease entities (Evidence Table 4).

For instance, telephone technology has traditionally been used as a telehealth mechanism. While using a technology that is already in place in many patients' homes, this technology can be used to deliver important aspects of health care, including education,[21] psychosocial therapy,[16] and emotional support.

One of the most common technology configurations for telehealth applications uses two-way audio and video, or teleconferencing equipment. This technology allows patients and caregivers to communicate effectively, while allowing caregivers the benefit of seeing the patient. Other technologies can be incorporated into the main audio and video equipment to transmit specific health care data such as blood pressure and heart rate. These technologies makes telenursing possible because data to support patient safety in home care can be retrieved from home telehealth devices if proper terminology and data standards are employed.[24]

One innovative technology that has recently begun to be studied would allow patients to be monitored remotely with even less of a time burden placed on the nurse and the patient. Infrared technology offers perhaps the most continuous method of telehealth monitoring equipment. Infrared scanners have been shown to be effective in reporting deviations from a daily routine.[25] With this technology, the monitoring of elderly or dependent patients is done from a remote location; patients can be monitored at home, in a nursing home, or in the hospital. Safety of the patient can be assessed without the patient purposely getting in front of a camera or logging on to speak to a nurse.

Evidence-Based Practice Implications

The research related to telehealth and telenursing practice has shown great benefits related to diagnosis and consultations, monitoring and surveillance of patients, clinical and health services outcomes, and technology advancement. Each of these areas have important patient safety concerns, and while not studied as a unique entity, patient safety themes have emerged throughout the literature. Telehealth is a unique field that uses innovative technologies to improve patient care and thereby improve safety. These technologies range from the telephone to ubiquitous computing and only promise more in the future. Special concerns related to patient safety emerge with each of these methods of health care delivery.

Technologies have evolved to offer more and broader capability for telehealth/telenursing practice. With telehealth technologies, patient adherence to care increases, access to care is improved, providers can network with each other, and the safety of patients can be monitored more closely in homes and alternative living facilities.

With telephone-based telehealth, there is relatively no cost to the patient and no technical setup required for a telehealth interaction. Most patients already have a phone in the home that can be used for sessions. However, telephone discussions are usually limited to education and counseling because there are no visual cues for the provider/telenurse.

Two-way audio and video increases the functionality of telehealth by allowing the telenurse/health care provider to see the patient. In addition, peripheral monitoring devices can be used by the patient to transmit clinical information to the remote provider. More patient education is required initially for the use of the equipment with this type of technology, and the initial investment costs for the telehealth equipment can be large. Further, the patient must have Internet access or transmission lines to accommodate the video equipment.

Products such as the Glucoboy are innovative technologies that have been researched and shown to be effective in helping diabetic children maintain a healthy lifestyle.[22] The new product has taken a monotonous, sometimes painful task and made it into a game for children. However, the cost of this technology and who bears the cost remain to be seen.

Finally, infrared technology and sensor technology promise to deliver remote monitoring capabilities into the hands of providers. This has implications for caregivers and even family members of a person who lives at a distance. Falls, injuries, or illness will be easy to detect using such a system, offering immediate care to patients. However, the continuous monitoring nature of these devices may prove to be an infringement of patients' rights to privacy, and therefore an ethical issue for health care providers to consider.

With telehealth, confidentiality also remains a concern and must always be considered. While technology is becoming more sophisticated, telehealth sessions remain as a confidential interaction between a provider and a patient. Enclosed rooms without traffic or others present are imperative to maintain privacy. Health care providers need to be conscious of who is in attendance for the session and respect privacy and confidentiality of the patient. Further, as the numbers of new and innovative technologies emerge, researchers and developers must remember the security of patient information, regardless of how it is transmitted. In the researched technologies, data are transmitted over secure lines. However, new wireless technologies, increased use of e-mail by providers, and the continual threat of computer viruses increase the need for security and confidentiality of patient data to remain in the forefront of telehealth.

The different platforms for telehealth are diverse, yet all increase the ability of telenurses to communicate with and receive data about their patients. Regardless of the specific telehealth technology utilized, the reliability and validity of data transmission is essential to the safety of patients. Further, accepted and proven nursing practice must not be compromised. It is imperative for nurses to see the telehealth technology as a medium for care, and not a tool to replace high-quality nursing practice. Patient safety will be maintained with telenurses who are able to focus on patient care and not the technology itself.

Research Implications

The possibilities for telehealth technology abound, although pitfalls are also a potential. Telehealth has evolved throughout the years, from the first telephone interventions to the present-day use of sensors and remote monitoring devices. Much research has been completed on telehealth technology; however, it can be expanded upon exponentially—and should be expanded to include safety as a variable in all studies.

New wireless technologies have introduced new options for telehealth, which include nanotechnology and artificial intelligence.[26] Both of these offer great possibilities for diagnosis and treatment. However, researchers have only begun studying the potential of these technologies that offer promises for future health care.

In the shorter term, increasingly sensitive and accurate peripheral devices are needed for clinical monitoring. While the technologies currently exist, many can be improved upon to ensure valid clinical results. Peripheral device use can also be expanded. Ubiquitous computing is an option that will allow for clinical monitoring at home or in the community without being intrusive to the patient.[26] There is a greater chance of adherence in patients with this type of technology; however, research will need to be conducted to confirm the expectations.

Telehealth technologies will continue to evolve, as technology has in other business sectors. Health care needs to commit to this progress in order to provide up-to-date technology and safe devices for patients. The majority of studies that were reviewed compared telehealth care vs. in-person care and involved patient monitoring. Overall there were some positive outcomes indicating the benefits of telehealth. However, patient safety issues were not the main focus of these studies. Only one article was found that directly focused on safety issues: That article provided important information on the safety of wireless technologies; however, it was not a research article. Further, in a recent conference funded by the Agency for Healthcare Research and Quality, telehealth nursing experts were brought together to create a national agenda for telenursing research.[27] Themes for future research included cost effectiveness, clearly identified populations, standard outcomes, and standard methodologies to support telenursing. Specific research agenda topics identified were chronic disease management, patient empowerment, and enhanced self-care. While patient safety is a faction of all of these topics, it was not included specifically as a research agenda topic for telenursing. Therefore, the review of the current literature as well as decisions for future research goals indicate a gap of information and future direction regarding patient safety issues related to the use of telehealth in clinical practice.

Conclusion

The scarcity of research evidence focused primarily on patient safety in telehealth may in part be due to a lack of understanding about the emerging safety issues associated with telehealth and telenursing. The safety issues identified for telehealth and telenursing extend beyond the limited view of the precision of the information.[28] Telehealth encompasses a wide range of applications, including teleconsultations, telediagnosis, telepharmacy, e-health via the Web, telephone triage/telephone advice, tele-emergency support, disease management, and telehomecare. The safety issues associated with telehealth are, in turn, more complex and include not only apprehension about malfunctioning equipment, but also concerns regarding potential adverse effects on patient management decisions through delayed or missing information, misunderstood advice, or inaccurate findings due to patient or caregiver error.[29] Further research is clearly needed in the arena of patient safety as it is directly related to telehealth practice.

Search Strategy

The majority of research studies to date have focused upon teleradiology, telepathology, telepsychiatry, and other medical uses of telemedicine technology for medical care and diagnosis. These studies were purposely not included in this review. The purpose of this literature review was to focus upon the safety issues associated with care delivered by and relating to telenursing. The search strategy and distillation process of the literature consisted of three primary activities: (1) identification of meaningful MeSH® search terms and searching in

PubMed®, (2) an alternative process for locating articles, and (3) identification and validation of safety and quality related themes.

Identification of Meaningful MeSH® Search Terms and Searching in PubMed®

The U.S. National Library of Medicine developed MeSH®, a controlled vocabulary for indexing articles, which is located in the MEDLINE®/PubMed® databases. It took several iterations of MeSH® terminology to produce references that reflect the scope of safety and quality issues inherent in telehealth. For example, a search using the MeSH® terms "safety" and "telehealth" produced 12 articles, only 5 of which dealt specifically with monitoring equipment safety issues related to telehealth. Furthermore, the details of the MeSH search indicated that it could not find the term "telehealth" or "telemedicine" and instead suggested terms like "equipment safety" and "health care technology." A further search of the PubMed® database yielded zero results for "telehealth" and seven journal titles for the term "telemedicine."

Alternative Process for Locating Articles

Two of the seven journals identified through PubMed were *Journal of Telemedicine and Telecare* and *Telemedicine and e-Health.* Volumes of these journals were hand culled to locate any articles related to telehealth and its related safety concerns. As these articles were located, the reference list of each was also reviewed and relevant articles flagged for further searching. Additionally, professional organization sites such as the American Telemedicine Association and the Telehealth Information Exchange were searched to locate references to telehealth and safety.

Identification and Validation of Safety/Quality Themes

One author conducted the search and located all of the articles included in this review. A total of 41 articles were found to have some relevance to telehealth and safety. After an initial appraisal of the articles, they were examined for semantic similarities and differences. Four themes emerged among the 41 articles: (1) diagnosis and teleconsultations, (2) monitoring and surveillance, (3) clinical and health services outcomes, and (4) technical/ethical issues. The articles were then distributed among the authors, and the themes were validated. Where appropriate, articles were redistributed from their initial category to a more appropriate category. The included safety and quality topics are described in Table 1, below.

Table 1. Safety and Quality Topics as Related to Telehealth

Number of Articles	Category	Included Topics
2	Diagnosis and teleconsultation	The use of EKG leads in diagnosis and Web-based decision support in the care of leukemia patients.
11	Monitoring and surveillance	Adherence issues among patients using telehealth technologies to manage asthma, medication regimen, and CHF.
19	Clinical and health services outcomes	The use of telehealth applications and telenursing for managing CHF and diabetes at home. The use of telehealth technologies for consults such as dermatology, cardiology, intensive care, and emergency care/trauma.
19	Technical and ethical issues	Questions surrounding interoperability of equipment, algorithms for applying telehealth development, and issues in developing various technologies.

It became clear to the authors that issues such as measuring return on investment are often tied to clinical outcomes; thus these studies were included in the review. Additionally, articles that addressed disparities to access in health care and the potential benefits of telehealth are included, as these articles address the prevention of safety problems.

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Evidence Tables

Evidence Table 1. Diagnosis and Consultations Using Telehealth

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Belachel 2005[11]	Web-based clinical decision support tool	Changing practice projects/ research	Observational study with controls (Level 3) Other measurable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	191 Acute leukemia cases from the database of Cliniques Universitaires Saint-Luc Brussels, Belgium	Web-based clinical decision support tool to virtually diagnose and support secure and timely electronic data exchange regarding acute leukemia.	The percentage of correct classification in this experimental testing was consistent with the proposed prototype. 96.4% of acute leukemia cases were correctly classified, proving that Web integration can be a promising tool for dissemination of computerized decision support system tools. The system is robust and capable of deployment for referring physicians.	D

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Schwaab 2005[10]	The study compared the accuracy of a 12-lead electrocardiogram (ECG) recorded by patients and transmitted to a cardiology call center via telephone (tele-ECG) with standard 12-lead ECGs.	Non-randomized trials	Nonrandomized control trials (Level 2) Surrogate outcomes (Level 2)	158 post myocardial infarction cardiac patients living at home with the capacity to communicate the tele-ECG via telephone.	Tele-ECGs were compared with standard ECGs by two cardiologists and one internist, independently and blindly.	In 155 of 158 patients (98%), the quality of the tele-electrocardiogram (tele-ECG) was adequate for diagnosis. Reliability coefficients ® for PQ, QRS, and QT intervals between tele- and standard ECG. Additionally, negative T-waves and ST segment detection was very good. Residual signs of myocardial infarction could be detected by tele-ECG, with very good agreement for anterior as well as for posterior localizations. The tele-ECG technique seems a promising approach to reducing pre- and in-hospital time delays to the initiation of thrombolytic therapy.	D

Evidence Table 2. Monitoring and Surveillance Related to Telehealth and Telenursing Practice

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Chan 2003[30]	Test the use of an Internet-based store-and-forward video home telehealth system to manage asthma in children	Prospective cohort study	Observational studies with controls (Level 3) Surrogate outcomes (Level 2)	Pediatric patients ages 6–17 years with persistent asthma were recruited from among the population of patients with asthma in pediatric clinic at Tripler Army Base, Honolulu.	The use of an Internet-based store-and-forward video monitoring system for patients with asthma, and followup with virtual visits via the Internet in comparison to in-person office visits.	No overall change in quality of life reported by patients. However, the caregivers in the virtual followup group reported an increase in the patients' quality-of-life survey scores. Emergency department visits and hospital admissions for asthma were avoided. Rescue therapy was infrequent. A high rate of satisfaction with home telemonitoring was reported. Internet-based, store-and-forward video assessment of children's use of asthma medications and monitoring tools in their homes appeared effective and well accepted.	M

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Fragou 2005[31]	Adherence to medication regimen	Randomized controlled trial	Randomized controlled trial (Level 1) Clinical outcomes (Level 3)	108 diagnosed schizophrenic outpatients, part of the South London and Maudsley NHS.	Telementoring using a new platform called @HOME, which offered clinicians early warnings about impending nonadherence as well as information about the pattern of medication taking.	In comparison to the other two groups, patients using @HOME showed improvement in the Global Clinical Impression Scale and a significant reduction in emergency visits and medical appointments.	M
Gilbert and Sutton 2006[32]	N/A	Randomized controlled trial (Level 1)	No outcome relevant to decreasing medical errors/ adverse events.	1,457 callers to Quitline (smoking cessation program) were randomly allocated to a control group to receive usual care or to a repeated contact group to be offered abstinence 6 & 12 months after recruitment, quit attempts and 24 hours of periods of abstinence in nonquitters.		Proactive telephone counseling did not significantly decrease abstinence from smoking rate.	M

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Lamothe 2006[17]	Increased need for home care services	Non-comparative studies	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	Patient homes in Quebec and Manitoba, Canada; patients with chronic illness.	Telehomecare monitoring, including disease measurements.	Positive impacts on patients and health crisis prevention.	M
Manfredi 2005[33]	N/A	Observations	No outcome relevant to decreasing medical errors/ adverse events	15 inmates were assess & treated in 37 consultations. Subjects were young white males.	Interactive two-way audio-video communication between the psychiatrists & inmates.	Services were readily accepted by inmates and staff. Telepsychiatric examinations & treatment appear to be a feasible method to increase access to mental health care in rural jails.	M
Marinella 2006[34]	Use of telemedicine to monitor patients and deliver care.	Observation, convenience sample	No outcome relevant to decreasing medical errors/ adverse events.	14 Spinal cord injury (SCI**)** patients at home after discharge from James Peteres VA Medical Center.	Monitoring patients for safety, home accessibility, exercise by messaging device or videophone on weekly basis.	Office visits increased, hospitalization and length of stay decreased. Poor reliability of monitoring device was identified as an obstacle.	M

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Prince 2005[35]	Seniors will be able to safely age in place with use of telehealth	Literature reviews/ narrative	Design (Level 4) Outcomes: telehealth technology and services (Level 4)	Review of previous research and reports of safer and longer aging in place for seniors when using telehealth technology and services.	Telehealth can delay nursing home care, support aging in place at home, and provide in-home monitoring and health care services.	Telehealth has been successfully used in hospital specialty areas to provide health care services. Research points to benefit of seniors use of telehealth in a systematic fashion to acquire services and information so they may age in place in their homes safely and with a good quality of life.	M
Rogers 2001[36]		Randomized controlled trial (Level 1)		121 adults with essential hypertension.	A home service consisting of automatic transmission of blood pressure data over telephone lines, computerized conversion of the info into report forms, & weekly transmission of the report forms to physicians and patients.	Telecommunication service was efficacious in reducing the mean arterial pressure of patients with established essential hypertension.	M

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Rotondi 2005[37]	Descriptive study of provision of Web -based support services/ information to families of patients with traumatic brain injury (TBI) to improve their patient outcomes, to include safety	Nonrandomized trial	Observational study without controls (Level 4) Self-reports of satisfaction and Web utilization (Level 3)	17 female caregivers of patients with TBI were provided access to Web site for support/services from home.	Study evaluated use of WeCare Web site for information, answers to questions, and support group with other caregivers for those with TBI.	Caregivers used support group as the most frequent function on the Web site. There is strong correlation between caregiver capability and patient outcomes for TBI patients, to include safety outcomes of TBI patients who may have gait or motion dysfunction as a result of their injury.	M
Savard 2003[38]	No outcome relevant to decreasing errors/ adverse events	Case observations, two rehabilitation centers, convenience sample	No outcome relevant to decreasing medical errors/ adverse events.	117 teleconferences with 75 patients ages 9m–-86 yrs. (38 of the visit were with neurological diagnoses.)	High-speed video conferencing with real-time audio-video communication.	Care of individuals with neurological issues can be supported.	M
Smith 2006[14]	Adherence with sleep apnea treatment—Continuous Positive Airway Pressure (CPAP)	Randomized controlled trial	Randomized controlled trial (Level 1) Surrogate outcomes (Level 2)	In-home patients with nonadherence to CPAP regimen.	Telehealth educational sessions.	Increased use of CPAP in the group with the telehealth education sessions regarding CPAP.	M

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Wang 2005[39]	A feasibility study on an Internet-based compliance system to provide personalized care for patients suffering from chronic diseases.	Changing practice project/research	Observational studies with controls (Level 3) Other measurable variables with an indirect or unestablished connection to the target.	The study monitored the chronic disease management of oral anticoagulation treatment in Spain, asthma care in the United Kingdom, and morbid obesity care in Greece in 25 patients residing at home with access to a personal computer and an Internet connection.	The C-Monitor System consisting of an integrated service aimed at monitoring patients' adherence to therapy at home via the Internet.	Health care providers credited the C-Monitor in helping with the adherence in disease management as determined by the system's ability to create personalized therapeutic schemes, provide an efficient communication channel between providers and patients, and offer satisfactory monitoring of patients' adherence with treatment and their physical status. The performance of the system was assessed by all participants. Most of the patients and physicians agreed that C-Monitor system provided a more valuable service than the traditional ambulatory system and would like to use the C-Monitor service in the future for disease management. Suggestions for improvement of the system were offered by both types of participants.	M

Evidence Table 3. Outcomes Related to Telehealth and Telenursing Practice

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Adkins 2006[16]	Type 1 diabetes adherence	Pre- and post-test	Observational studies without controls (Level 4) Surrogate outcomes (Level 2)	In patients' home: patients ages 7–18, elevated HbA1c levels and/ or DKA within the last year.	Telephone therapist intervention.	HbA1c levels decreased for patients when they received the telephone intervention.	O
Bunn 2005[40]	The effects of telephone consultation and triage on safety, service use, and patient satisfaction was examined.	Systematic literature review	Randomized controlled trials (Level 1A) Clinical outcomes: morbidity, mortality, adverse events (Level 1)	The researchers reviewed randomized controlled trials, controlled studies, controlled before/after studies, and interrupted time series of telephone consultation or triage in a general health care setting; however, the majority of studies were in primary care.	The researchers searched registers such as the National Research Register, Cochrane Central Register of Controlled Trials and searched databases like PubMed, EMBASE, CINAHL, SIGLE. A list of identified studies and review articles was produced and verified by two independent reviewers.	The findings are mixed. There was inconclusive evidence about the frequency of return visits to general practitioners (GPs) and in the reporting of accident and emergency department (ED) visits. Although telephone consultation appears to have the potential to reduce unnecessary visits to the GP or ED, questions remain about its effect on service use. Further rigorous evaluation is needed with emphasis on service use, safety, cost, and patient satisfaction.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Dale 2004[41]	The safety of nurses and paramedics offering telephone assessment, triage, and advice as an alternative to immediate ambulance dispatch for emergency ambulance service callers with "nonserious" problems was examined.	Randomized controlled trial	Randomized controlled trial (Level 1) Clinical outcomes (Level 1)	635 patients treated by ambulance services in London and the West Midlands, UK, were the subjects. A multidisciplinary expert clinical panel reviewed data from various ambulance and ED records and call transcripts for patients triaged by nurses and paramedics. Calls were placed into categories that indicated if the dispatch of an ambulance was necessary or not. All cases for which one or more members of the panel rated that an emergency ambulance should have been dispatched were further re-reviewed for an assessment of the "life risk" that might have resulted.	The intervention comprised nurse or paramedic telephone consultation using a computerized decision support system to assess, triage, and advise patients whose calls to the emergency ambulance service had been classified as "nonserious."	From the 239 usable cases, in 237 cases the majority of the panel concurred with the nurses' or paramedics' triage decision. Telephone advice may be a safe method of managing nonemergency (category C) calls. Further study is needed to exclude the possibility of rare adverse events.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Dang 2006[42]	Care coordination using telehealth reduces hospitalizations, thereby reducing exposure to medical errors	Pre- and poststudy	Design (Level 2) Outcomes (Level 3)	59 chronically ill VA patients. Outcomes were hospital admissions, bed days of care, number of emergency room visits, number of outpatient visits.	Telecare management via an Internet-based home messaging device and whether it can impact health care utilization rates.	Significant reduction in hospital admission and number of emergency room visits occurred pre- to post-6 months with use of telehealth care management. Significant reductions in acute care utilization rates among chronically ill patients imply a reduction in medical error rates since exposure to acute care is less.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Finkelstein 2006[43]	A study that examined patient outcomes and cost when home health care was delivered by telemedicine or by traditional means for patients receiving skilled nursing care at home.	Randomized clinical trial	Randomized controlled trial (Level 1) Clinical outcomes (Level 1)	53 rural Minnesotans participated. Candidates for TeleHomeCare had to be (1) eligible to receive skilled home nursing care for either congestive heart failure (CHF), chronic obstructive pulmonary disorder (COPD), or chronic wound care; (2) able to use the equipment or have a supportive care partner who could do so; (3) live in a technically functional home environment.	There were two separate interventions with two intervention groups. In group a, video intervention and traditional skilled nursing care at home was used, and the second group received traditional skilled nursing care at home, virtual visits using video-conferencing technology, and physiologic monitoring.	There was no difference in mortality between the groups. Morbidity, as evaluated by changes in the knowledge, behavior, and status scales of the Omaha Assessment Tool, showed no differences between groups except for increased scores for activities of daily living at study discharge among the intervention groups. The average visit costs were $48.27 for face-to-face home visits, $22.11 for average virtual visits (video group) and $32.06 and $38.62 for average monitoring group visits for CHF and COPD subjects, respectively. The findings showed that virtual visits between a skilled home health care nurse and chronically ill patients at home can improve patient outcome at lower cost than traditional skilled face-to-face home health care visits.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Grady and Melcer 2005[44]	N/A	Retrospective record review. Non-randomized trials	No outcome relevant to decreasing medical errors/ adverse events	Service members & their adult family members of National Naval Medical Center.	Telemental health care via video-conferencing vs. care provided in person.	Telemental health care improved adherence, & shorter times to next followup appointment.	O
Grigsby 2005[45]	A meta-analysis of the home telehealth literature using a systematic application of a health services research (HSR) method for assessing the impact of telemedicine on access, quality, and cost of care.	Meta-analysis	Randomized controlled trial (Level 1A)	The criteria for inclusion included the use of telemedicine as a substitute for home visits by nurses and the use of information technology in the management of chronic conditions in the home environment.	A comprehensive model for the evaluation of telemedicine based on an applied research matrix consisting of: cost of care, quality of care, and access to care as used in HSR.	Despite its limited use in telemedicine, the scope of HSR is broader than that of clinical trials, with a focus on the system of care; its acceptance by the users; and outcomes, costs, and access. The methods of HSR provide a valuable analytical framework for the assessment of telemedicine and to discern the real merit of telemedicine.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Heizelman 2005[46]	Comprehensive review and synthesis of the literature concerning clinical outcomes associated with various telemedicine applications.	Systematic literature review	Randomized controlled trials (Level 1A)	Inclusion criteria were based on Donabedian's Medical Care process as defined by clinical care processes (diagnosis, clinical management, and clinical outcomes) and user satisfaction.	Key terms were used in searching the PubMed Web site to identify published studies in peer-reviewed journals that focused on the care process and outcome in telemedicine. Inclusion criteria included (1) published between 1996 and February 2004, (2) contained an abstract, (3) had a control group, and (4) not limited to voice communication only.	There were 356 articles analyzed. 160 studies related to diagnosis, 61 studies related to clinical management and clinical outcomes, and 168 studies dealt with user satisfaction. Most clinical outcomes studies to date have focused on diagnosis and patient satisfaction. A few studies investigated telemedicine's effects on clinical management or patient-oriented clinical outcomes. Diagnostic accuracy seems to be well documented in radiology, dermatology, pathology, and ECG interpretation. Psychiatric diagnosis is promising, but study sizes have been small, and ophthalmology diagnostics require further study. The most evidence for outcome and management appears to be with home/institution-based applications for CHF, diabetes, and blood pressure monitoring. Among clinic- or hospital-based applications, the fields of dermatology, cardiology (i.e., echocardiography), and intensive care and emergency care/trauma have stronger evidence for their benefit. Overall user satisfaction is well demonstrated, especially in the areas of psychiatry, dermatology, and other multispecialty applications.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Henault 2002[47]	Communication between care-givers for long-term diabetes management	Case control studies	Nonrandomized controlled trial (Level 2) Surrogate outcomes (Level 2)	VA Boston Healthcare System, male diabetic patients with elevated HbA1c levels.	Using e-mail for communication of recommendations from pharmacist to primary care provider.	Intervention and control groups both had a decrease in HbA1c levels.	O
Hilty 2004[48]	Telepsychiatry clinical and educational videoconferencing applications are equal to or better than in-person and also reduce health care utilization	Meta-analysis	Design (Levels 1 thru 4) Outcomes (Level 3)	Review of telepsychiatry studies from January 1, 1965, to July 31, 2003, containing the terms videoconferencing, telepsychiatry, telemedicine, effectiveness, efficacy, access, outcomes, satisfaction, quality of care, education, empowerment, costs.	All 110 telepsychiatry studies that mentioned videoconferencing were reviewed.	Telepsychiatry is effective and has been successfully used to increase access to care, provide patient and provider satisfaction in general, improve outcomes of care, and empower those using it. Further research on impact on patient outcomes is needed. Reduced hospitalizations and decreased use of acute services are two key findings that point to impact on hospital-based medical errors.	O
Hopp 2006[49]	Clinical outcomes with telehealth use; research for evidence-based practice	Randomized controlled trial	Randomized controlled trials (Level 1) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	Veterans Affairs Center home care patients.	Interactive telehealth with voice and video and some peripheral attachments for home care patients.	High level of patient satisfaction and health-related quality of life (HRQOL) scores; trend toward decreased outpatient health visits with the intervention group.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
James 2001[12]	Obesity in the military, difficulty in long-term program sustainability	Non-randomized trials	Non-randomized controlled trial (Level 2) Clinical outcomes (Level 1)	48 U.S. Navy and Army personnel in Hawaii, with a body mass index of at least 27.	Obesity treatment program through telehealth.	Successful weight management with the use of telehealth.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Joseph 2006[50]	The Veterans Health Administration (VHA) evaluated a care coordination program for diabetic, CHF, COPD, and mental health chronically ill patients using technology to promote self-management.	Changing practice projects/ research	Observational studies with controls (Level 3) Surrogate outcomes (Level 2)	Enrollment in the program began by identifying patients with frequent ED visits or frequent admissions. Additionally, patients with hemoglobin A1c greater than 10 were identified. Following identification, collaboration from the primary care provider was obtained and the patient contacted to request their involvement in the program. Patient had to have a standard plain old telephone system (POTS), electrical service to the house, and be agreeable to monitor and transmit data daily.	Patients were asked to answer a series of questions about their health status and habits using a digital messaging unit placed on their phone line. In some instances ancillary monitoring devices (i.e., glucometers) were directly connected to the messaging device or the patient entered the results information. This information was transmitted to the care coordinator, who would note abnormalities and contact the physician and monitor the patient closely for followup care.	Defined clinical and utilization outcomes were defined and compared to the findings for ED visits and bed days (utilization) and hemoglobin A1c measurement for all diabetic patients, low density lipoproteins (LDL) levels on patients followed for hypertension, diabetes, and CHF (clinical). There were no statistically significant findings; however, care coordination efforts have demonstrated improved glycemic control for diabetic patients, improved lipid management, and decreased use of costly resources, such as ED visits and hospitalizations. The authors concluded that substantial gains in both clinical and resource outcomes have been shown.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
LaFraboise 2003[51]	A pilot study to determine the feasibility of providing a heart failure disease management program through an in-home communication device, Health Buddy.	Randomized clinical trial	Randomized controlled trials (Level 1) Clinical outcomes (Level 1)	90 home care patients capable of living independently who had been discharged from the hospital within 6 months with a primary diagnosis of heart failure.	The intervention, a telecommunication device named Health Buddy, was compared with traditional methods for home management of heart failure, including in-person visits and telephonic case management.	Confidence in managing disease, quality of life index, functional status, and depression were measured in each of the clinical trial groups. Patients who received telephonic case management experienced decreased confidence in managing their disease; all other groups experienced increased confidence. Functional status, depression, and quality of life did not differ among the groups. The findings suggest that using telehealth to manage home care for heart failure is feasible; however, further study is needed to determine differences that might exist between various treatment methods.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
McCue and Palsbo 2006[52]	A demonstration of the business case for telemedicine in nonrural areas was shown. The study differed from earlier investigations in that return on investment did not include the variables of provider or patient travel time.	Changing practice project/ research	Observational studies with controls (Level 3) Other measurable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	The case study of poststroke rehabilitation in urban settings in Oklahoma.	Interactive spreadsheet was used to conduct multiple financial analyses under different capital investment, revenue, and expenses for poststroke rehabilitation services to urban patients, including five speech-language pathology (SLP) provided to poststroke patients over videophones or videoconferencing equipment and two physical therapy (PT) codes (individual activities and physical therapy evaluation).	The outcome measures were financial breakeven points and internal rate of return. It was found that a Total of 340 telemedicine visits has the potential to generate a positive net cash flow each year. By the fourth year, this type of service can produce a positive present value return of more than $2,000, and earn rate of return of 20%, which exceeds the hospital's cost of capital. Thus business case was demonstrated. Urban telemedicine programs can be financially self-sustaining without accounting for reductions in travel time by providers or patients.	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Reardon 2005[53]	A comprehensive review of telemedicine cost research and major issues affecting the yield from this research.	Systematic literature review	Randomized controlled trials (Level 1A)	The criteria for inclusion included studies with major analytic components of health care services cost evaluations, cost analysis decision framework, and methods of inference that affect the quality and productivity of telemedicine cost research.	Keywords evolved from first considering previous studies and then using keyword and database selection strategies to augment the literature. This approach is referred to as iterative triangulation. These terms were used to create a database of keywords, which resulted in overlapping sets of literature. The database of resulting articles consisted of 1,430 telemedicine articles. Sources for the studies were varied and included the NLM Database, CINAHL, Journal of Economic Literature, and AHRQ.	This review supports previous conclusions on the potential net savings to society through specific uses of telemedicine. Most specifically populations in remote areas, in prisons, or on ships may have reduced total cost of care by accessing it through telemedicine. However, these specific reported gains in the cost effectiveness of telemedicine depend on the reduced cost of access to care. Specifically, the greatest potential for cost savings from telemedicine seems to be the production of health or wellness. When study outcomes are measured as health maintenance or wellness, as is usually done in home care, potential savings, especially for high-risk chronically ill patients, are seemingly greater. The review also concludes that the productivity of telemedicine cost studies suffers from an underutilization of appropriate program evaluation and economic methods. Better consensus guidelines and best practices on costs can provide common benefits to cost research and are needed to accurately	O

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Slater 2005[22]	Type 1 diabetes noncompliance	Pre- and post-test	Observational studies without controls (Level 4) Surrogate outcomes (Level 2)	In the community, children with type 1 diabetes and their parents.	Use of Glucoboy device for monitoring blood sugar levels.	Testing adherence increased by 200%; HbA1c levels were lowered.	O
Wu 2005[54]	This pilot study evaluated the feasibility and patients' acceptability of using the Internet to communicate with patients with symptomatic heart failure.	Changing practice projects/ research	Observational study with controls (Level 3) Surrogate outcomes: observed error, intermediate outcomes (e.g., laboratory results) (Level 2)	62 home care patients with symptomatic heart failure were enrolled into the program and instructed how to use the Internet communication tool.	The study measured the proportion of patients who used the system regularly for at least 3 months and the safety and maintainability of the tool. Additionally, researchers conducted a content analysis of patient and clinician messages.	The majority of the patients quit using the system; however, 45% of the patients used the system and continued to use it on average for 1.5 years. In a 3-month time period there were over 5,000 entries made by patients. The content analysis of a subset of the patient comments revealed the following major categories of communication: patient information, patient symptoms, patient questions regarding their condition, patient coordinating own care, social responses. The study concluded that an Internet tool is a feasible and safe method of communication in a substantial proportion of patients with heart failure.	O

Evidence Table 4. Technical and Ethical Issues Related to Telehealth/Telenursing

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Bell 2004[21]	Traumatic brain injury (TBI) patients and their transition to the community	Changing practice projects/ research	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	Patients' homes, TBI patients discharged from University of Washington Medicine.	Telephone followup program.	Telephone support is a feasible means for followup of TBI patients in the community.	T
Boye 2006[55]	Risk to patients from use of wireless devices.	Literature review	Possible outcome relevant to adverse events (Level 5)	Review of sources of electromagnetic interferences in hospitals.	A description of wireless communication devices used in the hospitals and the industry standards.	Wireless technologies are deemed suitable for use throughout hospital areas, including ICUs & ORs, given that recommended separation distances from medical devices are observed.	T
Britt 2006[15]	Access to specialist care for high-risk pregnancies	Pretest and post-test	Observational studies without controls (Level 4) Other measurable variables with an indirect or unestablished connection to the target safety outcome	Across the State of Arkansas, high-risk pregnancy patients.	Using the ANGELS telehealth program to facilitate care and provider consultations.	An increase in telemedical and telephone consultations. A slight decrease in transports to the high-risk clinic, with a decrease in the length of stay for patients.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Dansky and Ajello 2005[56]	The strategic objectives and marketing strategies for telehealth	Non-comparative studies	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events	29 home health agencies of a Midatlantic State, person at the organization responsible for implementing telehealth.	Qualitative interviews were conducted to discover the reasons for telehealth adoption and the marketing strategies.	Clinical excellence and cost containment were the main reasons for adopting telehealth. Marketing strategies were broad, but included brochures, articles, Web site content, and fact sheets.	T
Ferrante 2005[26]	Wireless capabilities available to telemedicine for patient care	Literature reviews, non-systematic/ narrative	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)		Literature review of current and future technology applications for medicine.	Many applications of new technologies exist for telemedicine.	T
Frey 2005[20]	Nursing shortage having an effect on home health agencies and their patients	Changing practice projects/ research	Observational studies with controls (Level 3) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	Home health agencies of a Midatlantic State.	Use of telehealth for home health agency visits vs. traditional visits.	Average daily census of patients seen was increased.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Ganguly 2005[57]	The development methodology for interoperable telemedicine systems	Changing practice projects/ research	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	School of Computer Science and Engineering, The University of New South Wales, Kensington, NSW 2052, Australia.	Development of an ontology-driven, multiagent system for diabetic treatment using diabetes ontology and agent system called Foundations of Intelligent Physical Agents (FIPA) standard-based ontology development.	Yet untested design that focuses on a FIPA-compliant model for interoperable telehealth technologies.	T
Keeys 2002[58]	Overnight pharmacist access in an acute care facility	Quality improvement projects/ research	Observational studies without controls (Level 4) Other measurable variables with an indirect or nonestablished connection to the target safety outcome (Level 3)	A 340-bed acute care community hospital, hospital staff.	Enhancing current after-hours pharmacy on-call coverage with a telepharmacy group.	Successful quality improvement.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Masucci 2006[59]	Descriptive study of patients without computer experience and whether they were able to safely and effectively use telemedicine technology	Non-randomized trial	Observational study (Level 4) Self-reports (Level 3)	44 subjects with little/no computer experience and with hypertension, diabetes, and other cardiovascular risk factors were provided telemedicine systems.	Patients with no or limited computer experience were given a 2-hour class in use of the telemedicine technology system.	Patients utilized the system accurately and safely using IDs and passwords. Prior access to computers and prior computer experience was not a predictor of use of telemedicine systems. Having access to telemedicine systems may reduce risk for cardiovascular disease.	T
McConnochie 2006[18]	Social and economic burden of childhood illness/access to health care	Randomized controlled trial	Randomized controlled trials (Level 1) Surrogate outcomes (Level 2)	University of Rochester Medical Center primary care practice or pediatric ED, pediatric patients.	Three models of telemedicine: basic, simple, and extended.	Approximately 85% of visits offered successful telemedicine intervention.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Miller 2006[60]	The use of telehealth technology in home health care for adult persons with developmental disabilities was examined, and algorithm for delivering telehealth services to developmentally disabled persons developed.	Changing practice projects/ research	Observational study without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	The researchers examined the utilization of telehealth needed by multidisciplinary clinicians, including physicians, nurses, physical therapist, occupational therapist, and speech language pathologists, etc., to meet the health care needs of rural adults with developmental disabilities.	Following an examination of the utilization of services, the authors developed an algorithm for telehomecare for adults with disabilities.	A practice-based algorithm and model for telehealth care delivery to meet the needs of rural adults with developmental disabilities was developed. The unique consideration regarding the need to determine the risk-management needs for using telehealth technologies with this population is also described.	T
Seren 2005[61]	Postoperative nasal airflow pattern detection for the prevention of hospital visits	Case control studies	Nonrandomized controlled trial (Level 2) Other measurable variables with an indirect or nonestablished connection to the target safety outcome (Level 3)	In-home, 27 patients post septoplasty.	Use of Web technology, Web Add, and Odiosoft-rhino programs to record and transmit sound from nasal passages.	Significant difference in the sounds transmitted between the group with nasal blockage and those without nasal blockage.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Suzuki 2006[25]	Daily health monitoring of elderly	Non-comparative studies	Observational studies without controls (Level 4) Other measurable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	Nursing home, three elderly patients.	Use of infrared scanner sensor output in nursing home patients' rooms, as compared with the reported activities of the patients.	The sensors were able to identify the reported patterns of activity.	T
Tang 2006[62]	Medical errors related to usability and interface design	Quality improvement projects/ research	Observational studies without controls (Level 4) Other measurable variables with an indirect or nonestablished connection to the target safety outcome	Digital emergency medical system interface prototypes.	Heuristic evaluation of interface usability.	Heuristic evaluation serves as a useful technique in designing user interfaces.	T
Thomas 2004[13]	Improved education for surgical patients	Quality improvement projects/research	Observational studies without controls (Level 4) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	University of Kentucky Chandler Medical Center/ Kentucky Telehealth Network locations Patients undergoing joint surgery	Use of telehealth for preoperative education in addition to the conventional method of education.	Patient satisfaction was positive with the use of the telehealth model.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Wei 2006[19]	Access to experienced ophthalmo-logists	Changing practice projects/ research	Observational studies without controls (Level 4) Other measurable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	Los Angeles County Department of Health Services, high-risk diabetic patients.	Use of Web-based telemedicine system.	Web-based architecture successful in capturing and transmitting images.	T
Whited 2005[63]	Access to routine eye examinations for diabetics	Quality improvement projects/ research	Observational studies with controls (Level 3) Other measurable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	Indian Health Service, Department of Veterans Affairs, and Department of Defense, diabetic patients.	Monte Carlo simulation, modeling the use of the Joslin Vision Network telehealth model vs. conventional clinic-based ophthalmoscopy.	The Joslin Vision Network is less costly and more effective in detecting diabetic retinopathy than conventional clinic-based methods.	T

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)	Category of Telehealth Article O = Outcomes M = Monitoring D = Diagnosis/ Consultation T = Technical/ Ethical
Yoon 2005[64]	The accuracy of a single finger probe using photoplethysm-ography (PPG) was tested as a digital monitoring device for hematocrit, SPO2, respiration, pulse, and blood pressure	Changing practice/ research	Observational studies with controls (Level 3) No outcomes relevant to decreasing medical errors and/or adverse events (Level 4)	Sample size varied for each type of measurement. Hematocrit testing was performed on 549 patients at Samsung Hospital, Seoul, South Korea. Five healthy adults were used to test the predictive power of the PPG waves for the other parameters.	A palm-sized digital health monitor used a finger probe and a light emitting diode (LED) array. The light was measured to obtain PPG signals. Hematocrit, pulse, respiration rate, and saturated oxygen in arterial blood (SpO2) were measured and predictive algorithms developed to measure the clinical accuracy of the PPG diagnostics.	The accuracies were within clinically acceptable errors. This work showed that the method and algorithm for multiple physiological signal measurement based on a single LED sensor are valid.	T
Zimmer-Galler and Zeimer 2006[23]	Adherence in retinopathy screening and treatment	Retro-spective cohort study	Observational studies without controls (Level 4) Other measureable variables with an indirect or unestablished connection to the target safety outcome (Level 3)	Primary care practices throughout 7 States and the District of Columbia. Diabetic patients who are not receiving recommended eye examinations.	Use of DigiScope imaging.	DigiScope implementation is shown to be a practical alternative for patients not receiving routine eye examinations	T

Chapter 49. Documentation and the Nurse Care Planning Process

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Background

Tools are needed to support the continuous and efficient shared understanding of a patient's care history that simultaneously aids sound intra- and interdisciplinary communication and decisionmaking about the patient's future care. Such tools are vital to ensure that the continuity, safety, and quality of care endure across the multiple handovers made by the many clinicians involved in a patient's care. A primary purpose of documentation and recordkeeping systems is to facilitate information flow that supports the continuity, quality, and safety of care. Since recordkeeping systems serve multiple purposes (e.g., legal requirements, accreditation, accountability, financial billing, and others), a tension has arisen and is undermining the primary purpose of the record and instead fueling discontinuity of care, near-misses, and errors. Among the more specialized types of documentation is the plan of care, a requirement of the Joint Commission.[1, 2] Though planning and plans should facilitate information flow across clinician providers there is little generalizable evidence about their effectiveness.

In the first part of this chapter, evidence from studies on nursing documentation, care plans, and interdisciplinary plans of care is presented and synthesized into a framework for the Hands-on Automated Nursing Data System (HANDS) method. The method is an intervention that addresses the need for broad-based standardization of key aspects of documentation and communication to facilitate patient-centric information flow. HANDS standardizes the plan of care documentation and processes by replacing the current widely variable forms. It supports interdisciplinary decisionmaking that is based on the shared knowledge from clinicians. Finally, a case study presenting the history and future plans for the ongoing refinement of the HANDS method is presented.

Research Evidence

Recordkeeping Practices of Nurses and Nursing Documentation

Information work is a critical part of the medical endeavor. Strauss and Corbin[3] note that trajectory work, as they view medical care, requires information flow before and after each task or task sequence to maintain continuity of care. Tasks are not isolated but are intertwined and build on one another to achieve patient goals. Nurses bear a large burden in both managing and implementing the interdisciplinary team's plan for the patient, as well as documenting the care and progress toward goals. As a result, nurses spend considerable amounts of time doing information work. There are several genres of nursing documentation studies: those that examine recordkeeping practices as a whole, those that examine issues relating to the documentation (time, content, completeness), and comparative evaluations of different types of changes in the documentation regime including automation versus paper. Taken together, these provide both

detailed and broad knowledge of nurses' recordkeeping practices and highlight the reasons why any change (manual or computerized) is so difficult to integrate into nursing practice.

General Recordkeeping Practices of Nurses

Nursing documentation covers a wide variety of issues, topics, and systems. Researchers, practitioners, and hospital administrators view recordkeeping as an important element leading to continuity of care, safety, quality care, and compliance.[4–7] Studies, however, reveal surprisingly little evidence of the linkage between recordkeeping and these outcomes. The literature features multiple exhortations and case studies aimed at improving nurses' recordkeeping in general[8–10] or for specific diagnoses.[11, 12]

The literature also reveals the tensions surrounding nursing documentation. These include: the amount of time spent documenting;[13–15] the number of errors in the records;[9,16,17] the need for legal accountability;[18–20] the desire to make nursing work visible;[21] and the necessity of making nursing notes understandable to the other disciplines.[22, 23] For the purposes of this review, we confine ourselves to discussions of either manual or automated nursing systems of documenting patient care, primarily in hospitals. As we have found, while there are good and well-designed individual studies, the different methodologies, populations studied, and variables analyzed have led to little generalizability across the research, making comparisons between them impossible.

There are several literature reviews of nursing documentation systems. Urquhart and Currell[24] completed the most systematic and comprehensive review, examining the literature through 2004. They focus on nursing record systems as variations in the systems effect nursing practice and patient outcomes. Currell and Urquhart conclude that nurses experience tensions between patient care needs and hospital management-promoted documentation rules. They also found that the studies show both mixed responses to new systems and inconclusive links between the nursing documentation system used and its impact on patient care. Also noted was the lack of standardization among systems.[25]

In a more targeted literature review, Langowski[26] examined the relationship between quality health care, particularly safety, and point-of-care online nursing documentation systems. Unlike Currell and Urquhart,[25] Langowski found that overall documentation quality improved with an online electronic health record (EHR). The measures used, however, varied between the studies, and documentation impact on quality was assessed through evaluating the presence of certain types of information and the frequency of data entry. The accuracy of the information was not evaluated. Nurses' satisfaction with documentation systems has also been used as a measure of quality though the relationship between satisfaction and documentation is never clearly delineated. The variation in the definition and measures used for evaluating quality is characteristic of this literature.

The final review was carried out by Karkkainen, Bondas, and Eriksson.[27] They conducted a metasynthesis of 14 qualitative research reports to determine how well individualized patient care was represented in nursing documentation. Karkkainen and coworkers identified three themes in the literature reflecting the tensions in the record: demands of the organization, nurses' attitudes and duties, and the patient's involvement in care. This mirrors the findings of Currell and Urquhart. In conclusion, Karkkainen, Bondas, and Eriksson argue that individualized patient care is not visible in nursing documentation, and that current methods used to standardize communication in the records (forms with check-off lists) contribute to this gap. In another work, Karkkainen and Eriksson[28] note that, although standardized forms of documentation can enhance concise and directed information, poorly designed forms may enhance document content but do

little to support patient-centric care. The challenge is to design systems that are patient focused but also reap the benefits of standardization in terms of more accurate, precise, and up-to-date information transfer among all members of the interdisciplinary team.

Several single studies provide additional insight into nursing recordkeeping practices. Allen[29] examined nurses' views of the nursing record and its routine usage in practice. Using observations and interviews, Allen found that nurses were ambivalent towards the records, both seeing them as a symbol of the place of nurses in the clinical arena, but also reporting that the records are too heavily structured by management, a finding echoed throughout the literature (e.g. Lee and colleagues[30]). As a consequence, Allen points to the practice of nurses developing shadow documentation systems (informal nursing records and ward diaries) that help nurses maintain a high-level overview of the patient's care on one's shift.

In another qualitative study, Hardey and colleagues[31] observed nurses in five acute elderly care wards at a district general hospital in the south of England. They argue that "scraps," individualized information systems, contained a unique combination of personal and professional knowledge and changed dynamically in response to patient care on a shift. The main source of information in the scraps was information conveyed during the nurse handover. This finding suggests that scraps provide information not found in the patient record. Instead the scraps contain the summarized or synthesized version of the patient's story that includes only the information the nurse feels is needed to carry out care effectively on one's shift.

Ngin[32] picks up on the idea of information work as discussed by Strauss and Corbin[3] and provides an in-depth analysis of nurses' retrieval, interpretation, documentation, and passing of information. She, too, found that nurses relied less on the formal forms of documentation in the medical record and the care plan than on informal sources; her subjects preferred getting information directly from other nurses who had first-hand, observational knowledge of patients or from summary documentation, such as in Kardexes or personal notes. Ngin quoted nurses as saying, "The Kardex is a 'living document' which nurses have dubbed the Bible of nursing care. On the other hand, nurses tend to regard care plans as 'just a requirement'"[32] (p. 81). Ngin also differentiates between coordination of care (which she saw as the role of the Kardex, various worksheets, and more personalized information systems) and continuity of care (which she viewed as sustained by handovers).

In combination, these reviews and studies indicate that nursing documentation in the medical record does not meet the espoused purpose of being a communication tool that supports the continuity, quality, and safety of care. The evidence presented in this section also points to several conditions that perpetuate misunderstanding of nursing work and the means to track it. First, there is wide variation in recordkeeping practices between units and between health care organizations. Second, nurses heavily utilize shadow recordkeeping systems to aid in immediate patient care activities and decisions. Finally, there is an overwhelmingly negative attitude toward formal recordkeeping—either outright hostility or the view that documentation is "just a requirement."

Representativeness and Completeness of the Content

In several more targeted studies, the central issues of concern were how well the records reflected the care given and accuracy of the patient's condition. Tornvall and colleagues[33] audited EHR records and found that reports of medical status and interventions were more prevalent than nursing status. The authors concluded that nursing documentation was limited and inadequate for evaluating the actual care given. Ehrenberg and Ehnfors'[34] triangulation between

data from a chart review and interviews of nurses revealed little agreement between the records and the care nurses reported as having given. The researchers went so far as to state in their findings (p. 303) that "there are serious limitations in using the patient records as a data source for care delivery or for quality assessment and evaluation of care."[34]

Another set of studies examined the completeness of nursing documentation; these typically utilized chart review and audit as a methodology. The issue of completeness is important; Croke[35] cites failure to document as one of the six top reasons that nurses face malpractice suits. In terms of overall completeness, Stokke and Kalfoss[36] found many gaps in nursing documentation in Norway. Care plans, goals, diagnoses, planned interventions, and projected outcomes were absent between 18 percent and 45 percent of the time. Taylor[37] found that many of the care plans reviewed did not convey the specific information necessary to carry out the required procedure. One third of the nurses in this study mentioned accessing written documentation but did not express any preference for care plans.[37]

Other completeness studies have evaluated the impact of the form type and content required. In a controlled clinical trial utilizing a chart review method, Sterling[38] analyzed wound assessment documents from three different units. While more of the important details of wound assessment were recorded when using a wound assessment chart, missing information was found for both charting methods (conditions) in the study. In another controlled clinical trial with home care nurses, Tornkvist and colleagues[39] administered an educational intervention focusing on pain management. Their findings indicated that several statistically significant improvements in care were achieved after the introduction of the pain-advisers in the study units. Most pertinent to this chapter, the nurses' satisfaction with their written documentation on pain increased with the addition of several new types of assessments used for charting pain.[39]

While computerization has been referred to as a cure for incomplete records, the evidence on this is also mixed. Larrabee and colleagues[40] found that completeness increases over time after system implementation, with expected gains not being realized until 1 year after implementation. Care planning systems are also not immune from problems with the completeness of documentation. While Bjorvell and colleagues[41] reported increased completeness of documentation, particularly in the proportion of discharge planning notes, Griffiths and Hutchings'[42] audit of records from home health care nurses found initial nursing assessments poorly documented, affecting later care.

The studies in this section indicate two things. Completeness of a record may have an impact on the quality of care, but only if it reflects completeness of the right content. Echoed again here is that document focus, rather than the patient-centric nature of the medical record, does little to support shared understanding by clinicians of care and the communication needed to ensure the continuity, quality, and safety of care. The typical content and format of documentation—and its lack of accessibility—have also resulted in document-centric rather than patient-centric records.

Time Spent Documenting

Time spent documenting patient care is generally not regarded by nurses as being patient care, even though there is a Nursing Intervention Classification (NIC) term for it. Studies focused on time indicate that nurses spend a significant amount of time recordkeeping. In the most comprehensive literature review on time, Poissant and colleagues[14] reviewed 11 studies examining documentation time before and after moving from a manual to an online system. Of these studies, six reported a time savings when using a computer. There was up to a 25 percent savings by nurses charting with bedside systems. Three studies reported increased time,

particularly in the one study that employed handheld computers. However, of the three studies that assessed nurses' efficiency by using the patient as the sampling unit, the results were negative—more time was spent on documentation per patient after system implementation, with increases ranging from 7.7 percent to 128 percent. The authors propose that time efficiencies are gained by standardized forms in systems, although some systems require more information to be documented.[14]

Other studies have exposed the overall documentation burden carried by nurses. Hardey and colleagues[31] found that recordkeeping was given lower status and priority than was direct patient care. It was also viewed as excessively time consuming. Nurses regularly copied data from the medical record and other documents to create personal records that guided their activities. Korst and colleagues[13] conducted a work-sampling study over a 14-day period. Out of 2,160 observations, the average percent of time nurses spent on documentation was 15.8 percent; 10.6 percent for entry on paper records and 5.2 percent on the computer. The percentage of time spent on documentation was independently associated with day versus night shifts (19.2 percent vs. 12.4 percent, respectively). Time of day is also a factor in retrieving information.

The series of studies in this section indirectly expose the cost implications of maintaining medical records that offer little assistance to clinicians in the provision of patient-centric care. Moreover, maintaining medical records that bring little clinical value not only wastes nurses' time but also limits the time available to engage in value-added care activities. The cost implications alone justify a call-to-action to redesign documentation systems so that they are patient-centric and aligned with intended purposes.

Studies That Focus on Improving Documentation

Deficiencies in the nursing record, such as problems with accurately representing the patient, the time-consuming nature of recording, and the completeness of the record, have led to a series of interventions aimed at improving nursing documentation. The impetus for changing nursing documentation has come from several sources: hospital management, the nurses themselves, and nursing researchers. Compliance with legal mandates, paperwork reduction campaigns, and meeting professional standards are also common reasons for changing recordkeeping regimes.

The changes made to the documentation process to reach these goals vary broadly. Much of this literature is characterized by contradictory case studies. Scharf[43] reported a case study of one hospital that simplified a set of complex forms to enable nurses to spend more time caring for patients while still meeting the Joint Commission's documentation requirements. Another case study[44] involved a change from a preprinted form to a free-text, handwritten care plan for each patient. The studies reviewed include examples of those focused on understanding users' needs (through assessing attitudes and opinions) and those focused on implementing and evaluating interventions designed to improve documentation.

Dillon and colleagues[45] conducted a survey to assess nurses' readiness to adopt a new EHR. Their findings indicated that nurses had a positive overall attitude, although nurse age was a significant factor in determining nurses' attitudes regarding the EHR. Nurses were concerned, though, about the impact of the new EHR on quality health care delivery. In closing Dillon and coworkers noted that "these results clearly show that the nurses have real concerns about the new impending computer system and that the new system may be risky and might remove the human component of what they do"[45] (p. 144). For example, a comment made by one nurse reflected the concerns of many, "I just don't want the system problems to interfere with patient care." One of

her colleagues also commented, "I'm nervous about it [the impending system implementation]—hoping that it will not slow down my productivity—or be too time-consuming"[45] (p.144).

Other studies have used educational interventions designed to improve documentation alone or documentation and care. Karkkainen and Eriksson[46] completed a pre- and postintervention study, which involved an educational intervention to have nurses apply a theory of caring science to the care plans, to promote a more patient-focused documentation. Chart audit was done pre- and postintervention, and questionnaires assessed nurses' attitudes about this theory-based recording method. The major change observed was more attention by nurses to patient views and increased recording of these in the plan.[46]

Studies of computerized charting and care planning systems usually provide some measure for nurses' satisfaction. Two surveys of nurses' attitudes toward computerization are important to note. Axford and Carter's[47] study on how nurses believed computer technology impacted their practice is important in this regard. Their survey asked about resource consumption, nursing work practices, and professional and patient outcomes. Their findings indicated that nurses did not think technology would have a negative impact on practice. This was true for both those knowledgeable about computers and those less familiar with them— although the strength of this belief did vary, with experts feeling more strongly.

Other researchers have examined the effects of computers on nursing documentation directly. Nahm and Poston[48] did a quasi-experimental, modified time series study that measured the effects of the nursing module of a point-of-care clinical information system on nursing documentation and patient satisfaction. Data were collected before implementation, and after implementation at 6-, 12-, and 18-month intervals. Compliance with items applicable to nursing documentation in the JCAHO Closed Medical Review Tool was used to assess the quality of nursing documentation. Nahm and Poston found a statistically significant increase in the quality of nursing documentation after system implementation and a reduction in the variability of charting. Most importantly, charting compliance increased and continued at the 12- and 18-month time points after initiation of the new system. This indicates that change is incremental, and that longitudinal studies are critical to assess the impact of computer systems.

The body of the literature reviewed in this section provides evidence indicating that well-constructed interventions, such as education and revising formats (automation and forms), can enhance documentation and improve patient care. The evidence also suggests that there is a time-related pattern to user satisfaction, perceptions of value, and achievement of desired documentation outcomes following the implementation of new computer information systems. Nonetheless, the findings must be interpreted with caution due to wide variation of the settings examined, interventions applied, and methods of evaluation. As with all of the literature in this area, the main limitation is lack of generalizability, due primarily to the wide variation of documentation practices within and across organizations.

Nurse Care Planning and Plans

In health care organizations, the EHR, oral reports, handoffs, conferences, and health information technologies (HIT) are intended to facilitate information flow. In particular, the JCAHO specifically conceptualizes the care planning process as the structuring framework for coordinating communication that will result in safe and effective care.[2] The *Essentials of Baccalaureate Education for Professional Nursing Practice*,[49] drafted by the accrediting body the American Association of Colleges of Nursing, lists several core competencies that directly relate to the nurse's care planning process including the ability to "…diagnose, plan, deliver, and

evaluate quality care" (p. 11), "use appropriate technologies in the process of assessing and monitoring patients" (p. 14), "apply health care technologies to maximize optimal outcomes for patients" (p. 16), and "develop a comprehensive plan of care…" (p.16). Although there appears to be clear value to effective care planning and the process of communicating the plan, evidence of this in the literature lacks specificity.

The patient care planning literature encompasses a wide variety of concepts, studies, and interventions. The main subdivisions of patient care planning in the literature are advance care planning (care at the end of life), case management (working with the entire medical team and associated professionals), and critical pathways or protocols for treating specific diseases. As defined, these categories are all potential conceptual matches and should encompass nurse-related care planning and plans. The majority of the care planning literature, however, is disease-oriented or medically focused, with little attention to the actual judgments and actions nurses take in carrying out the interdisciplinary plan at the point of care. Nor does this literature evaluate the impact of nursing care on patient outcomes. We believe the following illustrates the content of literature related to nurse care planning and plans.

Several studies have been done focusing on the introduction of the Scandinavian VIPS (well being, integrity, prevention, safety) model into care planning. Ehrenberg and Enfors[34] performed a stratified, randomized controlled trial using chart audit and interviews. They reported that their study group that received a new form and educational intervention exhibited increased completeness and correctness of documented information, although there were still some areas in which the control group documented better than the study group.

Care plan findings from Mason's[50] qualitative study indicated that care plans were not thought to adequately represent the patient, and consequently were not used in the planning or evaluation of care. Observations conducted as part of this study confirmed that the major guides to practice were report, direct observation of the patient, and bedside charts. In these clinical units, the care plan was viewed as actually discouraging thinking, because the standardized formats hindered individualized care by operating as check-off lists that discouraged nurses from engaging in mindful care planning. In one unit, however, the care plans were successfully integrated with practice.[50] Nurses' attitudes toward care plans in this unit were generally positive and the plans were used to aid in explanation and communication, and to guide practice. In this unit, care plans were kept at the bedside. The success of nurses' adoption of the care plans was attributed to the fact that they were perceived as clinically driven, more representative of the patient's condition, and there was a sense of local ownership.

Smith and colleagues[51] studied the implementation of a computerized care planning and documentation system, using the NIC and nursing outcomes classification (NOC) framework. Data were collected through questionnaires, observations, and chart audits both before and after computer implementation. Post implementation data revealed that the nurses' attitudes toward computers were more negative and charting time was unchanged; however, chart audits revealed improvement in the completeness of the nursing record.

In research where the intervention has focused on changing the care planning process, findings have shown that patient outcomes can be improved. Implementation of a care pathway for post surgical patients, to streamline nursing care of postoperative colon resection patients, resulted in a statistically significant shorter length of stay.[52] In another controlled study, From and colleagues[53] found that new care planning forms, as opposed to a narrative written in the medical record, could be associated with earlier recognition of patient problems, a shorter length of stay, and a higher accuracy in planning the discharge time.

Other studies have reported finding previously noted problems in the care planning practices. Research on the effects of the NANDA International, Nursing Interventions Classification (NIC), and Nursing Outcomes Classification (NOC) terminologies in the care planning process has also shown mixed results. Scherb[53] found that nursing care did make a difference in patient outcomes. However, because the method of data capture, it was impossible to identify the nursing diagnoses and interventions that contributed to the positive patient outcomes.[54]

In a related study, Lillibridge[55] found that when nurses were asked to list the type of data they would normally collect using specific examination techniques, 23 percent provided nursing assessment details. It can be argued that if nurses were provided with an explicit nursing framework (and language) to document and communicate about their care that nurses and the interdisciplinary team members would more readily understand the importance and impact of nursing care and patient outcomes. Others have also found that the care plans typically do not reflect actual nursing practice.[56, 57]

Even when care planning interventions are similar, as in the case of the introduction of the Scandinavian VIPS method for nursing documentation, results vary among studies. Studies by Darmer and colleagues[58] show both more methodological rigor and more positive results. This controlled, longitudinal study introduced the VIPS care planning model to nurses on eight units (four study and control units, respectively). The intervention consisted of different educational interventions prior to utilizing the VIPS care planning model. Data included surveys of nurses' attitudes towards documentation and their knowledge of the new regime. Nurses in the study group had more confidence in their ability to create good care plans and did better than the control group on the knowledge tests. Overall, the nurses in the study by Darmer and coworkers were more positively predisposed towards documentation than those in another VIPS study, by Björvell and colleagues.[41]

The Björvell and colleagues[41] study also featured a VIPS intervention and results overall were positive. There was a statistically significant score increase in quantity (*P* values for the quantity variables ranged from $P < 0.0001 – 0.0003$) as well as quality of the nursing documentation (*P* values of the quality variables ranged from $P < 0.0001 – 0.0002$). In a followup study, Darmer and colleagues[59] reviewed 600 charts utilizing the VIPS model at four sites using a standardized audit tool. They found that nursing documentation significantly improved during the course of the study ($P = .00001$). After the second year, the participants used the keywords appropriately and correctly according to the VIPS model. Overall, this structured implementation program significantly improved nursing documentation.

Implementing a new care planning system without sufficient cultural, educational, and organizational support has been identified as leading to problems. Educational interventions, in particular, are a major focus in the literature. Hansebo and colleagues[60] found that although care planning documentation increased after an educational intervention, the level of assessment was low. The authors concluded that educational interventions were needed to improve clinical judgment.

Lee[61] also identified major educational issues associated with the implementation of computerized documentation systems. He argues that launching a care planning system alone, without knowledge of the diagnoses or how to use the care plans in clinical decisionmaking, limits their utility. For Lee and colleagues,[30] the new system also increased nursing workload, primarily due to a lack of computers, and competition for terminals with other professionals and students. In the end, the nurses found the care plan lacking in three aspects: (1) content, primarily the inability to individualize patient care; (2) poor system function; and (3) lack of system

integration with the other information technology systems. In another article, Lee and Chang[62] report on an interview-based evaluation of this system. In this latter study, the nurses interviewed saw the new system as paperwork and not patient-oriented.

The quality of and implementation strategy for care planning systems has impeded adoption as much as the actual care plan within the system. Ammenwerth and colleagues[63] found that planning and documentation of tasks ($P = .004$) and report writing ($P = .019$) required significantly more time with the computer based system than with the paper based system. For the care planning module, no statistically significant difference between the study and control groups was seen due to the limited number of items. At the conclusion of Ammenwerth and colleagues' study, seven nurses (58 percent) agreed that the PIK software application saved time for care planning, but only three agreed that PIK saved time for documentation of tasks or for report writing. The majority of nurses agreed that with PIK, nursing documentation is more complete (10 nurses), legibility is better (9 nurses), and that the quality of documentation is better (8 nurses).[63] However, Ammenwerth and colleagues did not tie these findings to patient outcomes or changes in nursing practice. The conclusion that the introduction of a care planning system alone, without supporting organizational change, will not work is also supported by Spranzo's[64] work.

In summary, the nurse care planning literature indicates several things. First, when thought goes into the care planning process, better patient outcomes are possible. Second, altering the care planning process has thus far been done in an ad hoc manner and most of the evidence is from case studies. Individualized approaches have been implemented in specific settings. Their replicability across patient care settings, even from acute care to stepdown units within one hospital, has not been tested. While supporting the continuity of care on an individual unit is good, the larger issue of increasing continuity of care across time and space (across units and health care settings) needs to be addressed if patients are to receive truly holistic care. Third, current approaches to care planning have focused primarily on the care planning document itself. While some studies[52, 53] have changed the care planning process, the focus has been the actual plan. Finally, when the care planning process has been computerized, there appear to be substantial system problems resulting from a lack of nursing input into the module's design and functionality.[30] Lack of nursing input has contributed to the failure of the nurses in these studies to embrace care planning and, at times, even to be able to judge whether a different care planning approach would result in better patient outcomes.

Towards an Interdisciplinary Plan of Care

Given the problems in developing a care planning system that works well for just nurses, it is clear why creating comprehensive systems that support interdisciplinary plans is that much more complicated. This is particularly true if Gage's[65] conception of interdisciplinary teams is utilized. He defines multidisciplinary teams as those in which consultation is a series of individual consultations, where interpretation is made independently by members of the medical team. On the other hand, interdisciplinary care planning occurs when the team collaboratively synthesizes the information and reaches consensus around treatment and goals for the patient. Much of the literature falls short of Gage's ideal and what is categorized as interdisciplinary care planning should more appropriately be viewed as case management.

The majority of articles on interdisciplinary care planning focus either on case management or clinical pathways. These emanate from specialties and areas that traditionally have had closer ties among a variety of professionals (doctors, nurses, social workers) to manage a patient's

condition. Typical among the case management genre are case studies of interdisciplinary care planning in nursing homes[66] or for the elderly.[67] The clinical pathways articles focus on a specialty or specific unit, such as acute care.[68] In one qualitative study of an interdisciplinary discharge planning process, Atwal[69] found that many parts of the discharge process were regularly ignored and assessments were not done collaboratively. Nurses mentioned lack of time as the biggest barrier to interdisciplinary collaboration. Interdisciplinary care planning and the resulting plan can bring value to patients and enrich all disciplines; however, in its current iteration the vision proposed by Gage has not yet become a reality.

Practice Implications

Though the literature in this area lacks generalizability, there are a number of important implications that can be drawn. First, the enormous variability in the documentation and care planning practices exposed in this literature is a serious problem in and of itself. Given patients typically receive care from a variety of points across the health care system, moving from place to place where record content and format is variable, renders current medical records virtually useless in supporting patient-centric care in day-to-day practice. Moreover, information about a patient, once recorded, is either not accessible or—if available—is often in an unstandardized format (e.g., clinicians' own words), resulting in countless errors of omission, misinterpretation, and redundancies in care. So too, most care planning methods are considered to bring little value and suffer from the same problems of poor design, poor accessibility, and no standardization. The lack of utility of the medical record in day-to-day practice begs the moral issue of whether the cost of maintaining the record in its current form (approximately 15 percent of a nurse's time) is justified. The dollars spent on maintaining the "broken medical record" would bring more value if shifted to fund developing and refining industrywide solutions to repair the broken record. Further, the literature suggests that to compensate for poor record keeping systems, clinicians develop individualized shadow methods (scraps, also not standardized) to assist with organizing what each believes to be key information needed to carry out patient care. Since these information practices are nurse-centric and therefore variable, shadow methods further impede the flow and easy accessibility of patient information that promotes care continuity, quality, and safety.

Finally, there are valid instances of successful education interventions that improve aspects of documentation and care. The examples, however, are all locally focused and consequently also do little to fix the broken medical record. We see the broken record as a serious and costly problem to the health care industry and one that deserves a patient-centric industrywide solution. There were no studies of industrywide solutions noted in the literature. Until there is a true commitment to developing and refining industry-wide solutions that ensure accurate and comprehensive documentation, facilitating patient-centric care, the improvements that are possible in the areas of safety, cost, quality, and continuity will not be fully realized.

Research Implications

The research imperative for further study of this problem is manifested by the current state of the medical record and the high cost being incurred to maintain it. One approach to improve medical records is a patient-centric approach, which redesigns the recordkeeping system, and

that will automatically ensure that the continuity, quality, and safety of care are a primary focus. From this review, there are several key questions that need methodologically rigorous research:

1. How does variability in documentation impact patient outcomes?
2. What are the key components of an effective documentation process that is patient centered and improves the transfer of information among clinicians and across settings of care?
3. What aspects of documentation are shared among an interdisciplinary team, and what contributions to the patient record can each team member effectively provide?
4. Should documentation vary across settings of care?

Conclusion

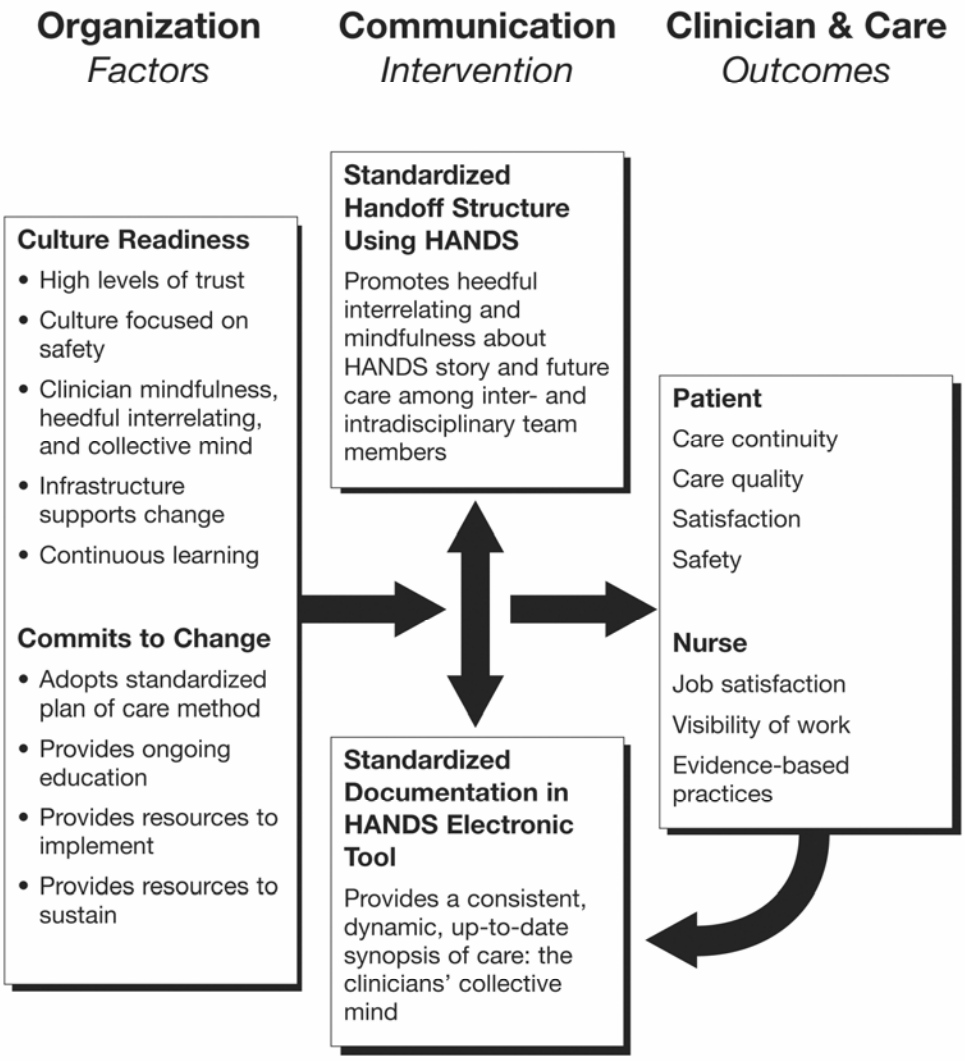
The evidence reviewed in this chapter suggests that formal recordkeeping practices (documentation into the medical record) are failing to fulfill their primary purpose, of supporting information flow that ensures the continuity, quality and safety of care. Moreover, disproportionate attention to secondary purposes (e.g., accreditation and legal standards) has produced a medical record that is document centered rather than patient focused. Cumbersome and variable formats, useless content, poor accessibility, and shadow records are all evidence of the extraordinary failure of the medical record. Given the exorbitant cost of the record and urgent need for tools that facilitate the flow of patient-centric information within and across systems, it is imperative to develop broad-based solutions.

Case Study: The HANDS Initiative and Plan-of-Care Method

The HANDS method is an intervention currently being refined to bring a strong patient focus to the medical record by replacing current forms of care plans with a single, standardized plan and related plan of care processes. The method addresses the needs, uncovered in this chapter, for summary patient care information that is standardized, meaningful, accurate, and readily available to all clinicians involved in a patient's care across time and space. The HANDS method embodies the concepts and characteristics of high reliability organizations and as such is fixated on ensuring the continuity, quality, and safety of patient care (See Figure 1: HANDS Method Framework, following this page).

As depicted in the framework, the central thrust of the HANDS plan-of-care method is to facilitate clinician behaviors (mindfulness) and communication (heedful interrelating) that form the basis of a collective mind among the clinicians (interdisciplinary team) involved in a patient's care. Organizations and systems factors must be aligned to support the mindfulness, heedful interrelating, and collective mind. The precursors to implementation of HANDS include culture readiness and a commitment to adopt and sustain the HANDS method (i.e., a commitment to change). Culture readiness is defined as an organization or system with an infrastructure that supports change and continuous learning, and is characterized by high levels of trust among its members and expectations that clinicians will engage in activities promoting mindfulness, heedful interrelating, and collective mind. Organization or system commitment to change is manifested by an organization or system formally adopting the HANDS standardized method for systemwide use, and by providing the necessary resources to educate, implement, and sustain the method across time. Finally, as is noted in the model, the patient care outcomes to be

Figure 1. HANDS Framework



HANDS = Hands-on Automated Nursing Data System

achieved by using HANDS and enabling mindfulness, heedful interrelating, and collective mind are safety, continuity, quality, and evidence based.

Earlier in this chapter, evidence from studies on nursing documentation and care plans as well as on interdisciplinary plans of care is presented and synthesized into a framework for the HANDS method. The method is an intervention that addresses the need for broadly based standardization of key aspects of documentation and communication, to facilitate patient-centric information flow. HANDS standardizes the plan-of-care documentation and processes, replacing the current widely variable forms, to support interdisciplinary decisionmaking that is based on shared knowledge among the clinicians. In this section, the history and future plans for the ongoing refinement of the HANDS method are presented.

This second part of the chapter focuses on the history of the HANDS Initiative and ongoing testing and refinement of the standardized plan-of-care method to date and future directions. The initiative addresses the gap previously identified in indicating the need for clinically relevant and patient-centric documentation and communication tools that support the collective mind (shared understanding) of the many clinicians involved in a patient's care across time and space. The project formally began in 1998[70] with the main purpose of bringing visibility, utility, consistency, and accessibility to the nursing portion of the interdisciplinary plan. As was previously noted, nursing care plans generally have brought little value in day to day practice due to the wide range of formats, lack of individualization and accessibility, and the infeasibility of keeping them current. During the initiative's early years the primary focus was on "perfecting" the format of the plan-of-care document through enabling technology and standardization. Through iterative refinement under real world conditions, we have learned that care plans, regardless of the quality of the document, bring little value unless they are an integral part of clinician-to-clinician (intra- and interdisciplinary) communication, serving as the basis upon which a collective mind among clinicians about a patient's care is formed. Our ultimate vision is to standardize the documentation and communication of a useful and dynamic interdisciplinary plan of care that is patient-centric, available, and used everywhere. In the following section, pertinent background information is presented, followed by a summary of the HANDS project accomplishments to date, future plans, and conclusions.

History of HANDS

The project began when our team of researchers attempted to use existing vendor software products to collect a nursing dataset coded with standardized terminologies, for a study of the Nursing Outcomes Classification in the mid-1990s.[71,72] The terminologies had been developed for the main purposes of representing nursing in health care databases and generating comparable nursing data for evaluating nursing practice. At the time, however, it became very apparent that, because of the wide variation in the practices used by vendors to integrate the terminologies into their systems, data was not comparable and frequently not retrievable. The HANDS initiative was thus born to remedy this situation and a prototype automated plan-of-care system with a database architecture that supported the generation of comparable nursing data was developed. It was clear to us, then and now, that the use of standardized terminologies alone is insufficient to produce comparable data. Instead, comparable data is generated when the same types of information are gathered at the same time intervals, using the same standardized response sets (standardized terminologies), same database architecture, and the same rules of data entry.

Standardized Nursing Terminologies

Since the late 1970s, efforts have been underway to identify nursing content and develop a means of representing it in computerized national health databases and clinical documentation systems. Werley and Zorn[73] first described a minimum set of elements needed in Nursing Minimum Data Sets, and they noted that content (terminologies) would need to be developed to represent the nursing-specific items of diagnosis, intervention, and outcome. It was projected that collection of the elements represented by standardized terminologies would provide comparable data that allowed multiple uses (e.g., describe, evaluate, trend, and benchmark nursing practice).[73] Subsequently, a number of terminologies have been developed to serve as response sets for nursing diagnosis, outcomes, and interventions. It is currently the purview of the American Nurses Association (ANA) Committee on Nursing Practice Information Infrastructure to set recognition criteria and formally recognize those terminologies meeting the established criteria. Over the years, the recognition criteria have been expanded and revised to align with the improvements in methods and tools for generating computable concept representations.[74] Unfortunately the Committee's actions have inadvertently confused the nursing constituency and thwarted progress toward achieving the vision of collecting comparable nursing data.

Since the early 1990s, the Committee on Nursing Practice Information Infrastructure has recognized more than one terminology (response set) for each of the data elements (diagnosis, intervention, and outcome), thus causing potential adopters to ask the question, "How are we going to get standardized data if nurses use different standardized languages?" The more recent recognition of entities (e.g., Systematized Nomenclature of Medicine Clinical Terms [SNOMED CT], and ABC Codes) that encompass content from the originally recognized nursing terminologies (NANDA, NOC, NIC, Omaha System, Perioperative Nursing Data Set, Clinical Care Classification, International Classification on Nursing Practice) has begged the question of how we are to use these recognized entities to achieve our professional goal of generating comparable nursing data. In truth, it is not clear how the 12 ANA recognized terminology entities can be used to generate comparable nursing data.[75]

The Terminology Solution in HANDS

From the beginning the HANDS project team grappled with how to create a long-term strategy that would generate professionwide, comparable nursing data when there was no professionwide commitment to a single terminology system. Given the circumstances of the time, we realized that professional consensus around a single terminology system was unlikely to occur in the absence of real time testing that demonstrated the value. We thus selected the terminology system with the broadest applicability—and that possessed characteristics indicative of its potential to grow and evolve over the long term—to be included in the HANDS method. The terminology system includes what is now called NANDA Classification,[76] NIC,[77] and NOC[78] to represent the diagnosis, intervention, and outcome data elements respectively gathered in HANDS. All three of the terminologies have infrastructures in place to maintain and evolve the terminologies across time. The NANDA, NOC, and NIC (N3) terminologies provide comprehensiveness of terms, in that each includes terms to describe care in all types of settings. Additionally, all have been developed through research involving literature review and the extensive input of large numbers of nurses.

The rate of diffusion of a new language can be accelerated by defining a clear direction and taking action. For example, usage of N3 in the 43 nursing programs in Michigan substantially

increased from1997 to 2001 following a resolution by Michigan Nurses Association to support N3 use in the State. NANDA usage remained high in 2001, with 92 percent of the schools of nursing (community college and university programs) indicating use. NIC usage rose from 22 percent to 58 percent and NOC usage rose from 0 percent to 58 percent between 1997 and 2001.[79]

Finally, there are several other points of evidence worth mentioning that indicate the long-term viability of the N3 terminologies within the nursing community at large. First, the N3 terminologies form a subset of SNOMED CT, the comprehensive clinical terminology. The SNOMED CT terminology is recognized by the National Centers for Vital and Health Statistics and the Consolidated Health Informatics Initiative as an acceptable standard for the Federal Patient Medical Record Information effort[80] and is an ANA recognized terminology.[75] Though nursing-specific terminology content is available in SNOMED CT, it is not the purview of SNOMED CT to keep the content current. Rather, the responsibility falls to nursing entities (terminology developers) to ensure that the quality and comprehensiveness of the terminologies is sustained and improved across time.

The N3 terminology developers are already taking responsibility for ensuring that the content is updated regularly, and that the terminology structures evolve in alignment with accepted standards for computable concept representations. As was previously noted, all three have strong internal structures for maintenance and updating of these terminologies, which have been in place for over a decade. The ongoing maintenance and support for NIC and NOC are provided through the University of Iowa-based Center for Nursing Classification and Clinical Effectiveness. To date, NIC has been translated into eight foreign languages and NOC into seven, indicating a growing international acceptance of these terminologies.[81] The ongoing maintenance and development of NANDA are provided by the NANDA International office at info@nanda.org. Every 2 years a joint N3 international conference is held at a central location in the United States to promote crosspollination of ideas that support continuous diffusion of these terminologies both nationally and internationally.

Another indicator of the long term viability of N3 is its growing and extensive presence in the literature. The technique for measuring such presence, bibliometrics, has been used in health care to evaluate the extent and rate of diffusion of an innovation.[82] For purposes of this chapter, a systematic search was conducted (with the help of CINAHL® personnel) to identify numbers of journal articles, complete books, and proceedings in which some aspect of the ANA-recognized, "nursing developed" terminologies (nursing content only) were a "major focus" between 1996 and 2006. The results appear in Table 3, and are organized by the nursing terminology system defined as providing terms for the data elements of nursing diagnosis, intervention, and outcome. Using this definition, there are five currently recognized ANA nursing terminology systems in addition to N3: the International Classification on Nursing Practice, the Omaha System, the Perioperative Nursing Data Set, the Clinical Care Classification, and (formerly) the Home Health Care Classification. Though the results must be interpreted with caution, it is readily apparent that there are major and substantial differences in the number of literature entries and trends between the N3 system and the others. Moreover, the number of entries for N3 appears to be growing rather than diminishing. Further analysis and interpretation of the findings will be presented in a forthcoming manuscript. Also of note is that the HANDS research conducted to date is providing evidence that N3 can be successfully integrated into a standardized, technology-supported care planning method, and generate comparable data to evaluate nursing practice.

The HANDS Initiative: Phase 1

Phase 1 of the HANDS project emerged in response to the absence of a path that would lead to the collection and generation of comparable nursing data. In this phase, our team focused on creating a standardized prototype of a dynamic, technology-supported plan that would generate comparable data. Our vision, then and now, is to evolve a useful care planning method that standardizes both the plan and the planning processes, is used widely, and generates standardized and comparable data for identifying and disseminating best practices. For a more specific account of the prototype development, see Keenan and colleagues[70]

In creating the original HANDS prototype, the team made a deliberate choice to incorporate the N3 terminology system to represent the data elements of clinical (nursing relevant) diagnosis, interventions, and outcomes for the reason described above. The initial HANDS work thus focused on perfecting a tool that could be used to document the plan and generate comparable data. The teams' efforts focused on the plan format, database, and rules of data entry. The approach matched the assumed need for such a tool with the availability of the means, including the technology and terminologies.[83] It was believed that the tool would help meet the vision of the HANDS.

Version 1 of HANDS (single user application) was initially implemented and tested in one intensive care unit. A sociocultural approach, putting our users front and center, was used to gain an understanding of the impact of the HANDS technology on nurses' work practices.[84] Many qualitative and simple quantitative methods were employed and repeated across time in our evaluations, and the results were added to improve the HANDS tool and processes through iterations of the design, test, and refine cycle. Our methods included observations, surveys, focus groups, "think-alouds," analysis of individual use patterns available in transaction logs, and routine checks of term meaning reliabilities and NOC outcome ratings.

The findings[85] gathered from the multiple methods in the pilot study helped uncover a number of issues with the technology that were not always apparent to our nurse subjects and permitted us to implement remedies. Most importantly we learned that our initial approach was document-centric. And although our method improved compliance and satisfaction with the care planning documentation, it did little to promote the collective mind of the clinicians involved in care. In fact, we found that many of the individual nurses religiously and mindfully updated plans of care in isolation. Rarely did nurses use the plans to guide clinician-to-clinician transfer of information. In retrospect, this finding was understandable and echoed the evidence reviewed in this chapter, that the plans have typically brought little value in day-to-day practice. Expecting nurses to use plans in more patient-centric, rather than document-centric, ways without educating them about how this might be done is unlikely to bring about the desired change. These results were used to refine the software and revise the rules and training for Phase 2 of the HANDS research initiative.

The HANDS Initiative: Phase 2

In preparation for this phase, the HANDS tool was converted to a Web-based application. WEBHANDS allows the clinician to easily enter and update a patient's plan from any terminal on the unit. Since the plan-of-care histories are stored on a central server, clinicians involved in a patient's care also have ready access to the history of the patient's plan from previous episodes. This information provides the clinician an "at-a-glance summary" of the issues that have been

addressed through the care provided by the health care team, and progress toward outcomes across time. The improvements in the software accessibility were expected to streamline the documentation of the plan of care and make it easier to integrate the plan into handover communication (intradisciplinary heedful interrelating)

Phase 2 research built on lessons learned in Phase 1, as well as the integration of evidence on communication, handovers, and behaviors characteristic of high reliability organizations. There are two major aims of this 3-year, multisite study of the HANDS method, *HIT Support for Safe Nursing Care*, funded by the Agency for Healthcare Research and Quality.[86] The aims include demonstrating that standardization of the HANDS method can be maintained across multiple diverse sites and that that the method fosters mindfulness, heedful interrelating, and collective mind as described in our framework presented earlier in the chapter. As can be seen, our emphasis moved from a document-centered to a patient-focused plan-of-care method that encompasses both the plan and the planning processes.

In the study, the HANDS method is implemented and fully evaluated on the participating units. Nurse champions are first identified and educated (40 hours: combination of in class, and independent study). The champions, in turn educate the remaining nurses employed on the unit (6 hours: 2 hours of classroom, 4 hours of independent study). A greater emphasis was placed on educating nurses to engage in heedful interrelating during handovers in this phase of our research. At this writing, we have just entered year 3 of the study and all units are fully live with the HANDS plan-of-care method. Nurses are required to enter admission or update care plans on all patients and to use the plans to structure communication at every handover.

Similar to our pilot phase, we are using multiple and repeated methods of evaluation and have already analyzed and integrated early findings into the tool and method.[87, 88] Thus far, we have demonstrated that standardization of care plan entry, storage, and retrieval can be maintained across the eight participating diverse units with the HANDS software tool. As in the pilot unit, nurses have reported high levels of satisfaction with the tool and are nearly 100 percent compliant in entering admission and update plans on all patients at every handover. Still needing improvement is the use of the plan at handovers (heedful interrelating). From interviews with nurses from our four first-year study units, we learned that there was wide variation in how nurses used the plans in the handover, and this was thought to add little value.[88] So, too, nurses complained that the most current plan was not always readily accessible for the handover. To remedy the situation, the nurses recommended developing a consistent format for handovers and creating easy access to the most current plan via the computer. The feedback was used to improve the software and plans of care were made readily available to the nurse via the patient list screen. In addition the SHARE (S-ketch, H-ANDS, A-ims, R-ationale, and E-xchange) structure was devised to help nurses uniformly integrate the plan of care into the handover process and both were added to the training of nurses in our year-2 study units.[88]

At this writing the four year-2 sites have been live with the revised HANDS method for nearly 4 months and, as with the year-1 sites, indicate satisfaction with the tool and almost 100 percent compliance with entering plans as directed. Nonetheless, even with the new enhancements, issues are surfacing that indicate that the revamped handover process is not yet fully working as expected. Further study of this issue is planned to determine how the handover communication can be improved. Intervention will then be devised and tested in an effort to improve heedful interrelating through our continuous learning model. In addition, we will complete our planned data collection, which will allow us to more thoroughly evaluate mindfulness and the impact of the HANDS method on the safety culture and error rates.

Future Plans for HANDS

Even without completing the full evaluation of the HANDS method in the current study, findings to date suggest several next steps. First and foremost, the study has provided evidence that the HANDS method is valuable and stable and should be considered for fuller adoption. This is because most of the benefits of the method can only be realized through widespread adoption and use, which motivates commitment that cannot be achieved when only one or two units in a system have adopted the method. For example, plan-of-care histories are not readily available unless all units in the system are using HANDS. Nurses also are reluctant to change comfortable (though variable) handover routines to embrace standardization before there is a full organizational commitment to the standardization. So, too, without widespread adoption and use of the method, it is difficult to identify best practices and disseminate these to the practitioners at the point of care through HANDS infrastructure. As is noted in our framework, depicted in Figure 1, the level of success of HANDS is integrally connected to the level of commitment to the change by the overall organization. For this reason we are encouraging organizations who express interest and readiness to adopt HANDS, to commit to full organization and adoption of the HANDS method.

We also see the need to formally position the HANDS method as an interdisciplinary initiative. As was noted in the previous sections' conclusions, there is a pressing need for tools that support the collective mind of the entire interdisciplinary team around a patient's care. The HANDS method already includes a number of features that can be easily adapted to accommodate the needs of the interdisciplinary team members. At this time a future study is planned to collaborate with physicians on refining the method for interdisciplinary use.

Finally, the method has been designed to work in and across all types of settings where patients seek care. To bring the intended value the method must work regardless of the Clinical Information System (CIS) adopted within the institution. We have begun planning the development of a universal connector that will allow HANDS to seamlessly connect to an organization's CIS regardless of the vendor types. In addition, other studies are underway to determine how to make HANDS available for immediate and widespread use. Of deepest concern and the direction of the team's passion and efforts is achieving our longstanding vision for health care.

Even without completing the full evaluation of the HANDS method in the current study, findings to date suggest several next steps. First and foremost, the current study has provided some evidence that the HANDS method is valuable and stable and should be considered for wide scale adoption. This is because most of the benefits of the method can only be realized through wide scale adoption and use that motivates commitment that cannot be achieved when only one or two units in a system have adopted the method. For example, plan of care histories are not readily available unless all units in the system are using HANDS. Nurses also are reluctant to change comfortable (though variable) handover routines to embrace standardization before full organization commitment to the standardization has been established. So too, without widespread adoption and use of the method it is difficult to identify best practices and disseminate these to the practitioners at the point of care through HANDS infrastructure. As is noted in our framework, depicted in Figure 1, the level of success of HANDS is integrally connected to the level of commitment to the change by the overall organization. For this reason we are encouraging organizations who express interest and readiness to adopt HANDS, to commit to full organizational adoption of the HANDS method.

It could be important to formally position the HANDS method as an interdisciplinary initiative. As was noted in the previous section, there is a pressing need for tools that support the collective mind of the entire interdisciplinary team around a patient's care. The HANDS method already includes a number of features that can be easily adapted to accommodate the needs of the interdisciplinary team members. Finally, the method has been designed to work in and across all types of settings where patients seek care. As such, to realize the intended value, the method would need to be effectively integrated in all clinical information systems across institutions.

Search Strategy

The areas covered in this literature review were nursing documentation and care planning. The literature cited in this chapter was identified in several ways. The medical and nursing literature on care planning, standardized terminologies, documentation, and quality indicators has been reviewed, selecting and retaining only those references that pertain to this work in some way regardless of the quality of the evidence. Additionally, a comprehensive search of the health care and organizational behavior literature was conducted, from 1996 to 2006 in MEDLINE® (using the OVID interface), CINAHL®, Cochrane Library, PubMed®, Dissertation Abstracts International, and Business Source Complete (EBSCO) to find high quality evidence available on nurse care planning and documentation. The main MeSH® subject search terms included continuity of patient care, documentation, medical errors, nursing records, patient care planning, and quality indicators–health care. A successive fractions search strategy was employed—a large selection of articles was made and then this was pared down to create a subset of the most applicable articles. To generate a large collection of potentially appropriate articles, each subject term was searched with minimal parameters from the subject heading; generally methods, standards, trends, and utilization were selected generating 9,422 matches. The additional limits of clinical, controlled, and randomized controlled trials (English) were set, producing a total of 118 matches.

Review of the 118 studies revealed that a number were not pertinent. For example, none of the 22 patient care planning articles pertained to nurse care planning. Only 3 of the 31 documentation articles were relevant. Many of those in the overall category of documentation were general and did not pertain to nursing. Also documentation often referred to research data collection or some other intervention, and not to patient care documentation. Consequently the results of the three searches (patient care planning AND nursing records, patient care planning AND documentation, and nursing records AND documentation) were reviewed to identify other pertinent studies, largely evaluative in nature. In these secondary searches, articles by anonymous authors, foreign language materials, commentaries, letters, 1-2 page articles, and those that were out of scope were eliminated. The resulting summaries of these articles appear in two evidence-based tables. Table 1 includes 17 studies representing the literature associated with recordkeeping quality, including studies evaluating completeness, accuracy, and timeframe of documentation. In Table 2, 22 articles are included describing research aimed at improving documentation and care planning practices.

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Table 1. References Associated with Recordkeeping Quality (Completeness, Time)

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Allen 1998[29]	Examines nurses' views of the nursing record and its usage in practice	Qualitative study, United Kingdom	1 Hospital 2 Units 29 Registered nurses 8 Doctors 5 Auxiliaries 11 Clinical managers	Observations Interviews	-Written form of the nursing process comprises three main components: (1) pro forma, where biographical information is recorded; (2) a nursing care plan (patient's problems are identified and the appropriate nursing response is agreed upon); and (3) the nursing kardex (record of patient's progress). -Perceptions of care planning: (1) pressured to included 'problems' to satisfy quality assurance initiatives; (2) completed for fear of repercussion by senior staff; (3) mechanistic script to alleviate legality concerns; (4) devalued, as it is destroyed after patient's discharge; (5) rarely reviewed during patient stay.
Bjorvell 2002[41]	Evaluate effects of intervention on the quantity and quality of nursing documentation	Quasi-experimental longitudinal study	1 Hospital 3 Wards 269 Patients records	Intervention = organizational changes and education regarding nursing documentation, with the VIPS model using the Chart Audits (Cat-ch-Ing Instrument)	-Statistically significant score increase in quantity (*P* values for the quantity variables ranged from $P < 0.0001 – 0.0003$) as well as quality of the nursing documentation (*P* values of the quality variables ranged from $P < 0.0001 – 0.0002$), in the intervention wards, directly after the intervention.
Currell 2003[25]	Assess the effects of registered nurses' record systems on nursing practice & patient outcomes	Cochrane systematic review	8 Clinical Trials 1,497 people	Systematic Review	-No conclusive evidence was found of effects on practice attributable to changes in record systems. -RNs experience tensions between PT needs and hospital management documentation rules
Ehrenberg 2001[34]	Analyzes the concordance between nursing documentation & descriptions of practice	Case comparison study random sampling	17 Nursing homes wards 85 Patients 128 interviews	Audits of records; Interviews of patients and RN	-Problems more frequently reported than recorded in the patient records—between 11% and 59% of the patients' problems identified by the nurses were recorded. -Concordance between nurses' statements and recorded data was significantly better in the study groups on mental condition ($P < .001$), and mobility ($P < .005$)

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Griffiths 1999[42]	Determine adequacy of nursing documentation in describing patient care	Retrospective, criteria based audit Random sampling	1 Trust 103 care plans	Audit of Charts	-Room for improvement in the documentation of evaluation within the nursing care plans.
Hardey 2000[31]	Explore the role of RN interaction and documentation on patient care	Qualitative, nonexperi-mental ethnographic study	1 Hospital 5 Wards 34 Registered nurses 23 Handovers	Observations Interviews	-Nurses argued repeatedly that their scraps (personal notes) were more up to date, convenient, and therefore were a better source of information than was conventional paperwork. -Care plans were not used to inform care
Karkkainen 2005[27]	Synthesis of literature surrounding patient care & nursing documentation	Meta-synthesis evaluation study	14 Qualitative research reports	Literature Review and Synthesis (1996 – 2003)	-Individualized care not clearly visible in nurses' documentation; tasks described more frequently than patients' experiences of their care. -Documentation did not reflect the care being provided to the patient. The structure of nursing documentation, which is presupposed by the organization, may prevent individual recording of patient care.
Korst 2003[13]	Determine time spent on documentation	Work sampling study	1 Hospital 1 Unit 120 Observations	Observations (of documentation in the EHR and paper format)	-Percentage of time spent by nurses on each activity: 15.79% spent on all documentation: paper charting used 10.55% of nursing time, computer charting used 5.24% of time; 11.39% of time charting at the bedside, compared with 4.4% at other unit work areas.
Langowski 2005[26]	Determine electronic documentation systems link with improved quality	Literature review	5 Studies	Literature Review	-Overall, online nursing documentation systems would be beneficial in improving documentation requirements, end-user satisfaction, and influence how nursing is practiced
Larrabee 2001[40]	Evaluates differences in documentation after implementation of nursing information system	Time series evaluation study	1 Hospital 3 Units	Intervention = implementation of care planning feature in a NIS (Nursing Information System)	-Mean nurse assessments of patient outcomes (NASSESS) scores were statistically significant at the $p<0.000$ among nurses during each of the three study time points. No consistent pattern for which unit had the highest/lowest score, although Unit 3 did have the lowest score at Times 1 and 2. -Six months of using a nursing information system is not sufficient time for registered nurses to acquire documentation mastery (as evident by decrease in scores from Time 1 to 2 and increase from Time 2 to 3 for many of the variables).

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Ngin 1993[32]	Explores user acceptance of health information technology	Non-experimental, descriptive study	547 Registered nurses	Focus Groups Observations Surveys	-Health information technology required greater coordination so that information is entered and Registered nurse tasks are carried out in a timely manner. -Hospital membership, position occupied, and unit norms significant predictors of computer use. -Organizational variables were better predictors of actual computer use, and individual variables were better predictors of attitudinal user acceptance.
Poissant 2005[14]	Identify factors associated with differences in effectiveness among electronic health records	Systematic review	23 Studies	Literature Review	-Use of bedside terminal and central desktops respectively saved registered nurses 24.5% and 23.5% of time spent documenting during shift. -Desktop for computerized prescription order entry was found to be inefficient, increasing work time 98% to 328% (Medical doctor time per shift)
Sterling 1996[38]	Determine change in documentation of wound assessment	Nonexperi-mental, comparative independent groups study	2 Hospitals 3 Wards 46 Patient charts	Chart Audits	-Relevant parameters of wound assessment were documented more frequently when a wound assessment chart was used -Many of the delaying factors suggested as important in the literature for wound care were not documented.
Stokke 1999[36]	Evaluate quality and completeness of documentation	Nonexperi-mental, descriptive study	2 Hospitals 5 Wards 55 Patient Records	Chart Audits	-Nursing care plan was present in 62% of the records. Nursing goals were lacking in the remaining 38%, diagnosis and planned interventions were absent in 18%, and 45% of the diagnoses lacked information concerning patient progress or outcome. -The nursing care plans were updated in only 40% of the records and discharge notes were present in 35% (NBH recommendations not met).
Taylor 2002[37]	Identify problem-solving studies used while providing patient. care	Qualitative, nonexperi-mental study	1 Hospital 33 Registered nurse students/Registered nurses	Observations Interviews	-Nurses accessed four main data sources when preparing to carry out a procedure: nursing handover, patient documentation, previous knowledge of the patient, and a selection of other sources grouped as “miscellaneous.” -Patient documentation (history and care plan are two most significant sets of documents): Many of the nursing care plans reviewed in this study did not convey the specific information necessary to carry out the required procedures; 1/3 mentioned accessing written documentation, but did not express a preference for source.

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Tornkvist 2003[39]	Determine effects of an implementation of pain-advisers on satisfaction & documentation	Controlled clinical trial	5PHCCs 53 Registered nurses	Intervention = implementation of 'pain advisers' Survey	-Several statistically significant improvements were achieved after the introduction of 'pain-advisers' in the study units -Increased registered nurse satisfaction with documentation in study units
Tornvall 2004[33]	Determine what documented in the health record	Nonexperimental, descriptive study; stratified random selection	27 Primary health care centers 154 District nurses 41 Nursing records	Survey Chart Audit (using Catch-Ing,)	-Keywords "nursing intervention," "nursing outcome," and "nursing status" received the highest score, whereas keywords "nursing goal" and "nursing diagnosis" received the lowest score. -Patient status found in 30% of the notes under keyword "nursing intervention." All notes contained medical details and medically based treatments. -Predominance of documentation of medical/objective status rather than nursing status.
Urquhart 2005[24]	Update of Currell and Urquhart (2003) Cochrane Review assessing the effects of registered nurse record systems on nursing practice & Patients outcomes	Systematic review	26 Qualitative studies	Systematic Review	Qualitative research on nursing records systems, documentation of verbal exchanges concerning nursing care, and organization of nursing records are inconclusive concerning how well the records represent nursing practice and which systems (analog or computerized) improve patient outcomes.

Table 2. References associated with Improving Documentation and Care Planning Practices

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Ammenwerth 2001[63]	Investigate influence of information technology on time and quality of documentation	Randomized control trial	1 Hospital 5 Medical doctors 12 Registered nurses 60 Patients	Intervention = implementation of a nursing information system. Documentation Analysis; Survey	-Documentation of tasks (*P* = .004) & report writing (*P* = .019) required more time with the computer-based versus the paper system; time for preparing care plans was not significantly different between groups -Survey—7 registered nurses (58%) agreed that PIK saved time for care planning; only 3 (25%) agreed that PIK saved time for documentation of tasks or for report writing; 10 registered nurses (83%) agreed nursing documentation was more complete, 9 (75%) agreed that legibility was better & 8 (66%) agreed that quality of documentation was better.
Atwal 2002[69]	Understanding of RNs' perception of the discharge process	Case study	1 Trust 19 RNs	Interviews Observations	-Communication dependent on the relationship between members of the team. RNs noted difficulty in communicating with others on the team (i.e., time-consuming task) -RNs concerned that nurses did not question info that they did not comprehend at handover. Handover was the key area where information was miscommunicated.
Axford 1996[47]	Determine impact of CIS on nursing practice	Non-experimental, descriptive study	33 Registered nurses (interviews) 291 Registered nurses (survey)	Interviews Surveys	-Nurses (whether computer naive or knowledgeable) do not expect the technology to have negative impact on practice. -The two groups differed mostly in the strength of their beliefs. One startling outcome, that slow computer response time delayed care, was identified within the computer-user group and direct action was taken as a result.
Bjorvell 2002[41]	Evaluate effects of intervention on the quantity and quality of nursing documentation	Quasi-experimental longitudinal study	1 Hospital 3 Wards 269 Patient records	Intervention = organizational changes and education regarding nursing documentation with the VIPS model Chart Audits (Cat-ch-Ing Instrument)	-Statistically significant score increase in quantity (*P* values for the quantity variables ranged from $P < 0.0001 – 0.0003$) as well as quality of the nursing documentation (*P* values of the quality variables ranged from $P < 0.0001 – 0.0002$), in the intervention wards, directly after the intervention.

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Darmer 2006[59]	Evaluate the quality of nursing assessment and quantity of care plans using the VIPS model	Evaluation study	4 sites 600 Patient charts	Intervention = implementation program introducing the VIPS model Chart Audits (Cat-ch-Ing Instrument)	-Nursing documentation significantly improved during the course of the study (*P* = .00001). -The structured implementation program significantly improved nursing documentation and the simultaneous training of the entire nursing staff.
Darmer 2004[58]	Explores registered nurses' knowledge and attitudes towards documentation	Controlled clinical trial	1 Hospital	Intervention = implementation program introducing the VIPS Model Survey & Test	-Experimental group were significantly stronger in their convictions that they had the knowledge to make care plans (*P* = 0.03) and that they routinely made them (*P* = 0.01). -Experimental group showed less motivation than the control group, although both did consistently better on the knowledge tests
Dillon 2005[45]	Predict registered nurses intention to adopt Electronic Health Records	Nonexperi-mental, descriptive study	1 Hospital 140 Registered nurses	Survey	-Age was a significant factor in determining nurses' attitudes towards the electronic patient record system (*P* < .05). -Age had a direct (*P* = .02) and indirect (via Image, *P* = .02) effect on nursing attitudes towards the electronic patient record system. -Image had a direct effect (*P* = .000) on attitudes of nurses towards the electronic patient record system. -Nurses presented concern with the new electronic patient record system, thinking it may be risky and remove the human component of what nurses do.
Ehrenberg 2001[34]	Analyzes the concordance between nursing documentation & descriptions of practice	Case comparison study, random sampling	17 Nursing homes wards 85 Patients 128 Interviews	Audits of records Interviews of patients and registered nurses	-Problems more frequently reported than recorded in the patient records—between 11% and 59% of patient problems identified by the nurses were recorded. -Concordance between nurses' statements and recorded data was significantly better in the study group on mental condition (*P* < .001), and mobility (*P* < .005)

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
From 2003[53]	Evaluates care planning in 2 different ways, and its effectiveness on improving outcome	Randomized controlled prospective	Study 1 (S1): 1 Hospital 4 Units 222 Patients Study 2 (S2): 1 Hospital 4 Units 304 Patients	S1 Intervention = Registered nurses & Medical doctors collaboratively developed care plans S2 Intervention = care plan randomly removed from record Interview Chart Audits	(S1) -Problems identified earlier with intervention *P* = .01 (1 vs. 3 days) - Solutions initiated earlier with intervention (Not statistically significant); LOS same between both groups (Not statistically significant) (S2) -Patients with planning form still on record had lower length of stay (*P* = .02) and greater accuracy of expected length of stay (*P* = .02) -Accomplishment of plan of action and readmission unchanged.
Hansebo 1999[60]	Comparison of nursing documentation before and after a supervised intervention	Pre-/post-intervention study Sweden	3 Wards 58 Patients	Intervention = implementation of individualized and documented care using the RAI/MDS Chart Review	-Daily notes increased both in total (42% increase after intervention) and within parts of the nursing process (patient situations increased 63%, implementation by 61%, and evaluations by 100%). -52% of the Resident Assessment Protocol items not documented in care plans.
Karkkanien 2005[46]	Extent to which theory-based documentation reveals actual patient's experience with care	Pre-/post-intervention study	6 Hospitals 7 Wards 137 Registered nurses	Intervention = educational component to apply theory of caring science to care plans Audits Surveys	-Post-intervention, more attention was noted to patient views and increase in recording of patient care plans -RNs need strong support from managers to successfully implement a theory-based documentation system
Lee 2005[30]	Identify factors influencing effectiveness of information technology	Cross-sectional, non-experimental study	120 Units 738 Surveys	Surveys	-Major issues identified by users of computerized documentation systems**:** hardware insufficiency, content design, poor system function, policy requirement, privacy/legal violations, and other perspectives -Nurses were dissatisfied with the care plan content, inability to individualize, poor system function, and no system integration

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Lee 2005[61]	Explore factors affecting nurses' use of nursing diagnoses in charting standardized nursing care plans	Qualitative Taiwan	1 Hospital 12 Registered nurses	Interviews	-Themes described by nurses when using nursing diagnoses in standardized nursing care plans: (1) choosing familiar patient problems—fitting diagnoses to existing paper form; (2) Inapplicable related factors—turn to SOAP notes (some of the factors on the standardized forms were not applicable); (3) Unavailable subjective data—replaced with objective data; (4) Unrealistic expected goals—skip or ignore (expected goals largely ignored); (5) General intervention—selected or added to the chart as needed (listed activities comprehensive, but not realistic); (6) requirement for consistent evaluation created meaningless tasks (most labor-intensive aspect of documentation).
Lee 2004[62]	Explore nurses' experiences using a standardized care plan	Qualitative Taiwan	1 Hospital 19 Registered nurses	Interviews	-Themes describing impact of standardized care plan: (1) being reminded of care procedures; (2) time saved in making care plans (with standardized format); (3) Making shift reports very timely (too much paper); (4) Undesirable content design (inflexible & hard to apply to individual patients); (5) paperwork-oriented/not patient-centered (time consuming, double charting). -Some patient problems ignored to lighten the paperwork load
Lillibridge 1999[55]	Investigate health assessment and documentation practices	Nonexperi-mental, descriptive study	1 Hospital 2 Domiciles 65 Registered nurses	Survey	-Only 23% of nurses mentioned nursing assessment details when asked to list the type of data they would collect for specific examination techniques - Findings generally indicated that nurses appear to maintain a medical- versus-nursing perspective of their actions—perpetuates view that nursing practice is medically driven
Mason 1999[50]	Investigate current care planning and effects on practice	Qualitative United Kingdom	5 Trusts 5 Units	Observations Focus groups Subject Diaries	-In the 4 comparable units, the primary issues identified with care planning included lack of time, pressure, not seen as valuable, & lack of specificity. -Observation confirmed the main guides to practice were verbal report, direct observation of the patient, and bedside charts. -In the specialty unit, the care plans were integrated well with practice, were viewed positively, guided communication & practice, and were kept at bedside.

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Nahm 2003[48]	Determine effects of a clinical information system on documentation & patient satisfaction	Quasi-experimental study	1 Hospital 11 Units 288 Patient charts	Chart Audits Survey	-13% increase in compliance to JCAHO standards (85% vs. 98% at 18 months) (*P* = .0003) after intervention of a clinical information system -After intervention, each of the three time periods showed a statistically significant improvement in quality of documentation (*P* < .01)
Scharf 1997[43]	Examine the association between time associated with documentation practices and patient outcomes	Pre- and post-controlled pilot study	2 Units 100 Patients	Intervention = revised flow sheets replaced previous documents. Included standard nursing interventions for the most commonly identified nursing diagnoses.	-A decrease of 20 minutes in charting per shift (143 minutes vs. 123 minutes) after intervention, while patient outcomes (length of stay, nosocomial infection, medication errors, and falls) remained the same on both units. -Slight improvement in patient's satisfaction and knowledge rates on the experimental units, with decreases in satisfaction and knowledge rates in the comparison unit.
Scherb 2002[54]	Identify effects of nursing interventions noted in the EHR on patient outcomes	Longitudinal study	2 Facilities 669 Patients	Chart Review (care plan and NOC outcomes on admission and discharge)	-Nursing care did make a difference in patient outcomes, although it was not possible to identify which interventions contributed to achievement of outcomes -3 outcomes with the largest sample size for each patient population were significantly improved at discharge compared to the admission rating (*P* < .008).
Smith 2005[51]	Identify association between a computerized documentation system with satisfaction, completeness, and timeliness	Quasi-experimental, evaluation study	3 Units 46 Registered nurses 141 Patient Records	Intervention = implementation of electronic care planning system Survey Observations Audits	-Statistically significant decreases in scores from pre- to post-intervention: (1) computers make registered nurses ' jobs easier (*P* < .001); (2) computers save steps and allow registered nurses to become more efficient (*P* = .002); (3) increased computer usage will allow RNs more time for patient care (*P* = .002); and (4) computer increases costs by increasing the registered nurses' workload (*P* = .002). -Completeness of documentation post-intervention: 28 (34%) documentation elements (of 8 NIC categories) were significantly more complete post computerization; 49 (60%) of the data elements remained unchanged, and five data elements (5%) were less complete post-intervention. -Time spent with the patient directly reduced from pre- to postintervention (40.4 minutes to 35.5 minutes, not statistically significant) although documentation time remained unchanged

Source	Issue	Design	Sample	Methods/Measures	Selected Findings
Spranzo 1993[64]	Effects of computerized care planning on select outcomes	Pre-/post-intervention study with qualitative component	1 Hospital 4 Units 88 RNs 153 Patients	Intervention = implementation of a computerized care planning system Survey & Patient interviews	-Introduction of care plans had little effect on patient outcomes. -Quality of nursing care remained constant despite the difference in documented care planning.
Stephen 2003[52]	Identify link between implementa-tion of critical path and patients length of stay	Pre-/post-intervention Study	1 Hospital 138 Patients	Intervention = implementation of the critical pathway for Patients undergoing colon resections	-Mean total length of stay was less in post clinical pathway patients compared to preclinical pathway patients ($P < .001$) -Average cost per patient, with readmission costs added, was higher in the pre-pathway group compared to post-pathway group ($P = .002$).

Table 3. Number of CINAHL "Major Focus" Entries for the 5 ANA Recognized Nursing Interface Terminology Systems 1996-2006*

Terminology systems**	1996-2000	2001-2005	2006 – 10/27/06	Total
1. N3				
NANDA	115	189	45	349
NIC	38	126	23	187
NOC	26	114	25	165
Total/***duplicates	179/19	429/145	93/26	701/190
Total minus duplicates	160	284	67	511
2. ICNP	5	44	4	53
3. OMAHA	25	19	3	47
4. PNDS	5	8	1	14
5. CCC****	2	6	-	8

* Includes journal articles, books, and conference proceedings in which a terminology system or component of it was considered a "major focus."

** Includes terms for nursing diagnoses, interventions, and outcomes. NANDA diagnosis, NIC interventions, and NOC outcomes, though recognized singularly by ANA as interface terminologies, are used in combination (N3) as a terminology system. Thus there are currently "5" nursing interface terminology systems recognized by ANA.

*** Duplicates include entries where two or more of the N3 terminologies are considered a "major focus."

**** Formerly the Home Healthcare Classification.

Chapter 50. Patient Care Technology and Safety

Gail Powell-Cope, Audrey L. Nelson, Emily S. Patterson

Background

The general public believes that technology will improve health care efficiency, quality, safety, and cost. However, few people consider that these same technologies may also introduce errors and adverse events.[1] Given that nearly 5,000 types of medical devices are used by millions of health care providers around the world, device-related problems are inevitable.[2] While technology holds much promise, the benefits of a specific technology may not be realized due to four common pitfalls: (1) poor technology design that does not adhere to human factors and ergonomic principles,[3] (2) poor technology interface with the patient or environment,[3] (3) inadequate plan for implementing a new technology into practice, and (4) inadequate maintenance plan.[4]

Patient care technology has become increasingly complex, transforming the way nursing care is conceptualized and delivered. Before extensive application of technology, nurses relied heavily on their senses of sight, touch, smell, and hearing to monitor patient status and to detect changes. Over time, the nurses' unaided senses were replaced with technology designed to detect physical changes in patient conditions.[5] Consider the case of pulse oxymetry. Before its widespread use, nurses relied on subtle changes in mental status and skin color to detect early changes in oxygen saturation, and they used arterial blood gasses to confirm their suspicions. Now pulse oxymetry allows nurses to identify decreased oxygenation before clinical symptoms appear, and thus more promptly diagnose and treat underlying causes.

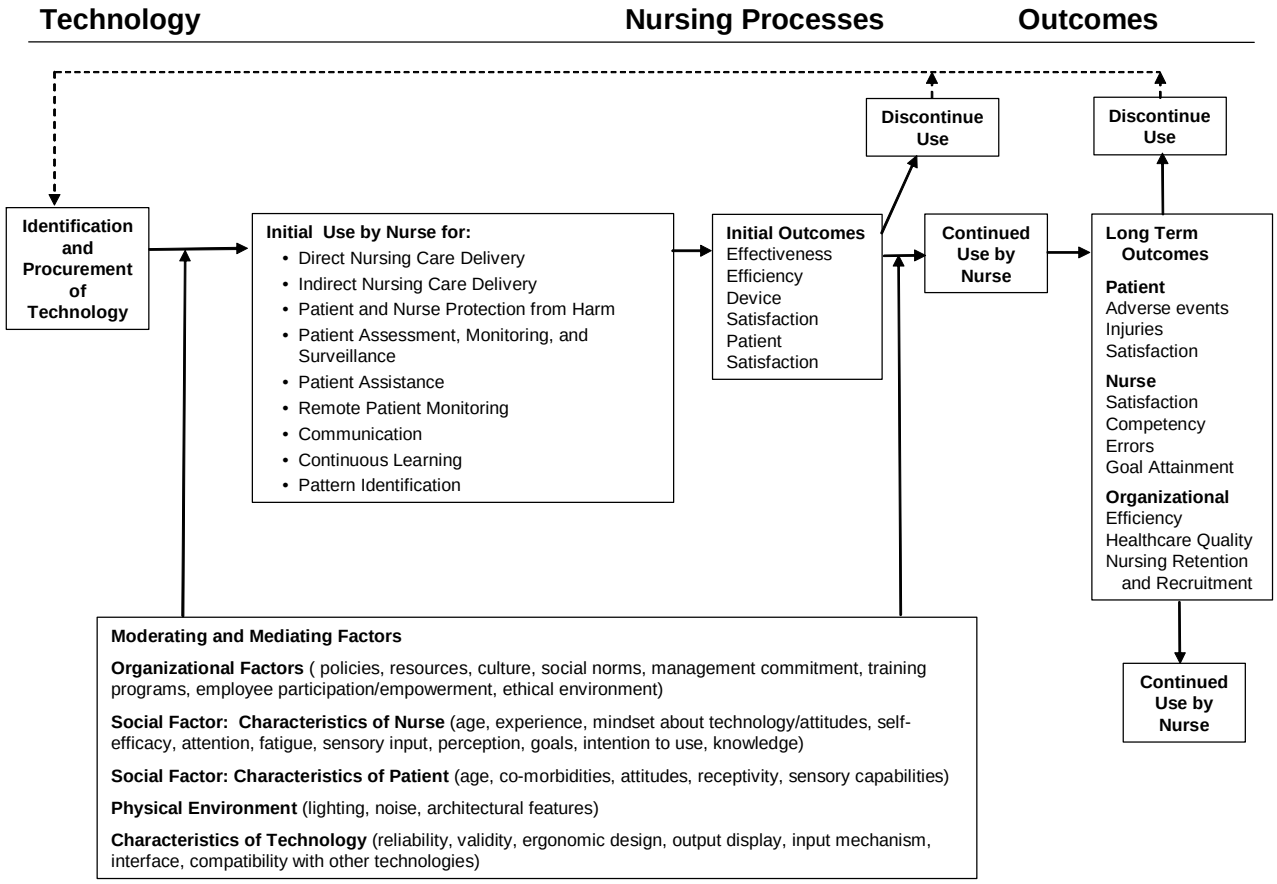
While technology has the potential to improve care, it is not without risks. Technology has been described as both part of the problem and part of the solution for safer health care, and some observers warned of the introduction of yet-to-be errors after the adoption of new technologies.[6] For example, nurses and other health care providers can be so focused on data from monitors that they fail to detect potentially important subtle changes in clinical status. Problems may emerge based on the sheer volume of new devices, the complexity of the devices, the poor interface between multiple technologies at the bedside, and the haphazard introduction of new devices at the bedside. Despite the billions of dollars spent each year on an ever-increasing array of medical devices and equipment, the nursing profession has paid little attention to the implementation of technology and its integration with other aspects of the health care environment.

Patient care technologies of interest to nurses range from relatively simple devices, such as catheters and syringes, to highly complex devices, such as barcode medication administration systems and electronic health records.[7] Technology can be broadly defined to include clinical protocols and other "paper" based tools, but for the purpose of this chapter, we will focus more on equipment and devices that nurses are likely to encounter in delivering direct care to patients. The purpose of this chapter is to provide a conceptual model for technologies that nurses are likely to encounter and to delineate strategies for promoting their effective and safe use.

Conceptual Framework

Based on a review of the literature, a conceptual framework was developed that depicts the relationship among the nurses' use of technologies; moderating and mediating factors that affect use; and the potential nurse, patient, and organizational outcomes (Figure 1). This model was developed independently, but is similar to the work of Fuhrer and colleagues,[8] whose framework of assistive technology device outcomes is patient-centric. We included key nursing processes and outcomes for which technology plays an important role in care delivery and in preventing adverse events.

Figure 1. Conceptual Model for Technology, Nursing, and Patient Safety



This conceptual model places the use of technology in the context of nursing practice and offers a framework for examining both the short- and long-term outcomes of technology use on the patient, the nurse, and the organization. Fuhrer's model focused on assistive technologies, that is, a spectrum of interventions—including structural and nonpermanent alterations of the physical environment, equipment attached to the physical environment, devices used by individuals, and behavioral modification—for promoting independence and function with a disability. This model is extended to include a full range of technologies used by nurses in the delivery of nursing care (Table 1). Patient care technologies can be classified in many ways. These technologies are categorized by commonly understood nursing activities: direct nursing

care delivery technology, indirect nursing care delivery technology, communication technology, patient and nurse protective devices, nurse protective devices, patient assessment, monitoring and surveillance, patient assistive devices, remote monitoring, continued learning, and pattern identification. Well-designed technology allows nurses to focus on caregiving functions and promoting the health of patients.

Table 1. Technology Commonly Used by Nurses

<table>
<tr>
<td rowspan="2">Direct Nursing Care Delivery Technology
Barcode medication administration
Intravenous (IV) tubing
IV pumps
Feeding pumps
Nasogastric tubes
Endotrachial tube
Tracheostomy tubes
Syringes
Needles
Urinary catheters and drainage bags
Ostomy appliances
Wound drainage tubes
Chest tubes
Suction equipment
Oxygen and air regulators, tubing, and face masks
Oxygen tanks and regulators
Nebulizers
Dressings (from gauze to specialized materials)
Traction systems
Code carts</td>
<td>Indirect Nursing Care Delivery Technology
Robotics
Radio frequency identification
Electronic inventory systems
Computerized staffing systems</td>
<td>Communication With People Distanced by Place and Time
Electronic medical records
Electronic ordering systems
Communication devices (cell phones, PDAs, “Voicera,” paging systems)
Call systems, including emergency call bell</td>
</tr>
<tr>
<td>Patient Protective Devices
Floor mats
Beds
Elopement/wandering alarms
Fall alarms
Hip protectors
Specialized mattresses (e.g., low air loss)
Specialized lighting
Hand rails in patient rooms, hallways, and bathrooms
Specialized seating cushions
Limb compression devices</td>
<td>Patient Assessment, Monitoring, and Surveillance
Telemetry
Bedside monitoring
Ventilators
Video surveillance
Stethoscope
Sphygmomanometer
Thermometer
Otoscope
Ophthalmoscope
Pulse oxymetry</td>
</tr>
<tr>
<td rowspan="2">Patient Assistive Devices
Canes
Walkers
Robotics
Stand assist lifts
Trapeze bars
Patient transfer devices ECD
Bed pans
Wheelchair
Prosthetic limbs
Orthotics (braces, shoes)</td>
<td>Nurse Protective Devices
Face masks
Gloves
Gowns
Hand sanitizer dispensers
Mechanical lifts
Patient transfer devices</td>
<td>Remote Patient Monitoring
Telemedicine and telehealth</td>
</tr>
<tr>
<td>Continuous Learning
Distance learning
Video conferencing
Online training</td>
<td>Pattern Identification (To learn from errors and systems influences on adverse events)
Electronic medical records
Workload and staffing data systems</td>
</tr>
</table>

According to Stone and Wiener,[9] workplaces have four dimensions: (1) organizational arrangements, for example, goals, structure, policies, and rewards; (2) social factors, for example, organizational philosophy and values, management style, and interactions with employees and patients; (3) the physical setting/environment, for example, character, physical design, and ergonomics; and (4) technology. In our proposed model, these workplace dimensions affect the nurses’ initial and continued use of technology.

Technology

Technologies used by nurses offer the means for preventing errors and adverse events (e.g., medication errors, miscommunications, delays in treatment, and adverse events—such as failure to rescue, nosocomial infections, pressure ulcers, falls, and complications of immobility). Yet technology also introduces unintended side effects and opportunities for failures.[6] In a chart review, Samore and colleagues[10] found that devices most commonly associated with adverse events were foley catheters (57 percent of adverse events involving devices), arterial catheters (17 percent of such events), central venous catheters (17 percent of such events), and peripherally inserted central catheters (7 percent of such events)—all devices used by nurses in the direct care of patients. At one pediatric hospital, implementation of a computerized provider order entry system intended to reduce handwriting and transcription errors was unexpectedly associated with increased mortality, presumably due to a reduced ability by nursing personnel to anticipate the needs of patients prior to arrival of the patient.[11] Other research showed that although barcoding medication administration was believed by most nursing personnel to decrease medication errors, it was also believed to reduce the ability for physicians to review the accuracy of medication administration and decrease the ability to deviate from routine medication administration sequences.[12] In another example, a few years ago, in an effort to prevent hip fractures from falls from bed, some nursing homes used non-height-adjustable low beds. This solution for preventing hip fractures among residents, however, forced nursing staff to provide care on their knees or bent over, thus increasing staff risk for back and knee injuries. Green[13] noted that all injuries and unintended consequences of technology are impossible to know beforehand, and that they are an unavoidable aspect of technology development. In other words, without technology failures there cannot be progress in technology development.

Nurses may respond to unintended consequences of technology with "work-arounds," or temporary fixes to technology problems or malfunctions. While work-arounds fix an immediate problem at hand, work-arounds can be dangerous, not solving the underlying problem in a system,[14] and thereby increasing opportunities for error over time. For example, in early implementation of barcode administration, scanning devices that were attached to the medication cart with a cord often made it difficult for nurses to scan the patients' identification arm due to infection control restrictions. In response, nurses made duplicate arm bands that they kept at the medication cart. The duplicate bands allowed for ease in scanning, yet doing so bypassed the safety feature that required a positive patient identification (by scanning the band on the arm) before administering a medication and increased the likelihood of "wrong patient" errors. When this work-around was discovered by an independent evaluator, nursing worked with the vendor and infection control experts to use disposable plastic covers to scan infectious patients.[15, 16]

Organizational Factors

Organizational factors that influence the use of technology include policies, resources, culture, social norms, management commitment, training programs, and employee empowerment. It has been noted that the effects of implementing technology—for example, information technology—can vary widely depending on the setting,[17] presumably due to differences in the social-organizational environment such as workflow, work tasks and processes, and the people in the environment. Policy is often looked at as an effective means for implementing change. For example, when implementing safe patient movement and handling

programs, it is helpful to have firmly established leadership and management support, equipment, training, and coordination with other departments before mandating mechanical lifting through policy.[18] Policy hastily implemented before consideration of the impact of technology can result in staff averting the policy and risking the consequences or staff appearing to be in compliance with the policy when they are not. Both of these situations can adversely affect staff morale and satisfaction.

Social Factors

Sandelowski[19] noted the complex and often troubled relationship between technology and nursing since the establishment of nursing as a profession in the latter part of the 19th century. Nurses have been both users of technology and facilitators for gaining patient acceptance of technology, but it has sometimes been a struggle for nurses to define the role of technology in their profession. Technology has played out in the debates of caring versus curing and high-touch versus high-tech in explaining the role of nursing in health care. In the 1970s, the mastery of technology often took second place after the mastery of psychosocial skills such as communication and development of a therapeutic relationship. This relatively recent culture of nursing and the culture of health care have in many instances served to work against the systematic incorporation of technology into nursing practice to improve patient outcomes. Using a Heideggerian analysis of technology, Zitzelsberger[20] proposed that the usual ways in which we perceive technology in terms of function, utility, and positive outcomes overshadow other "modes of revealing," so that nurses and other health care personnel are likely to accept technology and incorporate it into practice without critical evaluation of its benefits and problems. For example, why is it that nursing that requires higher levels of technology, as in critical care, is valued more (e.g., paid more) than nursing that requires little technology, as in the personal care of residents in a nursing home?

Certainly, characteristics of nurses will affect the adoption of technology, although little empirical evidence was found to document this phenomenon. Nurses have been found to be willing to embrace safe patient handling and other technologies if they are convenient; easy to use; target a high-risk, high-cost, and high-prevalence problem (such as falls); are consistent with unit and/or organizational goals; and are either compatible with existing work patterns or have the potential for improving efficiency and time spent with patients. It is likely that nurse characteristics that influence the use of technology are specific to the technology in question. For example, in a study of implementation of a nursing documentation information technology system, the investigators found that adoption was influenced by a number of attributes of the nurses, including commitment to nursing care planning and written documentation, acceptance of computers in nursing, computer and typing skills, professional experience, level of motivation, and climate of trust and support within the nursing team.[17]

Physical Environment

The physical environment, particularly in older buildings that were never designed to accommodate newer technologies, is often a constraining factor in the use of many types of equipment used by nurses. For example, research has shown that an ergonomic approach that relies on equipment to promote safe patient handling decreases musculoskeletal injuries in nurses.[21] The environment is critical in the nurses' use of this equipment because if the

equipment is not readily accessible, the nurse will be less likely to use it. If the patient handling equipment is located at the end of a hallway in a room behind other equipment, the nurse is less likely to use it than if it is stored in an open alcove in the hallway where it can easily be retrieved.[22]

Mediating and Moderating Factors

Ergonomics and human factors engineering offer useful frameworks for examining many of the mediating and moderating factors (e.g., the user/technology interface) that will affect use of the equipment and outcomes of its use. According to the International Ergonomics Association,[23]

> Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.
>
> Ergonomists contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people.

According to Gosbee[24] (p. 3), "Human factors engineering is the discipline concerned with understanding human characteristics and how humans interact with the world around them and the application of the knowledge to the design of systems that are safe, efficient and comfortable." Without a complete understanding of human factors, the tendency is to focus on human failures as the major source of error, and to focus attention on automation of tasks to prevent errors. Several problems with this approach are evident: [4]

- By taking away the easy parts of the job, automation can make the difficult aspects of the job more difficult.
- While humans are known to be fallible, we leave staff to cope with tasks the designers could not figure out how to automate, most important, the job of restoring the system to a safe state after a failure.
- Humans are expected to "monitor" the automated processes, even though we know vigilance is not likely when abnormal events are relatively rare.
- Skills need to be practiced continuously to preserve them, yet the occasional system failure denies the staff the opportunity to practice the skills needed in such an emergency.
- Nurses are generally not exposed during educational programs and on the job to engineers, biomedical engineers, industrial designers, and ergonomists, the designers of the equipment they use in providing care.

Because nurses work at the front lines of health care—where nurses, patients, and technologies intersect and where actions are highly visible—there is a tendency to blame these frontline workers for human error associated with technology failures. Reason[4] called these "human operator problems," which can be classified at the individual or systems level. Examples of individual-focused problems include deficient procedures or documentation, lack of knowledge or training, failure to follow procedures, and deficient planning or scheduling. Systems-oriented problems include miscommunication, deficient supervision, and policy problems. Technology failure should be viewed in the broader context of the complex health care system, rather than inappropriately blaming the individual nurse.

Outcomes of Technology Use

As Fuhrer and colleagues[8] noted, a paucity of outcome measures is a significant barrier to the conduct of outcomes research related to technology. The lack of conceptualization of outcomes in the context of the type of technology and its context of use is added. The key initial outcomes of technology are effectiveness, efficiency, and user (i.e., nurse) and patient satisfaction with the device. Verza and colleagues[25] specifically examined "equipment abandonment," that is, the disuse of a previously obtained device, in the context of assistive devices for persons with multiple sclerosis. They found that abandonment could be reduced by an interdisciplinary prescribing approach.

Longer-term objectives reach beyond these immediate ones and include adverse events, injuries, satisfaction, competency, errors, goal attainment, and organizational outcomes such as efficiency, cost (including cost avoidance, return on investment, margins, and working capital),[26] health care quality, and nursing retention and recruitment. Karwowski,[27] in building a model of ergonomics, differentiated positive outcomes (e.g., improved work productivity, shorter performance times, improved product quality, and desirable psychological and behavioral outcomes) from negative outcomes (e.g., loss of productivity, low quality, accidents, injuries, and undesirable physiological and psychological outcomes).

Optimally, technology is designed to minimize errors and buffer the consequences of errors[1] by (1) eliminating errors and adverse events; (2) reducing occurrence of errors/adverse events; (3) detecting errors early, before injury occurs; and (4) mitigating the effects of errors after they occur to minimize injury.[3] In this "ideal" scenario, patient care technology would yield positive nurse, patient, and organizational outcomes. Consider all of the alarms and warning systems used in the delivery of nursing care to detect errors before injury. A partial list includes bed exit alarms, warnings on IV pumps that signal occlusions, patient-initiated call bells, staff-initiated code alarms, wandering and elopement alarms, cardiac monitor alarms, and ventilator alarms. All of these warning systems depend on the ability of the nurse to notice the warning, process the alarm and comprehend what is happening, and finally take the appropriate action to decrease risk to the patient.[28] In one recent study, medical/surgical nurses wanted "smart monitoring devices" that interfaced with the electronic medical record as well as with wireless communication devices.[29] However, this strategy of using automated alarms is challenged by "alarm fatigue" stemming from the sheer number of alarms. Further, alarm fatigue is exacerbated by the well-intentioned, yet misguided decision to deliberately set alarms with a high false alarm rate; the effectiveness of an alerting signal drops precipitously with just a small number of false alarms.[30]

A significant difference in the model presented here from Fuher's[8] is that both nurse and patient outcomes are included. In addition to the potential physical harm from technology, Monk and colleagues[31] proposed that for older adults living with disabilities in their homes, psychological harms are as important as the physical ones. These researchers argued for including three types of physical harm (injury, untreated medical condition, and physical deterioration), four types of psychological and social harm (dependency, loneliness, fear, and debt or poverty), and four generic consequences (distress, loss of confidence in ability to live independently, costly medical treatment, and death) for systematically evaluating technology used to promote independent living.

While patient care technology offers many opportunities to improve nurse productivity and satisfaction, operational efficiency, patient satisfaction, safety, and quality, there is little research evaluating the outcomes of specific patient care technologies. Barcoding, scanning, and robotics

have been shown to improve efficiency and decrease costs.[32] The Veterans Health Administration (VHA) has successfully implemented barcode medication administration software. This innovative automated system uses a wireless, point-of-care technology with an integrated barcode scanner. The system can dramatically reduce medication administration errors by letting clinicians verify a patient's identity and validate medications against active orders. After implementation at the Kansas VA hospital, the VHA estimated that the software prevented 549,000 errors while dispensing 8 million doses.[32] In a quality improvement project, Bahlman and colleagues[33] found that implementation of an integrated communication system in an operating room had a positive effect by reducing staff time for phone calls to relay messages; reducing time nurses had to spend hunting pieces of equipment; enabling more timely administration of antibiotics for total joint procedures; improving communication with family members about progress of the patient through preoperative, operative, and postoperative care; and providing a quieter environment due to less overhead paging and the use of vibration modes for wireless telephones.

Moderate evidence is available supporting use of electronic medical records and automated drug-dispensing machines, with reports of increases in nurse satisfaction, retention, and productivity, as well as decreases in errors.[32] Despite the limited research available to support the benefits of technology, a recent Institute of Medicine report identified use of information technologies to automate clinical information as one of the keys to safer, quality health care systems.[34]

Practice Implications

Being informed consumers and users of technology in health care means that nurses be involved in the selection of new equipment, receive the proper training for its use, and monitor equipment safety and the effect of technology on patients and families on an ongoing basis.

Selecting the wrong equipment and technology can be costly and expose the patient to errors.[35] Even when optional equipment/technology is selected, if it is not well integrated into the current delivery system, or it is implemented in a chaotic way, this can result in unexpected costs and increased errors.[35] In choosing the best equipment for the task at hand, we found ergonomic-based and social-marketing approaches extremely beneficial. An ergonomic assessment, focusing on the user/equipment interface, involves asking nurses to test equipment and provide feedback on usability, safety, and patient acceptance. Equipment fairs are one strategy to allow staff the opportunity to evaluate which brand or model of technology would work best in their setting. Manufacturers are usually willing to loan equipment to promote onsite clinical testing. From a social-marketing perspective, all stakeholders potentially affected by a device should be invited to participate in equipment trials.[36] Different user groups will have different perspectives and requirements of the equipment. For example, in evaluating a hospital bed, a patient may focus on comfort, a biomedical engineer may focus on compatibility with other technologies and the ease of maintaining the bed in good working order, and a nurse might focus on the usability of special features such as built-in scales and bed exit alarms. Once a purchasing decision is made, including input from staff nurses, training is critical and may require ongoing competency assessments over time.[35]

The World Health Organization Medical Devices and Equipment team described a life-cycle approach that systematically includes maintenance, training, monitoring, and vigilance reporting on medical devices in use.[37] Through surveillance, nurses play an important role in early

identification and correction of latent errors related to technology. Staff who operate equipment and are trained in its use can recognize maintenance problems and request timely maintenance.[38] Similar to the notion of patient surveillance to detect errors early and prevent adverse events[3] (p. 91), equipment surveillance means that nurses conduct purposeful and ongoing data collection to identify malfunctioning and broken equipment, interpret data that indicate equipment problems to determine the source of error, and act based on the interpretation by quickly and directly responding or appropriately reporting and following up.

The Safe Medical Devices Act of 1990, which became effective in 1991, *requires* (italics added) health care facilities to report to the manufacturer and/or the Food and Drug Administration (FDA) all incidents that reasonably suggest that the medical device might have contributed to a death or serious injury or illness. Nurses should be familiar with internal systems of reporting, as well as the FDA medical device reporting (MDR) system (available at http://www.fda.gov/medwatch/how.htm). MDR is the mechanism by which the FDA receives information about medical device adverse events from manufacturers, importers, and user facilities, so any problems with the device can be detected and corrected. ECRI Institute encourages the reporting of device-related incidents and deficiencies to determine whether a report reflects a random failure or one that is likely to recur and cause harm. (Reports can be submitted to ECRI's Web site at http://www.ecri.org/PatientSafety/ReportAProblem/Pages/default.aspx.) Health care failure mode effect analysis[39] and sociotechnical proactive risk modeling[40] offer methods for identifying equipment failures before they happen and strategies for preventing them. Both of the methods have been used in engineering, and both are prospective in that they can be used to identify and prevent product and technology-related problems before they occur. Proponents of proactive risk modeling methods, relatively new to health care,[40] suggest that nurses could play an active role in preventing equipment and technology failures and in responding appropriately to them should they occur.

Risk modeling, an established analytic method in high-risk industries such as aerospace and engineering, is a structured process of determining all the ways a failure can happen to identify likely prevention strategies. Proactive risk modeling has been described as a hybrid between traditional decision support models and process analysis techniques (e.g., root-cause analysis, failure modes, and effects analysis),[41] designed to address rare adverse events associated with high mortality and high costs. For example, after installation of mobile patient lifts into a facility, nurses may anticipate that they would be forced to perform manual lifts, putting themselves at high risk for a lifting injury, if all of the backup battery packs were not fully charged, rendering the electric lifts useless. In naming all of the ways this could happen, a group of nurses would identify processes that, if in place, would avoid the failure of charging batteries, for example, buying extra battery packs or plugging in equipment after each use. Competency checklists could be used to reinforce this process and ensure that everyone is performing it in the same way. Alternatively, the nurses may opt for an alarm system that notifies them when a battery's charge is running low and does not stop alarming until it is plugged into the electrical outlet to charge. Nurses could be proactive in equipment use by discussing "what if" scenarios to determine useful responses in the event of equipment failures. For example, a group of nurses could be asked to discuss what they would do if a patient became stranded in a ceiling lift that would not lower back down to the bed. After such a discussion, nurses would be in a better position to respond if that event were to occur than if they had not anticipated this possibility.

Nurse educators could advance the role of nurses in the use of technology by providing human factors content into nursing curricula and including human factors engineers into newer

interdisciplinary approaches to professional education. An engineering perspective views safety as a feature that needs to be "engineered" into technology and that human errors emerge from the human/machine interface. Equipment misuse is viewed as a failure of the designer to tailor the system appropriately to the cognitive strengths and weaknesses of human users.[4] Human factors engineering and good design can help trap failures so the end result is not a bad outcome,[42] and good design can be facilitated by more informed and sophisticated users. Nurses need to operate as though just because a technology is commercially available does not mean it is good. In our experience, manufacturers welcome feedback from nurses because it allows them to make design changes that not only improve patient safety, but also make products more marketable to nurses. Gosbee[42] suggested that nurses can be trained to more easily detect human factor design issues instead of dismissing them as human error or "somebody else's job."

Implementation of new technologies offers nurses yet another avenue for ensuring safe and efficient use of technology (Table 2). In our experience, we have found that staged implementation is often desirable, because it allows for formative evaluation that can be used to improve the implementation process. Staging also minimizes overload associated with training and behavioral changes. From the literature on research translation and our own experiences, clinical champions, local opinion leaders,[43] or "super users" of equipment may greatly facilitate smooth implementation of new equipment. These clinical leaders are most effective when they are respected by coworkers and perceived by coworkers as knowledgeable, clinically competent, and accessible. Clinical leaders can offer on-the-spot training, encouragement, advice, and troubleshooting expertise to other staff as workers are learning to use new equipment.

Table 2. Tips for Nurses To Influence Technology at the Bedside

- Organize equipment fairs to gain input from key users and stakeholders before purchases.
- Examine performance of technology on challenging scenarios in a simulated setting with a small number (three to five) of untrained, representative users.[44]
- Mentor and oversee temporary (agency) nurses and other personnel (e.g., resident physicians) during first-time use of sophisticated technology.
- Develop cogent arguments to administration to justify purchase of new equipment and technologies, balancing the cost of equipment (costs of purchase, training, and maintenance) against costs saved if equipment was not purchased.
- Become critical users of technology by identifying problems early and communicating them to vendors and in-house biomedical engineering staff.
- Report adverse events associated with medical devices to the Food and Drug Administration MAUDE reporting system and/or ECRI's Problem Reporting System.[45]
- Serve as a resource person on your unit for new technologies by getting training early, communicating with vendors, training others on your unit, and offering to field questions as new technology is implemented.

Research Implications

As previously described, there are a number of moderating and mediating factors for how useful technology is in practice. Appropriately addressing these factors will require collaboration across a number of disciplines. Clinical experts are needed to provide critical input into the design and application of technologies in health care. Direct patient care nurses need to be actively involved in the design and testing of technology. Human factors experts aid in integrating technology into existing workflow and in making interfaces easy to learn and use under stressful conditions.

It has been suggested that some of the mismatches between device design and health care settings might stem from a more fundamental disagreement about the nature of work.[46] An area for further study is whether the implicit theories of work by designers and managers are oversimplified in relation to the actual work setting, and whether these oversimplifications doom technologies to fail regardless of how usable the interface is or how many clinical experts have provided input during the design, procurement, implementation, and maintenance phases.

A major barrier to widespread use of technology is cost. Further research is needed to build a business case for use of technology, including return on investment and cost-benefit analyses.[35] Proactive assessment of key stakeholder perceptions of the technology is also essential, including end-users (nurses and others directly involved) as well as patients and their families.[35]

Chaotic implementation of new technologies appears to be the norm in health care. More research is needed to more effectively introduce new technologies, minimizing risk to the patient, and reducing stress on nursing staff. Likewise, once technology is integrated into nursing care delivery systems, adequate maintenance programs are needed.

Specific research priorities include the following:

1. There is a paucity of research evaluating the outcomes of specific patient care technologies. Further research is needed to evaluate the immediate and long-term outcomes associated with specific technologies used in nursing practice. Research should include nursing, patient, and organizational outcomes.
2. Nursing practices and care delivery systems vary across sites. Further research is needed to evaluate the effects of various nurse processes and environmental conditions on the use, effectiveness, and efficiency of specific technologies used in nursing practice.
3. There are a number of moderating and mediating factors affecting technology use in health care (e.g., organizational factors, social factors, physical environment, and characteristics of technology). Further research is needed to examine these mediating and moderating factors and how they affect both the use of technology and outcomes.
4. Variations in how technologies are implemented exist across organizations and practice settings. Research is needed to improve the processes for introducing technology into the workplace to optimize outcomes.
5. Given that a major barrier to widespread use of technology is cost, further research is needed to build a business case for use of specific technologies, including return on investment and cost-benefit analyses.
6. Because learning from errors and near misses is critical for building an effective culture of safety, research should be conducted to identify effective ways to learn from equipment-related adverse events across practice sites.
7. Research and development needs to focus on how to best integrate multiple technologies into patient care to maximize outcomes and decrease burdens on nurses.
8. Recognizing the inordinate amount of time nurses spend in performing indirect or nonnursing care, research is needed to evaluate the effect of technologies designed to reduce the time spent on nonnursing tasks (such as hunting and gathering supplies) and in indirect nursing care activities (such as documentation) to maximize the time nurses can spend in providing direct patient care.

Other considerations are:

1. What are the most critical challenges to successfully implementing new technologies into health care environments and nursing practice?

2. How do nurses serve as the last line of defense in protecting the patient from harm associated with technology?
3. What are the opportunities for nurses at the bedside to become involved in technology design and testing?

Conclusions

Research on the quality of care reveals a health care system that frequently falls short in its ability to apply new technology safely and appropriately.[34] Workplaces, instruments, and equipment can be developed according to human factors design criteria,[47] but as an end-user, nurses can maximize safety through the selection process, ongoing surveillance of equipment, and proactive risk-assessment methods.

The approach offered for nurses is consistent with the following four-pronged strategy developed by the World Health Organization Medical Devices and Equipment team:[37]

- **Policy:** Nurses providing direct patient care should be involved in setting and evaluating institutional, organizational, and public policy related to technologies.
- **Quality and Safety:** Nurses providing direct patient care can ensure that the technologies they use meet international quality and safety standards and technical specifications needed to perform in the clinical environment in which they are used.
- **Access:** Nurses providing direct patient care can ensure that institutional decisions are made with their input and the input of other critical stakeholders.
- **Use:** Nurses providing direct patient care should be involved in their intuitional policies and processes related to maintenance, training, monitoring, and reporting adverse events related to technology.

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Chapter 51. Enhancing Patient Safety in Nursing Education Through Patient Simulation

Carol Fowler Durham, Kathryn R. Alden

Background

The alarming rise in morbidity and mortality among hospitalized patients throughout the United States heightens concerns about professional competency.[1] Nurses and other health care professionals are under increased scrutiny to provide safe, effective care. Likewise, nursing education programs are faced with increased pressure to produce graduates who are capable of providing safe patient care. Toward that end, nursing education programs develop curricula, hire qualified faculty, and select learning experiences for students in an effort to train and graduate competent, effective nurses. The instructional strategies utilized in both didactic and clinical components of nursing education courses are highly influential in determining critical thinking and clinical decisionmaking ability as well as in developing the psychomotor skill performance of new graduates.

Of course, it is unrealistic to think that graduates of nursing education programs have received all the training they need when they depart the doors of academia. Orientation programs for new graduates and continuing education for nurses are essential tools to help practitioners improve their knowledge, skills, and expertise so that quality patient care is provided and outcomes are optimized while errors are minimized. Ongoing evaluation of nursing competence is necessary to promote patient safety.

In the Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health Care System*, simulation training is recommended as one strategy that can be used to prevent errors in the clinical setting.[1] The report states that "… health care organizations and teaching institutions should participate in the development and use of simulation for training novice practitioners, problem solving, and crisis management, especially when new and potentially hazardous procedures and equipment are introduced"[1] (p. 179).

Nursing education has long utilized simulation in some form to teach principles and skills of nursing care. Models of anatomic parts, whole body mannequins, and various computer-based learning programs have provided educators with training tools for students seeking to become professional nurses. Current interest in simulation as a clinical teaching tool has largely been fueled by development of the human patient simulator.

Human patient simulation is a relatively new teaching strategy that allows learners to develop, refine, and apply knowledge and skills in a realistic clinical situation as they participate in interactive learning experiences designed to meet their educational needs. Learners participate in simulated patient care scenarios within a specific clinical environment, gaining experience, learning and refining skills and developing competencies; all this is accomplished without fear of harm to a live patient. The use of simulation as a teaching strategy can contribute to patient safety and optimize outcomes of care, providing learners with opportunities to experience scenarios and intervene in clinical situations within a safe, supervised setting without posing a risk to a patient.

The focus of this chapter is on the use of patient simulation in nursing education programs. A review of the various types of simulation is presented, followed by detailed information about the human patient simulator and its use as an instructional strategy. Specific information is provided about use of patient simulation in relation to prevention of medication errors, developing critical thinking and clinical decisionmaking skills, use of effective communication skills, and the importance of teamwork. The use of the METI® Human Patient Simulator (HPS) in a university nursing program is described, and an example of a patient care simulation that is used with undergraduate students is given.

Types of Simulation

In general terms, simulation is a technique or device that attempts to create characteristics of the real world. Simulation allows the educator to control the learning environment through scheduling of practice, providing feedback, and minimizing or introducing environmental distractions.[2] In health care, simulation may refer to a *device* representing a simulated patient or part of a patient; such a device can respond to and interact with the actions of the learner.[3] Simulation also refers to *activities* that mimic the reality of a clinical environment and that are designed for use in demonstrating procedures and promoting decisionmaking and critical thinking.[4] In health care education, simulation can take many forms, from relatively simple to highly complex. The various types of simulation are listed in Table 1, along with advantages and disadvantages of each. The types are briefly described in the following paragraphs.

Part Task Trainers

Part task trainers, also known as low-tech or static task trainers, are designed to replicate only a portion of the body or the environment. Many of these represent selected anatomical areas of the human body and are used to teach basic psychomotor skills and procedures. They range in complexity from an item as simple as an orange that is used to teach injection technique to an arm for teaching venipuncture or a mannequin for teaching cardiopulmonary resuscitation (CPR). These simulation tools are relatively inexpensive, and multiple models are often available for use within the same institution, allowing for larger numbers of learners to practice simultaneously.

Simulated Patients

Simulating patients through role play between learners and educators is commonly used in medical and nursing education. Physical assessment skills, history taking, and communication techniques are often taught using student pairs. Trained simulated patients can be used to simulate psychiatric interactions where the learners can try out appropriate interventions. Live female pelvic and male prostate models/teachers provide a dual role of allowing students to refine their exam techniques on the model while receiving real-time feedback about the pelvic or prostate exam. Expense and scheduling are challenges for this type of simulation.

Screen-Based Computer Simulators

Screen-based computer simulators are designed to model various aspects of human physiology or specific tasks or environments. Through a variety of computer programs, learners

use information to make clinical decisions and observe the results in action. There is often feedback during and after the interaction. Computer-assisted instruction programs or Web-based programs are relatively inexpensive and reusable and can be used individually or in groups.

Complex Task Trainers

Complex task trainers involve virtual reality and haptic systems, representing the highest level of computer-based technology. Haptic refers to technology that can sense where touch occurs as well as the amount of pressure being applied. This type of technology is particularly useful in learning environments where the faculty cannot clearly see where the student is assessing the patient. For example, during a pelvic exam, it is difficult for the faculty to determine if the learner is doing a thorough exam. With haptic technology, sensors are placed inside a pelvic model to provide feedback to the learner about areas assessed with touch and the amount of pressure applied. Complex task trainers are often combined with part task trainers so that a physical interaction can occur within the virtual environment. This type of simulation is gaining popularity for training practitioners in surgical techniques such as laparoscopy. While such technology is reusable, it can also be relatively expensive.

Integrated Simulators

Integrated simulators combine computer technology and part- or whole-body mannequins to provide a more realistic learning experience. The degree of sophistication of the mannequin and the computer that drives it determine the degree of engineering fidelity of the system. According to Maran and Glavin,[5] fidelity can be defined as the degree to which the appearance and capabilities of the simulator resemble the appearance and function of the simulated system. Human patient simulators, therefore, are generally categorized as low, intermediate, or high fidelity systems (see Table 2).

Human patient simulators. Human patient simulators are among the most recent technologic advances in instructional methodologies for medical and nursing education. These interactive mannequins are capable of realistic physiologic responses, including respiration, pulses, heart sounds, breath sounds, urinary output, and pupil reaction. Additionally, the more advanced models can communicate with the student, responding to questions posed by the learner in real time during the simulation exercise.

The authors are most familiar with the Human Patient Simulator by Medical Education Technologies Incorporated (METI®) and SimMan™ by Laerdal™. Each company has a variety of portable simulators representing different patient ages to meet the educational needs of the learners at all levels. Both vendors have models with realistic anatomy and clinical functionality.

The METI HPS represents the latest in state-of-the-art simulation technology. Physiological and pharmacological models are used as the operating platform, allowing the simulator to react like a live human. These unique integrated models imitate the human response in a multilayered, real-time manner, providing a realistic clinical presentation.[6] The HPS has a data recorder that records the learner's actions, allowing precise accounts for review and debriefing. Additionally, the HPS interfaces with a patient monitor like those used in most hospitals. Adjustments to the patient scenario can be made "on the fly" as the educator deems necessary.

Laerdal's SimMan operates using personal computer (PC) software. The simulator displays patient physiologic parameters on a PC screen that emulates a patient care monitor. The SimMan software includes the first Integrated Video Debriefing System. The video Web camera records

video and audio that is synchronized with the event log, providing a valuable tool for debriefing. Laerdal's software allows ease of management of patient parameters during scenarios.[7]

Although most simulators owned by schools of nursing are adult males, infant and pediatric models are also available. The simulators have interchangeable genitalia so that the mannequin can present as a male or female. It is possible to adapt the appearance of the mannequin to represent a range of ages from young adulthood to geriatric. Additionally, with the aid of a wig, makeup, and female clothing, the realism can be enhanced as the male mannequin is transformed into a female patient. The mannequin can also be successfully outfitted to present as a pregnant female with the appropriate props.

Promoting Safety Through Education With the Patient Simulator

Patient safety is a multidimensional concept that is central to clinical education. Numerous aspects and principles of patient safety can be easily incorporated into education of nurses and nursing students using the patient simulator. This discussion will focus on four primary areas: preventing medication errors, developing critical thinking and clinical decisionmaking skills, promoting effective communication, and encouraging teamwork.

Preventing Medication Errors

The 2006 IOM report, *Preventing Medication Errors*, concludes that at least 1.5 million preventable medication errors occur each year in the United States. (This number does not take into consideration the errors of omission.) The report indicates that, on average, a hospitalized patient is subjected to more than one medication error each day.[8]

In the National Safety Goals for 2007 of the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCAHO),[9] improving the safety of medication use is listed as the third goal, preceded only by improving the accuracy of patient identification and improving the effectiveness of communication among caregivers. Goal #8 also relates to medication safety: "Accurately and completely reconcile medications across the continuum of care."

Research has shown that medication errors, otherwise known as adverse drug events (ADEs), are most likely to occur during the prescribing and administration stages and are attributed to a variety of factors. ADEs commonly occur at transition points during hospitalization: admission, transfer between units, and discharge. Errors are often due to confusion caused by similar drug names. Another factor is lack of understanding by patients about their medications, including the risks and side effects of medications and what to do if side effects occur.[8] Medication errors directly related to nursing practice usually involve inappropriate medication dosage, overlooked allergies, giving the wrong drug, and incorrect administration site. All these errors are impacted by environmental distractions, miscommunication, and drug labeling problems.[10]

Medication administration is a vital aspect of nursing practice and a critical component of nursing education curricula. Faculty in schools of nursing are concerned with teaching students about safe medication administration. Educating students about safe administration of medications is multifaceted and involves instruction about actions and uses of medications, safe dosage, side effects, and nursing implications.

A recent analysis of 1,305 medication errors by nursing students over a 5-year period showed that the most common medication errors were those of omission and giving the wrong dose of a drug. Errors were primarily attributed to students' performance deficits with significant contributing factors identified as inexperience and distractions.[11]

Calculation of medication dosages has been identified as a deficit for many nursing students.[11–13] This may be related to weak math skills resulting in computational inaccuracy and to the lack of opportunity to utilize dosage calculation in the clinical setting. The advent of unit-dose packaging has limited the need for calculation of medication dosages.

Safe administration of medications is more than a psychomotor or mathematical skill. It also requires critical thinking and clinical decisionmaking. To safely administer medications, students must be able to assess and manage side effects and educate the patient and family about the prescribed treatment regimen. The patient simulator provides a realistic approach to medication administration in a safe setting where patient risks are eliminated. The computer technology of the METI HPS utilizes a barcode system in which specific medications can be scanned to activate physiologic responses in real or compressed time.

Incorporating medication administration into patient simulation scenarios offers numerous learning opportunities and benefits to students. Understanding of the rationale for medication use is enhanced as students are able to see how medications fit into the treatment of selected conditions. They have an opportunity to identify the appropriate drugs, determine safe dosages, calculate dosages, properly identify the patient, administer medications by a variety of routes, observe for side effects, and evaluate the effectiveness of medications. The simulation presents a realistic simulated clinical setting with inherent distractions that may interfere with safe medication administration. For example, in the midst of activities surrounding a code situation, students are exposed to the reality of medication administration in an emergent situation and to the importance of providing the right patient with the right medication in the right dosage at the right time by the right route. Students can be taught to identify areas of potential error risk during patient transitions and handoffs, including shift report, transfer, and discharge. The importance of effective communication can be emphasized and practiced through accurate reporting of medications and aspects of the treatment plan through simulated handoffs.

Patient and family education related to medications can be incorporated into patient simulations. As part of a simulated scenario or role play, students can ask the patient or family member about current medications in an effort to identify medications, including over-the-counter medications and herbal medications the patient is taking, and to determine if the medications are being used appropriately. As students inquire about side effects of medications that the patient may be experiencing, they can use critical-thinking skills to determine if the medications may be related to the patient's current health problems. As part of a scenario, students may be required to provide patient or family teaching about medications.

Developing Critical-Thinking and Clinical Decisionmaking Skills

Nursing educators are challenged to teach students to think critically, to go beyond simply "knowing," to advance to synthesis and application of knowledge as they assess, plan, implement, and evaluate nursing care. Simulation provides an alternative to the traditional teacher-centered approach to nursing education with emphasis on the learning needs and preferences of contemporary nursing students. Simulated learning experiences with the patient simulator allow faculty to expose students to situations that they may never see in their clinical practicum experiences. Because students are placed in a variety of units for their clinical

experiences, there is a lack of consistency in learning opportunities across and among students. Use of the patient simulator enables faculty to provide structured simulation lab experiences instead of trying to find appropriate and/or rare patient care opportunities in a health care setting.[14]

Promoting Effective Communication

The overwhelming majority of untoward events occurring in health care settings involve miscommunication. The Joint Commission identifies communication as the root cause of approximately 70 percent of all sentinel events.[15] Effective communication and teamwork are fundamental to quality patient care. According to the Joint Commission, patient safety is improved when communication is clear, accurate, complete, and timely. The significance of the quality of communication among team members is emphasized by the Joint Commission in one of its National Patient Safety Goals for 2007: "To improve the effectiveness of communication among caregivers."[9] Because errors often occur during times of patient transition in health care settings, the Joint Commission specifies that facilities must "[i]mplement a standardized approach to handoff communications, including an opportunity to ask and respond to questions."[9]

Communication is an essential component of all health care curricula; however, intradisciplinary communication is typically the focus. Each discipline has its own terminology, expectations, and idiosyncrasies relative to communication, all of which can impact the effectiveness of communication across disciplines. Because health care involves multiple disciplines, a means of standardized interdisciplinary communication is needed to enhance quality of care and promote patient safety.

A recently proposed model of interdisciplinary communication, known as SBAR, is gaining increased attention. This is a shared model for standardized communication designed to facilitate and improve communication between and among health care personnel. SBAR can be applied to both verbal and written communication. The model consists of four components:

Situation—statement of what is happening at the present time that has triggered the SBAR

Background—information that puts the situation into context and explains the circumstances that have lead to the situation

Assessment—statement of the communicator's ideas about the problem

Recommendation—statement of what should be done to correct the problem, by when, and by whom[16]

Patient care scenarios using the human patient simulator provide an opportune way to teach students to effectively use a standardized communication method such as SBAR and to allow them to practice this technique. With minimal effort, SBAR can be added to each simulation, requiring practitioners at all levels to develop and refine their communication techniques to be more effective. Ideally, students representing various health care disciplines can work together in patient care simulations, practicing communication techniques that are representative of the actual health care setting.

Encouraging Teamwork

The 2000 IOM report has heightened awareness about the need for system changes to promote patient safety and quality. The report urges organizations to develop strategies to improve team function, thereby increasing the quality of care for the patient.[1] In an effort to enhance teamwork, many organizations have adopted the principles of Crew Resource Management (CRM), originated by NASA and used in the aviation industry in response to aviation disasters. The CRM training model focuses on leadership, decisionmaking, communication, and team training.[17] It also provides training in ever-changing team structures for members who need to have portable skills to apply to various health care settings such as operating rooms, emergency departments, or intensive care units.[18] Ostergaard, Ostergaard, and Lippert[19] suggest that the individual should develop general team competencies that can be transferred from team to team.

Medical and nursing educational programs train students as individuals; yet, as practitioners they are most often required to work in teams within organizational systems. In the practice setting, nurses and physicians interact on a regular basis with each other and with other personnel in the health care institution. Working together as a team and sharing information among team members can contribute to enhanced quality and safety of patient care. Research findings indicate that the risk of serious events seems to be reduced when team training has been implemented.[17, 20, 21]

Simulation emphasizes the importance of teamwork in providing care for patients. It allows the learner to practice as a team member. Working in small groups with the simulator, students may be assigned specific roles such as primary nurse, secondary nurse, medication nurse, communicator, or recorder. They learn how to delegate tasks appropriately, to follow directions, and to communicate effectively with nurses and other practitioners. The simulation allows learners to assess the patient and the situation, identifying pertinent information that must be communicated to the primary health care provider. Students determine appropriate nursing interventions and implement orders from the health care provider. They evaluate patient responses and the outcomes of their assessments and interventions.

To prepare practitioners to work as effective team members, educational programs for all health care personnel need to increase opportunities to work in interdisciplinary teams.[22] Simulation can be used to train individuals in the context of team activities, creating a more realistic clinical environment. Ostergaard and associates[19] state that simulation is the preferred educational strategy to teach teamwork skills such as leadership, communication, and cooperation. Students from several disciplines such as nursing, medicine, respiratory therapy, pharmacy, and social work can be brought together in a patient simulation scenario. This allows each learner to practice their patient care role and relate in real time to the other professionals with whom they will need to work to effectively provide safe and quality patient care. Johnson[23] states that CRM or team training needs to be introduced early and reinforced often. He further acknowledges that accomplishing quality teamwork requires that practitioners (crews) are trained as a team throughout their educational experiences.

While patient simulation scenarios provide a means of teaching interdisciplinary teamwork and communication, it is important to remember that it is also an excellent strategy for educating students about intradisciplinary teamwork and communication. For instance, as nursing students participate in simulated patient scenarios, they assume a variety of nursing roles, particularly if they are learning in groups. Acting as a team providing nursing care, someone must assume the

leadership role, directing other team members and delegating tasks and responsibilities. A primary nurse is identified as the team leader and is assisted by a secondary nurse. Other students may be assigned specific roles such as recorder, communicator, or resource person. Simulated scenarios allow students to work collaboratively as team members with the additional benefit of having faculty present to facilitate teamwork and observe the effectiveness of teamwork.

Use of Patient Simulation in Nursing Education Programs

Patient simulation is an instructional strategy that can be implemented in a variety of settings. The versatility and adaptability of the technology provide a broad range of uses for the patient simulator.

Nursing Education Programs

University and community college nursing education programs use patient simulators with a variety of learners. Patient simulators are used to teach basic assessment and psychomotor skills with beginning students, evolving to complex clinical scenarios as students advance in the curriculum.[4, 15, 24–30] Graduate nursing programs utilize the patient simulator to teach advanced practice skills and concepts in nurse practitioner and nurse anesthesia programs.[31–34] It is used by clinicians to teach new procedures, to validate competencies, and to transition new graduates into the clinical practice.[35, 36] The patient simulator can be used in research concerning best practice for patient care and education.[37] It has potential for use in master's and doctoral-level education programs to train future faculty members.

Continuing Education

The patient simulator can be incorporated into a variety of continuing education programs, departing from the traditional lecture format to provide a more experiential learning experience for participants. Physical assessment classes, nurse anesthesia updates (e.g., airway management), advanced cardiac life support (ACLS) certification, critical care courses, and nurse refresher programs can be conducted using patient simulators.[30]

Nurse refresher courses typically consist of didactic and clinical components to prepare nurses to return to practice after an extended absence. Using patient simulators, these nurses can practice assessment and psychomotor skills before entering the clinical area. This helps promote self-confidence in the nurse refresher students as they resume hands-on care in a setting that does not endanger a live patient.

Population-specific classes can also be taught using the patient simulator. For example, it can be utilized to teach nurses to recognize and respond to critical situations that may occur in geriatric patients in acute and long-term care situations.

Staff Development

Health care institutions can use simulators in staff development programs such as orientation of new graduates and continuing education programs. Orientation programs for new graduates can utilize the human patient simulator to present specific policies and procedures, to assess clinical competence, and promote communication and collaboration among the nurses. Simulators can be used in continuing education to introduce new equipment, to teach new

procedures, to assess competency of nurses in responding to specific clinical situations, to assess adherence to specific protocols, and to promote teamwork.[28, 35, 36]

Evidence Supporting the Use of Patient Simulation in Nursing Education

Search of the literature on patient simulation reveals that the majority of research related to use of the patient simulator has been conducted in medical and anesthesiology settings. Evidence supporting the use of simulation as an instructional strategy in medical education is clear, although experts have pointed out that such research needs improvement in terms of rigor and quality.[38]

Issenberg and associates[38] conducted an extensive review of the medical literature on simulation, identifying 670 articles, of which 109 were used in their analysis. Based on the available evidence, the researchers concluded that simulation can enhance learning by providing feedback (47 percent of articles), repetitive practice (39 percent of articles), curriculum integration (25 percent of articles), a range of difficulty level (14 percent of articles), multiple learning strategies (10 percent of articles), a capture of clinical variation (10 percent of articles), a controlled environment (9 percent of articles), individualized learning (9 percent of articles), defined outcomes (6 percent of articles), and simulator validity (3 percent of articles).

An integrative review of medical and nursing literature was conducted by Ravert[39] in an attempt to identify quantitative studies related to computer-based simulation in health care education and to determine the effect of simulation on learning. Nine studies out of 513 references met the inclusion criteria; five were conducted in medical schools with medical students and four were done by registered nurses using samples of nurses. Seventy-five percent of the studies indicated positive effects of simulation on knowledge acquisition and/or skills training.

Evidence in the literature related to the use of patient simulation in nursing education and practice is ever increasing, although still sparse in comparison to the medical literature. The majority of articles in the nursing literature are descriptions of how patient simulation is utilized in a particular setting. There is a definite paucity in actual research studies that have been conducted about patient simulation.

The first reports of patient simulation in nursing education describe its use with nurse anesthesia students.[31, 33, 40] Incorporation of the human patient simulator into nurse practitioner and clinical nurse specialist education programs occurred somewhat later and is described in articles by Hravnak, Tuite, and Baldiserri,[32] and Scherer, Bruce, Graves, and Erdley.[34]

Numerous articles have been published describing the use of simulation and how simulation programs have been developed within schools of nursing, primarily with undergraduate students.[4, 14, 24–29] There are limited reports of patient simulator use by hospitals to train registered nurses.[35, 36]

Seropian and associates[41, 42] provided detailed descriptions of simulation technology and guidelines related to development of a simulation program. The articles review the types of simulation and offer rationale for selection of the appropriate technology to fit the educational needs of learners.

Henrichs, Rule, Grady, and Ellis[43] explored perceptions of nurse anesthesia students about the use of a human patient simulator in their first year of clinical training. Analysis of data collected through observations, student journals, and focus groups indicated that students felt the

simulation experience was educational, although they experienced feelings of apprehension, uneasiness, or fear during the sessions.

In another study of nurse anesthesia students, Farnsworth and colleagues[44] examined the efficacy of the human patient simulator in teaching conscious sedation skills. A sample of 20 nurses completed pretests and then experienced a training session consisting of 4 patient simulation scenarios followed by a practical exam. They were asked to complete post-tests and evaluations of the patient simulation training sessions. Overall scores on the post-test were significantly higher than pretest scores. As part of the evaluation, students were asked to rate the training session on a scale of 1 to 4 with 1 = poor and 4 = excellent. The mean rating score was 3.75, indicating that the participants found the training session to be both beneficial and enjoyable.

Nehring and Lashley[30] conducted an international study of human patient simulation in nursing education. They examined the use of the METI HPS by nursing schools and associated simulation centers. The researchers mailed surveys to 66 nursing programs and 150 simulation centers, hospitals, and other institutions of higher education that were located near nursing programs. Thirty-four nursing schools (18 universities and 16 community colleges) and 6 simulation centers throughout the world responded by completing the 37-item closed- and open-ended survey designed by the researchers. Results were categorized and reported as follows:

(1) Curricular use: Greater use of the HPS was reported by community college programs for more hours in all courses with the exception of the maternal newborn course. In university programs, the HPS was most often used in basic skills courses, while community colleges reported the greatest use in advanced medical-surgical nursing courses. Most schools used the HPS as part of required clinical time.

(2) Faculty use: Ninety-three percent of schools indicated that 25 percent or less of their faculty used the simulator; more than half of the sample states that their faculty was generally receptive to HPS use in their courses.

(3) Student views: Twenty-one schools reported collecting information on student perceptions of the HPS. In relation to use of the HPS for competency evaluation of undergraduate students, 42 percent of schools stated that it should be used, 36 percent agreed it should be used in some circumstances, and 22 percent indicated it should not be used.

(4) Other uses of HPS: Only six institutions indicated that they were conducting research about HPS use. Six nursing programs and four simulation centers reported use of the HPS in continuing education programs.

Feingold, Calaluce, and Kallen[45] conducted a study to evaluate nursing student and faculty perceptions about patient simulations using the Laerdal SimMan Universal Patient Simulator. Using a 20-item tool, the researchers surveyed 65 students who had participated in simulations during 2 consecutive semesters. Four faculty members were surveyed using a similar 17-item tool. Findings showed that while the majority of students and faculty felt the simulations were realistic and valuable, only half of the students agreed that skills learned in the simulation were transferable to a real patient care setting. Faculty indicated that simulations reinforced clinical objectives and adequately tested clinical and decisionmaking skills. Concerns of faculty members relative to patient simulator use included extra preparation time and lack of faculty support to use the technology.

Bearnson and Wiker[46] explored the benefits and limitations of using the METI HPS as a substitute for a clinical day in a junior-level nursing course. Each student had a 2-hour session

involving three preprogrammed scenarios. Following the scenarios, the students completed a brief survey instrument (four items) consisting of a Likert-type scale (1 = strongly disagree to 4 = strongly agree) and three open-ended questions. Responses indicated that the HPS increased knowledge of medication side effects (mean = 3.13), increased knowledge of differences in patients' responses (mean = 3.31), increased ability to administer medications safely (mean = 3.06), and increased confidence in medication administration skills (mean = 3.00). Responses to the open-ended questions were overwhelmingly positive.

Alinier and colleagues[47] demonstrated the effectiveness of scenario-based simulation training on nursing students' clinical skills and competence. A sample of 99 undergraduate nursing students in the United Kingdom was divided into control and experimental groups, with the experimental group being exposed to patient simulation training using the Laerdal SimMan. Students in both groups completed a pretest and post-test as well as a questionnaire. There was a statistically significant difference in the mean scores of the two groups from pretest to post-test, with the experimental group demonstrating higher overall scores.

In a recent study, Bremner and associates[48] examined the value of using the human patient simulator as an instructional strategy with novice nursing students. A sample of 41 students completed a questionnaire about their learning experiences with the human patient simulator. The simulator session was rated as good to excellent by 95 percent of the students, and 68 percent recommended it as a mandatory component of their educational program. Over 60 percent of the students indicated that the patient simulation experience increased their confidence in physical assessment skills. Limitations of the technology identified by students included not having enough time to work with the simulator, initial anxiety when first encountering the patient simulator, and a lack of realism.

Advantages of Patient Simulation in Nursing Education

The major advantage of using the patient simulator as an instructional strategy in nursing education is that it provides opportunity for active and interactive learning without risk to an actual patient.[3] Learners can be permitted to make mistakes without fear of harming a live person.

Use of the patient simulator allows for an immersive, experiential learning activity.[50] Students are active participants, not merely recipients of didactic content as in a lecture class. Small numbers of students are typically involved in each scenario, with each student having a role in the simulation. The patient simulator provides a hands-on experience in which students are able to witness the results of their actions in real time.

Clinical simulation with the patient simulator is consistent with adult learning theory. It is a learner-centered approach to education, building on previous knowledge and experiences. The patient simulator provides opportunities for self-study as well as group interaction.[50]

The sophisticated computer technology of the patient simulator has appeal for contemporary learners. Although increasing numbers of nontraditional students continue to enter nursing programs, the majority of learners currently enrolled are younger than 25 years of age. They represent the computer-savvy Generation X and Generation Y, having grown up with gaming systems such as Nintendo®, computers, and the Internet. Individuals from these generations typically possess an inherent fascination with technology and are accustomed to fast-paced communication through means such as instant-messaging. They always want to be in touch; cellular phones, MP3 players, and personal digital assistants (PDAs) have become a way of life.

Effective educational strategies must capture the learners' aptitude with and desire to use technology as they gain and apply necessary skills and knowledge.

Patient simulation scenarios provide a bridge between theory and clinical practice. Working with the patient simulator, students are able to visualize physiological responses that may be difficult to understand simply through didactic classes or readings. Critical thinking and clinical decisionmaking skills are developed and refined as students apply previous knowledge in simulated patient situations. Synthesis learning experiences can be provided through patient simulations. Knowledge and skills attained from classroom and clinical experiences can be applied in patient care situations

Scenarios can be selected or designed to meet specific course objectives and in accordance with learning needs of the students. Simulations allow faculty to expose students to situations that they may never see in their clinical practicum experiences.

The instructor is in control of the events and timing of the scenario and can pause the action as needed for reflection or correction. Scenarios can be repeated to provide consistency of learning experiences across student groups.

Skills and procedures can be practiced in a realistic situation, and immediate feedback is provided as learners observe patient responses and interact with faculty facilitators. If needed, students can be allowed to repeat skills and procedures until proficiency is achieved.

Working in small groups with patient simulation scenarios, learners benefit from each other's successes and mistakes. They also learn to work as a team and can experience a variety of roles as team members.

Learning experiences with the human patient simulator can boost students' self-confidence and help reduce anxiety in the actual patient care setting. Students are able to practice assessment and psychomotor skills and implement nursing interventions under the supervision of faculty so that they feel more confident and competent when they enter the practice setting and are assigned care for patients.

Learning experiences with the patient simulator help students to identify gaps in their knowledge and experience base. The following comments from baccalaureate nursing students illustrate this point (note: "Stan" or "Stan the Man" refers to the human patient simulator):

- Stan stimulates me to want to learn more. I found that when I was in the situation and didn't know what to do, I wanted nothing more than to be able to go and look up what was going on and gain an understanding. After the first day of working with Stan, I went back and read about the specific illnesses that we had encountered in our practice. I found that while we had done many things right, there were many things we had missed.

- During my work with Stan the Man, I realized that my knowledge of normal ranges for central venous pressure, pulmonary pressure, and pulmonary wedge pressure was lacking. Also I realized that I didn't have a firm grasp of the ABCs of emergency care. Stan showed me what happens when these things (airway, breathing, circulation) are not taken care of and in that order. We had a simulation where a spontaneous pneumothorax (which is commonly treated in the ED) resulted in Stan crashing, and ultimately we lost him. This happened mainly because we didn't get a chest tube inserted in time, but had we paid more attention to the ABCs at the beginning of the simulation, we might have been able to avoid him coding on us.

> ♦ I think the most valuable thing I learned was what I do not know. For example, while my group was working with Stan, I discovered that my ability to apply what I thought I had learned in pharmacology is lacking. In several cases I had no idea which drug to use or why. If it had not been for the suggestions from the instructors, I would not have been able to figure out which drugs to use. Thus I have identified pharmacology as a topic that I need to study more.

A major benefit of using the simulator in nursing education is that most students and faculty enjoy this type of learning experience. The dynamic and interactive nature of simulation provides learning experiences that are stimulating and beneficial.[43–45]

Teaching with the patient simulator provides opportunity for faculty development and increased job satisfaction. Nursing educators who enjoy interactive teaching methods may welcome the use of patient simulation into the curriculum and volunteer to participate in training programs and implementation of this technology with students.

As nursing education programs are seeking to hire new faculty, the patient simulation may serve as a recruitment tool. Those schools of nursing that own or have access to patient simulators may be able to attract faculty members who desire to teach using creative and innovative strategies.

Limitations of Patient Simulators

Limitations or disadvantages of the patient simulator are primarily related to its cost, which is prohibitive for many schools. The cost of the equipment can range from approximately $30,000 to $200,000, depending on the manufacturer and features of the patient simulator. Additional expenses include physical space to house the equipment, supplies and equipment needed to simulate the desired clinical environment, the cost of training faculty to utilize the technology, and faculty time involved in developing scenarios.[14, 27]

While a justifiable argument against the use of the human patient simulator is the expense involved in purchase and maintenance, there are ways to make its use more affordable.[27, 30] Educators and administrators need to carefully examine what is the best fit for their agency. They need to identify a plan to integrate the simulator into their curriculum, develop the complexity of the simulated cases, and determine the degree of realism required. As educators become more adept at using the simulator, higher-level performance will be desired of the simulator, so long-term usability and adaptability of the simulator should be weighed against its initial cost. Nursing education programs may procure the simulator through their annual budget, grants, special allocations, or private donations. To help recover some of the costs, some schools of nursing rent the simulator to a variety of groups and agencies, charging an hourly or daily rate.[30]

The portability of the simulators facilitates multicenter sharing. Schools of nursing can partner with hospitals to share the costs of the simulator and training. Realistic clinical environments for simulation can be more easily created through shared props such as intravenous (IV) pumps, dressing supplies, etc. Nursing faculty can collaborate with expert clinicians to develop realistic scenarios that reflect current practice. The two groups can cooperatively teach with the patient simulator. For example, in a university setting, two clinical specialists from the intensive care units at a local hospital lectured to a group of senior students about how to respond in a “code” situation (cardiopulmonary arrest); these two clinical experts provided case studies of actual situations that were developed into scenarios for use with the human patient simulator. The scenarios were used with the seniors and, later, with a group of new intensive care unit staff

nurses. The faculty and the two clinical specialists worked together to facilitate the scenarios for both groups of learners.

The cost of the simulator can be shared by a variety of health care disciplines. The simulator can be used in a multidisciplinary environment where medical, nursing, and other health care specialists work as a team to assess, intervene, and evaluate care provided to simulated patients in specific situations. Collaboration among schools of nursing, medical schools, and other health care disciplines can result in the development of scenarios designed to incorporate the knowledge, skills, and experience of all the related professions.

Schools of nursing and health care institutions can partner with community agencies in purchasing the patient simulator. Community agencies that wish to utilize the patient simulator may be able to barter with schools or hospitals, trading other services for personnel and time to use the human patient simulator. Although use of the human patient simulator began in inpatient health care, its use has extended into the field for training programs that prepare first responders, military, and health care professionals to respond to natural disasters or acts of bioterrorism.

The complex nature of the technology requires a commitment to training educators in the use of patient simulation. This means that faculty time and energies are involved in learning to operate and incorporate simulation into existing curriculum. Since faculty workloads are already heavy, this may seem to be an additional burden. Faculty time involved in actual teaching with simulation has been cited as a potential disadvantage of its use.[45] Student/faculty ratios are typically lower when teaching with a patient simulator. While traditional clinical groups may consist of 8–10 students, the maximum number of students that can be accommodated in a patient simulated learning experience is 5 or fewer, depending on the scenario.

Another potential disadvantage or limitation of the patient simulation that has been identified is lack of realism in the scenarios and patient responses. The realism of any simulation depends upon multiple factors, including the fidelity of the simulator, the environment, props, and the description of the scenario. Realism is also affected by the facilitator's expectation of students to suspend disbelief and treat the simulator as a patient. As realism is enhanced, the effectiveness of the scenario as a learning tool is increased.[41]

Student anxiety related to the use of patient simulation is a potential limitation to its effectiveness.[43, 48] Unfamiliarity with the simulator and fear of the unknown may evoke anxiety. Students may worry about their ability to manage a critical care situation. They may experience some discomfort about working under the direct supervision of faculty facilitators. If students are being evaluated and assigned grades for their participation in scenarios, anxiety may be elevated. The authors' experience with undergraduate nursing students demonstrates that although students may be somewhat anxious when they first encounter the simulator, this anxiety is not necessarily a negative influence. Having participated in scenarios using the METI® HPS, one student commented, "The experience was outstanding! I was terrified, but teamwork got us through. This forced me to deal with my fear of what do I do when a patient comes in. I was proud of myself and the group. Together we did it."

Patient Simulation and Undergraduate Nursing Education

The use of human patient simulators for undergraduate nursing education and evaluation offers an excellent means by which to provide learning experiences and to measure competency of knowledge and skills.[14] In the simulation lab, students collaborate in patient care as they conduct assessments; monitor physiologic parameters such as vital signs, heart sounds, breath sounds, and symptoms; perform nursing interventions; obtain and carry out physician's orders;

administer medications; and evaluate patient responses. This type of learning activity allows the learners to synthesize and apply knowledge they have gained from structured courses and/or clinical experiences.

The use of human patient simulation as an instructional strategy can enhance patient safety and optimize outcomes, providing a means of allowing nursing students to "practice" critical thinking, clinical decisionmaking, and psychomotor skills in a safe, controlled environment, without potential risk to a live patient. Errors can be allowed and corrected without concern for patient safety.

Simulation allows a condensing of vital learning experiences that assists the learner in developing clinical reasoning and decisionmaking skills. Additionally, a simulation can be repeated to allow students to correct misconceptions, fill in knowledge gaps, and hone clinical skills. This can be beneficial in boosting self-confidence and self-esteem as students are learning to think and act like nurses.

The patient simulator is intended as an adjunct teaching strategy to complement—not to replace—the traditional clinical practicum. It may be an addition to clinical hours or may be utilized as a means of remediation for students who encounter difficulties in the clinical setting. Scenarios using the patient simulator can be useful for students who may have been away from the clinical setting for a period of time; for example, students who must drop out of the program temporarily may benefit from patient simulations to refresh clinical knowledge and skills before they return to the clinical area.

The patient simulator provides an alternative to traditional clinical experiences. As enrollments in schools of nursing are rising, there is increased competition for clinical sites. The use of the human patient simulator is one means of providing clinical learning experiences outside the health care institutional setting. Faculty may elect to send students through care scenarios with patient simulation in lieu of a day or portion of a day on the clinical unit in the hospital. The simulation experiences may be used instead of a clinical conference. The time spent in a well-structured simulation experience can be powerful and far outweigh what can be accomplished in a traditional clinical conference.

The patient simulator can help faculty address problems related to lack of consistency in students' clinical experiences. The traditional model of undergraduate clinical education dictates that students are assigned to groups of 8 to 10, supervised by a clinical faculty, working in a health care setting for several hours at a time. Students are placed throughout hospitals and community agencies, working on a variety of units. There is inevitably lack of consistency in student learning experiences. Even students assigned to the same unit will encounter individual patients with unique problems and needs. It is impossible to assure that every student who graduates from a nursing education program will have had the same opportunity to provide care for any specific type of patient. Many variables influence student learning experiences in the clinical setting. These include such things as patient acuity and diagnosis, facility access, time of day, as well as clinical and teaching expertise of clinical instructors and nursing staff. Use of the human patient simulator allows for greater consistency in learning experiences. Learning occurs in a controlled environment where groups of students are exposed to the same scenarios, under the same conditions. Simulation is an efficient way to offer "standardized [experiential] learning in concentrated periods of time"[51] (p. 13).

The versatility of the technology means that patient simulation can be incorporated into courses throughout the nursing education curriculum. It can be used in beginning nursing courses to demonstrate such things as pathophysiological and pharmacological principles, normal and

abnormal physiologic parameters, and responses to interventions. Faculty can utilize the patient simulation with beginning students in physical assessment courses to demonstrate principles and techniques of systematic assessment. Students can hone their assessment skills with the simulator as they practice assessment of specific body systems and as they learn the head-to-toe examination. The simulator can be used to help students understand the concept of doing an initial patient assessment, assist them to understand how to approach a patient, and provide them with introductory interaction skills.

Patient simulation is an instructional strategy that bridges theory and practice in a variety of courses throughout the undergraduate curriculum (e.g., medical-surgical nursing, pediatrics, obstetrics, community health, psychiatric nursing, geriatric nursing). Undergraduate nursing faculty often employ the patient simulator as part of a synthesis learning experience with students enrolled in "capstone" medical-surgical nursing courses.[30] Students are expected to apply theory from current and previous didactic courses and to draw from their previous clinical experiences as they respond in the various scenarios. In the last semester prior to graduation, students enrolled in the nursing program at the University of North Carolina at Chapel Hill participate in a series of medical-surgical simulations cases: congestive heart failure that has progressed to pulmonary edema, tension pneumothorax, and ventricular tachycardia that leads to a full "code." These three cases are presented in a 1-hour time frame. The congestive heart failure/pulmonary edema case takes approximately 30 minutes and is provided as an example in Appendix A. The next two cases move more rapidly due to the emergent status of the patient and the necessary interventions. Later in the semester the students return to the simulation lab for a second hour where they encounter a hyperglycemic hyperosmolar nonketotic coma case that incorporates factors such as cultural issues, use of herbs, use of an interpreter for a non-English speaking patient, regulations under the Health Insurance Portability and Accountability Act (HIPAA) regarding family communications, and issues related to access to care.

Teaching with simulation offers opportunities to experience and act in common situations that students are likely to encounter in the clinical setting. Likewise, simulation can be used to teach students how to respond in situations that are relatively uncommon, yet warrant prompt action to prevent deleterious consequences.

The patient simulator allows for purposeful exposure to critical care scenarios that the learner may not encounter in the clinical practicum. Acquisition of this type of experience is important because the nurse needs to intervene promptly to prevent adverse patient outcomes. Simulation allows students to be immersed in critical care scenarios, requiring them to be active participants identifying pertinent changes in patient status and intervening appropriately, in a timely manner, to effectively treat the changes or to limit adverse outcomes. Even if they do not intervene appropriately or quickly enough and the simulated patient dies, there is educational value to be gained through debriefing.

Most nursing students have minimal opportunities to work in a critical care setting during their clinical practicum, yet it is important that they recognize signs of deterioration in patient status and are knowledgeable about appropriate assessments and interventions. Students on the clinical unit have limited opportunities to participate in emergent situations. If a patient develops cardiac or respiratory arrest and a "code" is called, the team of experts rushes in; the student is typically pushed to the periphery to act as an observer. Students can be taught how to respond in a "code" situation. A cardiopulmonary arrest can be simulated and students are expected to intervene, calling the "code" team and participating in the resuscitation. Students can actually use the portable defibrillator to "shock" the mannequin.[52]

Communication with the team and the health care provider is an important element of any patient simulation scenario. As student nurses working on a clinical unit, there is typically little opportunity for students to contact health care providers directly to discuss concerns or questions about their patients. For example, students do not make calls to physicians to report a patient's declining health status. In simulation, they may be asked to notify the provider, conveying pertinent information in a concise, professional manner and acting as an advocate for the patient. As orders are received from the provider, the student must document and communicate accurately to the team so that they may proceed with implementation.

Scenarios using simulation also provide important lessons about the importance of documentation, particularly in fast-moving critical care cases. One student may be assigned to record everything that is happening, ranging from the patient's vital signs to steps in cardiopulmonary resuscitation. The old adage, "if it is not documented, it was not done," can be emphasized and important lessons reinforced.

Role of the Educator in Patient Simulation

Just as the construction industry emphasizes the importance of using the "right tool for the job," so it is with the choice of an instructional strategy in nursing education. While the uses for the human patient simulator are broad, it is not intended as a panacea that can be implemented effectively at any place and time within a nursing curriculum. There must be careful thought in selecting patient simulation as the instructional method of choice to meet specific learning objectives.

Benner[53] (p. xiv) states that "providing nursing care involves risks for both nurse and patient, and skilled nursing requires well-planned education programs. Experience-based skill acquisition is safer and quicker when it rests upon a sound education base." When planning an educational activity, it is helpful to consider what type of tool will be most appropriate to teach the task at hand and to optimize the situation for the learner. Beaubien and Baker[2] dispel the myth that simulation is a unidimensional concept that has been used to describe the capabilities of the equipment such as high or low fidelity. It is not the level of the simulation fidelity that determines the effectiveness as an educational tool, but rather the faculty who designs the educational experience. Simulation is a multidimensional concept requiring the educator to examine not only the equipment, but also the environment and the psychological perceptions of the learner and educator.[2]

The patient simulation is only as effective as the faculty who are using it. The creativity, clinical knowledge, teaching expertise, and technological abilities of the faculty are highly influential in the effective use of patient simulation. A combination of standardized patients, part task trainers, and static mannequins can be coupled with the mannequin-based high-fidelity simulator to provide a more comprehensive learning experience. Patient simulation is a learner-centered instructional strategy where faculty act primarily as facilitators. The role varies somewhat, depending on whether the patient simulation is utilized for student learning or as a means of evaluating student performance.[4]

It is important to acknowledge that the patient simulator is a highly sophisticated, technologically advanced teaching tool. Training is required to enable faculty to effectively utilize the simulator. In most institutions, one or two faculty members are initially trained and are subsequently charged with training other faculty members in use of the patient simulator. It is helpful to have a "champion" who can present the patient simulator to faculty in a positive way,

citing the advantages to be gained in educating students with this teaching tool. Faculty who are unfamiliar with the simulator can be invited to orientation sessions where they can have hands-on experience with the mannequin and witness the capabilities of the technology. They can also be invited to observe teaching sessions in which students are involved in patient care scenarios using the simulator. Faculty who see the potential benefits of patient simulation may be more likely to want to use the simulator in their teaching. Those who are innovative, creative, and enjoy learning through active participation may be more apt to try the patient simulator as a teaching strategy.

While the novelty and versatility of patient simulation technology can be very appealing, learning to use the equipment can be daunting. This may be especially true for older faculty who have grown accustomed to traditional teaching methods, while younger faculty who have grown up with computer technology may be more interested and adept at learning to use patient simulators. Teaching assistants, who are often graduate students, are utilized in some settings to operate the patient simulator and to assist faculty in writing and running scenarios.

The time factor associated with use of patient simulation may be seen as a disadvantage.[30, 45] Typically, the student/faculty ratios are lower than in classroom or clinical settings, which means that more faculty time is required to offer the simulation experience to students. Faculty may be unwilling to commit more of their time, particularly if they already feel stretched. Those faculty who see the value of the learning experience for the students may be more likely to commit to using the simulator. Using patient simulated scenarios in place of clinical hours may enhance the appeal of this technology; substituting a day of clinical practice for equivalent time in the simulation lab may be an option. In many curricula the credit hours allotted to labs and clinical are the same and allow for 1:1 hour exchange between the two learning environments.

Developing and Using Patient Simulation Scenarios

Manufacturers of patient simulators provide a variety of predefined scenarios for use in health care education. Both METI HPS and Laeradel's SimMan have preprogrammed patient care scenarios. These standardized cases serve as the foundation for other scenarios that can be created by the user to fit curricular and learning needs. The METI Program for Nursing Curriculum Integration™ focuses on nursing educational concepts and competencies. It provides a strategy for implementing simulation use across a 4-semester nursing curriculum. The 90 clinical simulations include objectives, pre-scenario questions, evidence-based references, and more.

Faculty members may choose to adapt or create their own patient simulator scenarios to be more consistent with specific learning objectives and student needs. When adapting an existing simulated program or developing a case scenario, there are important considerations:

- **Q: Are there preprogrammed scenarios that can be used, or is it necessary to develop a scenario?**
  A: Even if an existing program is used, it is likely that the faculty will choose to elaborate and embellish it, including information to make it seem more realistic, framing the scenario with patient background and history. The patient simulator may be used in conjunction with other instructional strategies such as unfolding case studies or problem-based learning activities. Other types of simulation such as part task trainers may be used in conjunction with the patient simulator. If faculty choose to create their own simulated scenarios, they may draw ideas and data from previous experiences, from staff members,

or from students. As a course assignment, students may be asked to write a critical incident paper that can provide ideas for simulated cases. Students may be asked to create cases that can be adapted to the simulator. Of course, patient anonymity must be protected.

- **Q: What are the goals of the experience?**
  A: It is important to identify specific learning objectives. There may be primary and secondary objectives. For example, one of the primary goals may be for students to identify physiologic responses to hemorrhage, while a secondary objective may relate to recognition of cultural and religious beliefs related to use of blood products. Beyond the major objectives, the educator should think about what other teaching points can be incorporated into the case, such as family dynamics, cultural issues, use of alternative therapies, HIPAA regulations, working with an interpreter, etc.

- **Q: Is there an evaluation component to the simulation?**
  A: Students tend to be less anxious in working with the simulator when their performance is not being evaluated. Prior to beginning the case, it should be made clear to the students whether or not any type of evaluation would be done during the simulation. If there is evaluation involved, students should be provided with clear information about the criteria used for evaluation.

- **Q: What is the context of the patient simulation learning experience?**
  A: If used within a specific course, it is important to consider didactic and clinical content that precedes use of the patient simulator. Additionally, previous courses or clinical experiences that students have had should be considered. The patient simulator provides an excellent opportunity for a synthesis experience in which students can apply what they have learned previously to the current situation.

- **Q: What is the level of the students? Are these beginning students who have not yet started the first clinical practicum, or are these advanced students who will be graduating in a few weeks?**
  A: Cases are developed to match the level of the learners. Ideally, students can be introduced to the simulator early in the curriculum as they practice assessment and other basic psychomotor skills. Then, as they progress through the program, they can be involved in patient simulation scenarios that increase in complexity as their knowledge level increases. Ultimately, the patient simulator can be used as a synthesis experience in which students are expected to apply knowledge, experience, and skills that they have acquired up to that point in the program.

- **Q: How much time is allotted for the scenario?**
  A: In general, the more complex the scenario, the greater the time required for completion. It is reasonable to think that most scenarios can be conducted in 30 minutes. It is important to allow time for debriefing when the scenario is over.

- **Q: How many students will be assigned to each scenario?**
  A: Generally, small groups of no more than five students work well together in a simulated scenario. The case is designed with consideration of the number of roles that students can assume and the tasks that are to be accomplished during the case. Although

there is benefit to having students act as observers if space allows, there is greater learning potential when there is hands-on participation in the scenario.

- **Q: Have the students had previous experience with the patient simulator? If so, how much?**
  A: Orientation to the equipment and the technology is essential prior to having students participate in an actual case scenario. There is some anxiety associated with encountering a new teaching method, particularly when it is novel and unfamiliar. Both students and faculty need the opportunity for hands-on orientation to the mannequin, doing such things as listening to breath and heart sounds, being informed of the capabilities of the system, viewing the bedside computer display, and identifying the location of supplies and equipment within the environment.

- **Q: How many faculty/staff are available to assist with the scenario?**
  A: Ideally, there are at least two to three persons involved in running a patient simulated case. It is advantageous to have a coordinator or team leader who is familiar with all aspects of the simulation. This person is responsible for assigning and delegating tasks to other team members, checking the setup and equipment, directing, and troubleshooting as the scenario progresses.[41] The team leader may also be involved in facilitating the scenario, although there are usually one or two other faculty members serving in that capacity. There must be an operator who runs the computer and makes the simulation happen in real time, making adjustments as necessary according to learning needs and actions of the participants. The operator, facilitator, or other staff assistants may periodically move into acting as family members, friends, or other health care personnel who may be involved in the scenario. All faculty/staff who are serving as facilitators will need to be flexible to also assume such roles intermittently as needed during the case.

- **Q: What type of environment is needed to represent the clinical setting for the scenario?**
  A: The educator needs to examine the situation, props, and environment to determine if they are as realistic as possible. Realism of the situation is critical to the learning experience for the student during the scenario. Suspending disbelief by creating a situation as realistic as possible encourages learners to immerse themselves in the experience with minimal distractions. Gaba[3] suggests that learners who are immersed in experiential learning are more able to suspend disbelief and perform as they would in a real-life situation. Additionally, it may enhance the ability to transfer what has been learned in the scenario to an actual patient situation. While the patient simulator is typically housed in a particular room or space, it may be possible to adapt the environment to increase the realism of the simulated case. Real patient care equipment should be used whenever possible. Visual and auditory props may be as simple as a telephone that can be used to simulate phoning the health care provider. Gather the props and equipment and have the environment prepared in advance of the case. For example, intravenous fluids or blood products may need to be mixed and hung. Depending on the patient being simulated, the mannequin may need transforming with makeup, masks, or a wig.

- **Q: What audiovisual equipment is needed and available?**
  A: A whiteboard, blackboard, or flipchart is needed for recording patient data and nursing interventions during the scenario. Video recording of a simulation session is useful in providing feedback for the participants. Video playback can be a powerful teaching tool as participants are able to observe and critique the scenario. The video recording is also helpful for the operator and others to see the simulation from all angles.[41]

- **Q: Is there time for debriefing?**
  A: The debriefing is a critical part of the patient simulated scenario, providing participants with an opportunity to reflect on their learning experience. During this time, participants may be asked to consider key questions such as: "What went well?" "What could have been done better?" "How did you feel in the role of _____?" (See Postsimulation.) The debriefing is also a time to review key concepts and knowledge related to the scenario. Important points can be discussed; pathophysiology of patient symptoms and responses to interventions can be reviewed; rationale for interventions can be identified; actions, dosages, side effects, and administration of medication can be discussed.

Presimulation

Presimulation Faculty

Prior to use of the simulator with students, faculty must be fully prepared to facilitate the learning experience. This means familiarity with the equipment and with the particular scenarios that are to be used. The computer operator needs to be skilled in the technology of the simulator. They need to know how to set up the equipment, connecting the mannequin to the computer, and initiating the program to be used. If a preprogrammed scenario is used, the operator starts the program and allows it to run. However, if the scenario allows physiological parameters to change outside of the program, the operator must be knowledgeable about how to make the necessary adjustments as students are in the midst of the scenario. For example, if students do not intervene promptly and appropriately in recognizing and treating hemorrhage, the "patient" may progress to hypovolemic shock and subsequently arrest. The operator can determine how quickly the patient's condition deteriorates and the patient's response to interventions.

It is important to provide all involved in the case with a script a few weeks prior to the simulation so that they can prepare adequately to be a facilitator. You might color code each role in the script to allow ease of following the case. The script should be in a large font and double-spaced, allowing quick referencing during the case. It is helpful to rehearse the simulation scenario before utilizing it with students. This allows for refining and adjusting the scenario and/or roles as needed prior to implementation to promote its effectiveness as a learning strategy. Because this is an unfamiliar educational method for most nursing educators, faculty may benefit from in-service classes about teaching with the simulator. Additionally, they need the opportunity for hands-on learning with the simulator so that they are better able to assist students and facilitate their learning experiences. Having faculty participate as students in scenarios can be very effective in increasing their comfort level with the patient simulator.

Using clinical faculty as facilitators of patient simulator scenarios can be very effective, particularly with their own clinical groups. This can provide opportunity for faculty to gain

insights into how the students function as team members; to identify leadership qualities; to assess communication, critical thinking, and skill performance; and to observe how students react under pressure if a critical situation occurs.

Using the METI HPS With Baccalaureate Nursing Students

The following paragraphs describe how the METI HPS is used with senior students in the baccalaureate nursing education program at the University of North Carolina at Chapel Hill. Simulation is used to provide students with a synthesis learning experience in which they have the opportunity to utilize previous knowledge and experiences as they assess, intervene, and evaluate the care of a rapidly deteriorating patient. This critical care experience requires that students demonstrate competency in assessment, critical thinking, communication, teamwork, skill performance, and documentation. It is an excellent means of reviewing important concepts as students prepare to take the National Council Licensure Exam for Registered Nurses (NCLEX-RN) and enter practice within a few months.

Presimulation logistics. The course coordinator for the senior-level capstone medical surgical nursing course assigns students to groups for the simulation experience. Each clinical group is divided into two groups of five students. (Five seems to be the maximum number for effective use of the HPS.) Each clinical faculty member assists with the simulation experience for his or her group. Students spend a total of 2 hours in the simulation lab during the semester as they encounter four simulation scenarios involving care of an acutely ill adult patient. The cases that are typically used include congestive heart failure progressing to pulmonary edema, tension pneumothorax, hyperglycemic hyperosmolar nonketotic coma, and cardiac arrest. These cases were adapted from preprogrammed HPS scenarios.

The HPS is located in a room that is dedicated to its use. The room houses the mannequin on a stretcher, the patient monitor display, a cart with medications and emergency supplies (oxygen, IVs, syringes, etc.), a set of cabinets that includes a countertop and sink, a white erase board, resource books, and a telephone. There is an adjoining control room that houses the operating tower and computer interface. A one-way mirror enables the computer operator to observe the students and faculty as they participate in the scenario. An infant sound monitor is placed near the head of the mannequin and the receiver is placed in the control room so the operator can hear what is being said in the simulation room.

Two nurse educators who act as facilitators and a graduate teaching assistant who operates the computer usually conduct the simulation scenarios. The nurse educator who is most knowledgeable and experienced with the HPS takes the lead and directs the simulation. The other nurse educator (usually the clinical faculty) assists and supervises students' performance. Both faculty members assume additional roles as needed, such as a family member and physician or nurse practitioner. The graduate teaching assistant operates the computer from the control room, initiating and managing the physiologic responses of the mannequin in accordance with each particular scenario or simply starting and stopping a preprogrammed scenario. The teaching assistant also is the voice of the patient (the HPS mannequin has a voice box in his neck), responding to the students' history and assessment questions. The infant sound monitor allows the teaching assistant to hear the students' questions.

Presimulation student instructions. In an effort to promote realism in the cases, students and faculty dress as they would for the clinical experience in the hospital. In addition, they are asked to wear identification badges and to bring their stethoscopes. It is made clear to students that the HPS simulation is a required experience. Students are expected to come to the HPS

simulations with some background knowledge and experience. They may have assigned readings or written assignments to complete prior to the simulation. A completed written assignment (e.g., study questions) may be used as a student's admission ticket to the scenario.

Presimulation briefing. All simulation scenarios begin with a presimulation briefing (see Simulation Box 1). During this time, students are oriented to the mannequin and the learning environment. A faculty member who will be assisting with the subsequent scenarios conducts this session.

Each group of students enters the simulation room, accompanied by one of the nursing educators who will facilitate the cases. The first time students encounter the human patient simulator, the technology and equipment involved with the mannequin are explained (see Simulation Box 2). Students are encouraged to uncover and examine and touch the mannequin, listen to the heart and breath sounds, palpate the pulses, and observe pupil response. The voice of the mannequin is demonstrated. It is important to remind students that they are to treat the mannequin as they would a patient in the scenarios. Students are oriented to the environment, including the computer display and the location of equipment and supplies. After each student has had an opportunity to become acquainted with the mannequin and the environment, the group of four or five is escorted outside the simulation lab where they receive instructions about how the scenarios will proceed. Each student is assigned a specific role during the scenario: primary nurse, secondary nurse, communicator, recorder, and resource/medication nurse (see Simulation Box 3). The students draw 5" × 7" index cards to determine their assigned roles. Each card identifies the responsibilities of that particular role. In subsequent scenarios, role assignments are changed so that no student repeats a role they have already performed. During the briefing, students are given a concise report on the patient they will meet in the scenario. The setting (e.g., emergency department, intensive care unit), patient history, presenting problem, family situation, and other pertinent details are described to the students.

The use of index cards to assign specific student roles evolved after conducting a few simulations in which students appeared disorganized and confused about what each one should be doing. For example, one student would think of something to do and all the students in the group would set about attempting to perform that intervention. There was no evidence of teamwork. In an attempt to remedy this problem, students were asked to volunteer for a role in the scenario (primary nurse, secondary nurse, communicator, recorder, and resource/medication nurse). Students were hesitant and took too long deciding who would perform each role. Subsequently, faculty developed index cards to identify each role and the associated responsibilities of that role. During the presimulation briefing, a faculty facilitator shuffles the cards and asks students to draw their roles prior to each scenario. In addition to saving some time, this technique provides the students with some direction as they begin the scenario.

Simulation Box 1. Presimulation Student Preparation

Instructions to the student:

- Prior to simulation, complete assigned readings, case materials.
- Be prompt to your assigned simulation time.
- Dress as in clinical.
- Wear name badge.
- Bring stethoscope.
- Address and treat mannequin as though a patient.

Simulation Box 2. Presimulation Briefing—Orientation to Simulator & Learning Environment

Orientation to the mannequin:

- Heart and lung sounds
  - Instruct students to listen to the heart and lungs sounds so that they are be able to differentiate from normal, which is what they are hearing during orientation, and abnormal, which is what they will hear when the scenario begins. Help students to adapt to the mechanical sounds associated with the heart and lung sounds.
- Palpate peripheral pulses (no posterior tibia pulse).
- Perform PERRL (no A or accommodation).
- Explain to students what mannequin does not do/have:
  - Bowel sounds
  - Sweat
  - Seizure
  - Change color such as cyanotic, flushed, or pale
- Demonstrate how to connect mannequin to monitor.
- Inform students that patient data is located on the patient care monitor. Detail the data as presented so that they can interpret later in a case.
- Differentiate for them what data they can expect to get from the monitor and what will require their assessment.

Orientation to the learning environment:

- Monitor
- Mannequin on stretcher or hospital bed
- Oxygen and delivery devices
- Defibrillator
- Medications
- Suction
- Patient chart
- Realistic lab values, chest x-rays, EKGs
- Phone to call physician/nurse practitioner and labs

Simulation Box 3. Role Assignment Cards

Position:	**Role**:
Primary RN	Team leader, assessment, history, sets priorities, and delegates.
Secondary RN	Assists with assessment, performs nursing skills and medication administration as directed by primary nurse.
Recorder	Writes down pertinent information on whiteboard.
Communicator	Speaks to family, health care provider, lab, radiology, etc.
Resource/Medication RN	Looks up needed information for team (e.g., safe medication dosage, rate of administration of medications) and administer medications as needed**.**

**The roles are printed on colored 5" X 7" index cards with the role name on one side and the responsibilities of role on the other side. These cards are laminated and used over and over for each simulated case.*

Intrasimulation

The actual simulation begins as students enter the simulation room. If it is their first encounter with the simulator, they may need some assistance and encouragement in getting started. The faculty facilitators coach the students as needed. The students acting as primary and secondary nurses are expected to introduce themselves to the patient and family. The communicator assumes the position near the telephone, the recorder goes to the whiteboard, and the resource/medication nurse locates the reference materials. The primary nurse begins the assessment and directs the secondary nurse to assist or to do other tasks as needed. Based on the assessment findings and any physiologic changes that may occur, the primary nurse determines the interventions that are needed. He or she may collaborate with the secondary nurse or other team members as necessary. The recorder documents all assessment findings on the whiteboard. At the point it is determined that a call to the health care provider is warranted, the communicator gathers the necessary data and contacts the provider by telephone. Using the SBAR communication method, pertinent information is relayed to the provider and orders are obtained. The communicator documents the orders. As soon as she or he is finished, the facilitator uncovers a foam board with the orders prewritten large enough that they are visible to the entire team. The orders are implemented at the direction of the primary nurse, who is also involved in carrying out the orders. The resource nurse looks up any medications that are ordered to identify the type of drug, the actions, dosage, administration, and potential incompatibilities with other medications. This information is communicated to the team prior to administering any medications. The primary nurse can delegate some of the medication administration to the resource nurse.

The faculty facilitators may be involved in numerous aspects of the simulation. One may be assisting with medications, while another may be helping with skills such as applying oxygen or testing blood sugars on the patient. If the students do not intervene appropriately, the patient may go into respiratory arrest and/or experience cardiac arrhythmias. Faculty assist the students as they perform CPR and administer emergency medications. The simulation ends at the predetermined “end” of the case, when the patient “expires,” or as determined by the faculty.

Postsimulation

Debriefing is used to correct any misinformation or improper practice techniques the students may demonstrate. Beaubien and Baker[2] stress the importance of feedback to enhance the ability of students to integrate correct behaviors into their skill set. Through the simulation, gaps in knowledge are identified in individual students that would otherwise go undetected. Additionally, in the debriefing students are asked to reflect on their own skills and knowledge. They identify what they have done well and areas that warrant improvement. Because there are multiple activities occurring throughout the simulation and students may be focused only on their specific roles, debriefing can be used to review key points about the simulation. This includes discussion of the events that occurred, psychomotor skills such as setup of a chest tube drainage system, selection of oxygen delivery method and application, rate and technique for IV push medications, etc. (see Simulation Box 4)

Simulation Box 4: Postsimulation Debriefing and Discussion

Ask students:

- What do they think they did well? – Validate what they know and affirm what they are currently doing well.
- How did this case make them feel?
- What would they do differently if they had to do it again? – Critique their performance as a group and assist them to identify additional learning needs.
- How did they like working with the HPS?

Review key concepts:

- Describe and interpret scenario.
- Students will
  - Discuss roles of team members – point out teamwork, communication, and use of appropriate and inappropriate delegation.
  - Highlight areas for potential patient safety issues – communication with each other, transcription of orders, handoff and transfer of patient.
  - List what signs and symptoms Mr. Jones exhibited.
  - State how Mr. Jones' presenting signs and symptoms varied from the textbook picture.
  - Identify what precipitated Mr. Jones' CHF and pulmonary edema – past medical history and pathophysiology.
- Discuss pathophysiology of CHF and pulmonary edema.
- Review lab reports, x-ray, EKG.
- What should be immediate interventions? (Focus on ABCs.)
- Review communication with health care provider:
  - SBAR
  - Key points to include
- Discuss rationale for each of the health care provider's orders.
- Identify important nursing considerations:
  - Conserve Mr. Jones' energy – do not ask complete history while he has dyspnea.
  - Explain to Mr. Jones what you are doing – be brief, concise.
  - Communicate with Mrs. Jones – provide information, but do not offer false reassurance; have staff member escort her out of room.
- Do a skill review:
  - Non-rebreather mask and why it is best choice for oxygen delivery
  - Insertion of IV: choice of angiocath size, insertion site, fluid, rate of administration
  - IV push medications and technique for administration
  - Foley catheter to straight drainage (urometer for hourly outputs)

It is important to provide students with an opportunity to evaluate their experiences and the use of the patient simulator as an instructional strategy. This is done as part of the debriefing, but should also be part of a computerized or written evaluation. It may be part of a course evaluation or a separate evaluation tool specific to the patient simulation experience.

Student Evaluations of HPS Scenarios

The students who have participated in METI HPS simulations in the baccalaureate of science in nursing and continuing education programs have given overwhelmingly positive evaluations of the simulator as an instructional strategy. This is consistent with other reports of student evaluations in nursing[43–45, 48] and medical education.[51, 54, 55] One student commented, "Simulation was very effective. It took into account many facets of care, for example, assessment, communication with family, doctor's orders, medications, including herbs."

Many students feel that the simulation experience taught them all they know. This concept is evident in the following student evaluative comment:

> The simulator was awesome and so realistic. We were required to do rapid assessments of a critically ill patient and to pull it all together to provide care. Now I better know what I do not know and can work on improving. I learned more in this hour than I have my whole curriculum.

Students do not recognize that the simulation provides a synthesis experience in which they draw from previous knowledge and experiences. The didactic and clinical components of their educational experience to date have been instrumental in preparing them to think and act like nurses. The "aha!" experience of patient simulation promotes student confidence in their critical-thinking and clinical-decisionmaking skills and in their ability to practice as safe, competent nurses as they enter the workplace.[46, 48]

Practice Implications—The Future of Patient Simulation in Nursing Education

Use of the patient simulator as an instructional strategy holds great promise for nursing education. Simulation can become an integral part of nursing education because of its ability to improve patient care and patient safety. No live patients are placed in jeopardy at the expense of the learner. Simulation provides standardization of cases, promotes critical thinking, allows mastery of patient care, provides immediate feedback, and helps students integrate knowledge and experience. It is an ideal synthesis learning experience.

Because the patient simulator is a relatively new educational tool, nursing educators must become acquainted with the technology, its potential uses, and benefits to learners. Toward that end, it is important that the nursing literature on patient simulation is increased, both in descriptive articles and in research reports. As faculty become more aware of the advantages of educating students with patient simulation, its utilization in educational programs should increase.

Because of the investment of money and faculty time associated with patient simulation, it is imperative that administrators and educators see the value of teaching with simulation. Administrators need to commit financial resources to procuring patient simulation equipment and training faculty in its use. Faculty time must be dedicated to the development and implementation of simulation programs.

Nursing faculty need to look for new ways to utilize the patient simulation technology with all types of learners. Schools of nursing can optimize the use of a patient simulator and increase its cost effectiveness by incorporating it into undergraduate, graduate, and continuing education programs.

Research Implications

The paucity of nursing research on the use of patient simulation demonstrates the need for further study. Studies are needed to investigate the best ways to utilize patient simulation in nursing education.[39] Evaluative studies are needed to examine the success and effectiveness of patient simulation in all types of nursing education programs. Research is also needed to demonstrate that knowledge and skills acquired in a simulated environment are transferable to actual patient care situations. The cost effectiveness of using simulation also needs to be explored.[47, 56–58]

Conclusion

The use of patient simulators in nursing education is a relatively new instructional methodology. The rationale for using simulation as an educational strategy includes the absence of risk to a live patient; the ability to provide standardization of cases; the promotion of critical-thinking, clinical-decisionmaking, and psychomotor skills; the provision of immediate feedback, and the integration of knowledge and behavior. Through patient simulation scenarios, essential elements of patient safety can be emphasized, such as prevention of medication errors, promotion of effective communication, and the importance of teamwork. Learners can be exposed to critical care scenarios and have the opportunity to respond without fear of harming a live patient.

By providing students with exposure to a variety of clinical situations through clinical practicum experiences and patient simulations, they can be better equipped to provide safe, effective care and work as contributing members of the health care team.

The challenge is for faculty to embrace patient simulation as an instructional strategy and to seek its effective implementation in nursing education programs. The exciting technology of patient simulation is only as good as the faculty who use it. The potential benefits to learners outweigh the costs of the equipment and faculty training.

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Table1. Teaching/Learning Strategies Using Simulation

Type of Simulation[59]	Description[59]	Advantages[60, 61, 62]	Disadvantages[60, 61, 62]
Low-tech (static) task trainers e.g., food items: oranges for injections, chicken breast for biopsy, pigs feet for suturing, injecta pads, adult/child/infant mannequins, breast and gyn/prostate models, eye/ear models, IV arms, CPR mannequins, case studies, etc.	Props, models, or mannequins used to practice skills and procedures	No threat to patient safety Readily available Reusable Develop role memorization Allows for return demonstration of skills Large groups of learners Low to moderate cost	Task training Consistency Learner – memorization Lower veracity Return demo without critical thinking
Simulated patients e.g., standardized patient (trained actors), learner/learner, educator/learner, patients playing role of patient, female and male human models for pelvic and prostate exams, unfolding case studies	Role-play patients for training, simulates assessment of history taking, physical exams, communication, and therapeutic psychiatric interventions	No threat to patient safety Great tool for high communication skills Provides relatively consistent experience for all students	Moderate to high cost with each use Limited learners
Screen-based computer simulators e.g., computer-assisted instruction (CAI), virtual reality excursions (VRE), Web-based programs	Programs to train and assess clinical knowledge and decisionmaking.	No threat to patient safety Provides relatively consistent experience for all students Reusable	Variable amount of critical thinking Moderate cost
Complex task trainers e.g., virtual reality devices such as bronchosocpy, laparoscopic surgery, IV access (Cath Sim^{R}), haptic (touch cue) simulators such as pelvic exam, cardiac catheterization and stent placement, respiratory intubation, neonate (umbilical artery, lumbar, intubation) models	High-fidelity visual, audio, touch cues with interfaces with computers	No threat to patient safety Provides relatively consistent experience for all students Promotes realism Improves psychomotor skills	Moderate to high cost Limited learners

Type of Simulation[59]	Description[59]	Advantages[60, 61, 62]	Disadvantages[60, 61, 62]
Human Patient Simulators ***Low-fidelity*** e.g., Noelle birthing mannequin – uses compressor to birth newborn every 7 minutes ***Moderate-fidelity*** e.g., Laerdal™ SimMan™ ***High-fidelity*** e.g., METI Human Patient Simulator®	Full-length human mannequins Simulated anatomy and physiology Computer-driven scenarios that responds as programmed Computer-driven physiologically based that responds in real time to interventions	No threat to patient safety High degree of realism and veracity Low educator/learner ratio (1:5) Active involvement of learner Decreases emphasis on memorization Consistent experience for all students: serious or uncommon clinical problems can be presented to all learners Creates a standardized setting for honing and enhancing critical-thinking, problem-solving, and decisionmaking skills Enhances ability to assess variations in patient responses and the learners' ability to pick up important assessment data Increases competence and ability to formulate a strategy for a specific situation Learners are better prepared for clinical practicum Practice communication with multidisciplinary team members. Teamwork and leadership skills can be practiced Communication and delegation skills can be fine tuned Psychomotor skills can be applied and refined Increased organization of patient care	High cost (startup and ongoing cost) Maintenance Resource intensive: monetary and faculty Limited learners High staffing ratio No validation of transfer of learning to clinical setting Learner's disbelieving attitude Hypervigilance because being observed Anxiety of learner interferes with performance Lack of knowledge at time of simulation experience of learner Physical space for simulator and associated teaching sessions needed Lack of comfort with simulator as teaching strategy for educators

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Table 2. Key Terms and Definitions

Terms and Acronyms	Definitions
ABCs	airway-breathing-circulation
ABG	arterial blood gases
ACLS	advanced cardiac life support
ADE	adverse drug event
ASA	aspirin
BSN	baccalaureate of science in nursing
BP	blood pressure
CAI	computer-assisted instruction
Capstone	A course occurring at the end of a curriculum allowing students to synthesize what they have learned.
CBC	complete blood count
Champion	A person who will be a leader in the use of a new technology, helping to bring additional faculty along in their implementation of the technology across the curriculum.
Chem 7	Blood work that is done on serum examining seven chemical tests: blood urea nitrogen (BUN), serum chloride, carbon dioxide, creatinine, glucose, potassium, and sodium.
CHF	congestive heart failure
Code	Respiratory and/or cardiac arrest
Complex task trainer	Highly sophisticated computer technology that provides training on specific skills or procedures; includes virtual reality and haptic systems.
CPR	cardiopulmonary resuscitation
CRM	Crew Resource Management
CXRs	chest x-rays
ED	emergency department
EKG	electrocardiogram
Fidelity	The degree to which the appearance and function of the simulator resemble the simulated system; low, intermediate, or high[5]
FiO_2	fraction of inspired oxygen
Generation X	Refers to the generation of people born between 1961 and 1981 (dates vary among different sources) and describes behaviors in terms of life experiences.
Generation Y	Refers to the generation of people born between 1977 and 2003 (dates vary among different sources) and describes behaviors in terms of life experiences.
GYN	gynecological
Haptic	Technology that interfaces with the user via the sense of touch.
High-fidelity patient simulators	Highly sophisticated computerized mannequins, capable of realistic physiologic responses.
HHNC	hyperglycemic hyperosmolar nonketotic coma
HIPAA	Health Insurance Portability and Accountability Act
HOB	Head of bed
HPS	human patient simulator; high-fidelity computerized mannequin, produced by Medical Education Technologies Incorporated (METI®).
HR	heart rate
Hypovolemic	Decreased circulating blood volume.
ICU	intensive care unit
I/O	intake and output
Integrated simulators	Simulators that combine computer technology and part- or whole-body mannequins.
Injecta pad	Gel-filled pad used to teach and practice giving intramuscular and subcutaneous injections.
IVs	intravenous line or intravenous fluid
K-Dur	Oral form of potassium chloride, a potassium supplement.
JCAHO	Joint Commission on Accreditation of Healthcare Organizations (now known as the Joint Commission)
Laparoscopy	Minimally invasive surgery in the abdomen or pelvic area where thin instruments are used to view, remove, or repair areas through small incisions.
mEq	milliequivalents
METI	Medical Education Technologies Incorporated
mg	milligram(s)

Terms and Acronyms	Definitions
MD	medical doctor
ml	milliliter(s)
MP3 player	MPEG-1, Audio-3, a portable, compressed, digital encoding device that allows a person to listen to music and/or watch video.
MSO_4	morphine sulfate
NASA	National Aeronautics and Space Administration
NRB mask	non-rebreather mask for delivery of oxygen
NCLEX-RN	National Council Licensure Exam for Registered Nurses
NS @ KVO	normal saline (intravenous fluid) at keep-the-vein-open rate (30 ml per hour)
O_2	oxygen
Part task trainers	Low-tech or static task trainers, designed to replicate a portion of the body or the environment; many represent selected anatomical areas of the human body and are used to teach basic psychomotor skills and procedures.
Patient simulators	High-fidelity computerized mannequins.
PC	personal computer
PDA	personal digital assistant, a hand-held data device.
Pedal edema	Excessive fluid in the extremities. When the tissue is pressed with a finger over a bony prominence, the depression remains, and the amount of depression is graded from 0 to 3+ to indicate severity of the fluid overload.
PERRLA	pupils equal round and reactive to light and accommodation
PERRL	pupils equal round and reactive to light
PMH	past medical history
PO	*Per os,* Latin for "by mouth"
Pulmonary edema	Fluid collecting in the lungs primarily due to left-sided heart failure but may occur with right-sided heart failure.
QD	every day
Q 5 min	every 5 minutes
RN	registered nurse
RR	respiratory rate
SBAR	Situation, background, assessment, recommendation: A model of communication that is clear, concise and to the point. Sharing key information about situation, background, and assessment, and providing a recommendation.
Screen-based computer simulators	Computer programs designed to model various aspects of human physiology, specific tasks, or environments; learners use information to make clinical decisions and observe the results in action; feedback is provided during and/or after the interaction.
SimMan™	High-fidelity patient simulator produced by Laerdal™
Simulated patients	Live persons acting as patients through role play; student partners practicing assessment skills or procedures; live actors as trained patients.
Simulation	A technique or device that attempts to create characteristics of the real world; in health care, a device representing a patient or part of a patient that can respond and interact with actions of the learner;[3] activities that mimic a clinical environment, designed for use in demonstrating procedures and promoting decisionmaking and critical thinking.[4]
SL	sublingual
SOB	shortness of breath
Stat	*Statim,* Latin for "immediately" or "now"
T	Temperature
Tension pneumothroax	A patient care emergency where air enters the pleural cavity but cannot exit, causing increased pressure in the pleural space and leading to the collapse of the lung on the affected side. This change in pressure will eventually compress the heart and major vessels, and the lung on the affected side will not be able to expand.
TV	television
VRE	virtual reality excursions

Appendix A: Simulation Case Presentation

Simulation Scenario: CHF Pulmonary Edema

Simulation participants:

- Lead faculty: director and facilitator
- Clinical faculty: facilitator, assume additional roles (wife, MD), assist students with psychomotor skills, etc.
- Computer technician: (in control room, behind two-way mirror): "patient" voice and computer operator
- Students

Note: To facilitate ease of role identification, when we prepare scripts for the faculty, we color code all the different roles, double space, and highlight key points. The case is then bound and distributed to all the facilitators.

Facilitator: Role context is an RN who has worked the night shift in a busy emergency department (ED). Students are told they are coming reporting to work on the day shift in the ED. It is 7:00 a.m. and time for report.

> *Thank goodness you all are here. We have had a terrible night. There is a code going on down the hall, so I'll be quick. I need for you to take over care of the patient in room 1. His name is Alex Jones; he is a 62-year-old Caucasian male, just brought in by his wife. He is complaining of shortness of breath and chest pain. He says he has been up all night, and his wife finally made him come to the ED because it had gotten so bad. His wife has gone to park the car and has all of his meds. I'm sorry; all we have done so far is get him in a room. He hasn't been connected to the monitor, and no one has assessed him yet. Thanks for taking him over! I'll check on you later. I have to run back to the code.*

Facilitator: Escorts students into the simulation room. Direct communicator to area where phone (phone is a prop and is not connected) is located; direct recorder to white erase board and resource nurse to reference materials. If students are hesitant to begin their assessment, provide encouragement.

Students:
Primary and secondary nurses should introduce themselves to Mr. Jones and begin to do the following:

- Connect patient to the monitor.
- Obtain vital signs.
- Auscultate heart and lungs.
- Administer O_2 – 100 percent non-rebreather (be sure to fill bag with O_2 before putting mask on patient).
- Start IV – NS @ KVO.
- Elevate HOB.

- Assess pain (rate and describe).
- Assess for peripheral edema (he has on puffy socks to simulate 3+ pedal edema).
- Obtain history – recognize the need to limit questions due to his SOB.

Facilitator: Students need to ask patient appropriate questions. If they seem like they are getting off track, give redirection and guidance to their assessment and history. (The primary and secondary nurses may take directions/suggestions from the other team members.)

Computer technician: (Computer operator on other side of one-way mirror is the voice of Mr. Jones, voice is transmitted through microphone).
Voice of Mr. Jones: Make voice sound very anxious, keep repeating until nurse intervention, *"I just can't catch my breath," "It hurts all over my chest," "I can't take lying down like this,"* and *"You've got to help me."*

When asked by the students, Mr. Jones gives the following responses:

- Pain: *"10" on a scale of 1–10, all over my chest, feels different from when I had heart attacks.*
- PMH: *I've had four heart attacks. When? The first one was when I was 36 and my last one was 2 years ago. I've never had open-heart surgery.*
- Medications: *"Oh, honey, I can't keep track of all of them. My wife is bringing them in." "I took all of them this morning at about 3:00 a.m. before we came in."*
- Social history: *No alcohol, quit smoking 20 years ago.*
- Recent changes: *"When I take my socks off, my leg looks like they are still on," "I tell my wife that I fall asleep watching TV every night in the recliner, because I don't want her to worry. But, the truth of the matter is, I just can't sleep lying down anymore,"* and *"I thought maybe I just ate too much at (fill in appropriate holiday), because I've gained 10 lbs in the past 2 weeks."*

Faculty facilitator: (One of the faculty facilitators acts as wife of Mr. Jones.) At some point, preferably when the students are engaged with the patient, a concerned wife runs into the room, anxiously asking about her husband, trying to get to him to hold her hand. Ask the nurses, *"Is he okay? What is going on? Is he having another heart attack?"* Continue to be "in the way" until one of the students responds to you and takes you aside to talk to you.

Give the paper bag full of his medication bottles from home to one of the students.

List of meds:

- Nitrostat 0.3mg SL prn chest pain Q 5min x 3 doses
- Ramipril 2.5 mg PO QD
- K-Dur 20 mEq PO QD
- Furosemide 20mg PO QD
- Tenormin 50mg PO QD
- Lanoxin 0.25mg PO QD
- ASA 81mg PO QD

Student: The student acting as **communicator** should take the wife out into the hall and identify herself/himself and explain who she/he is and what role they have in the care of Mr. Jones.

Use therapeutic communication to explain that Mr. Jones's heart rhythm is regular, which is a good sign, but that you will have to do an EKG and additional tests to determine if he is having/has had another heart attack. Assure her that the team is doing everything they can for him. Attempt to calm the wife down and give her no more than two tasks. Tell her that the secretary will accompany her to registration/admitting and then she should come back to the waiting room. Tell her your name again, and explain that you will be here for the next 12 hours. Tell her you will be out very soon to update her on her husband's condition. Thank her for bringing in his meds and reassure her that she did the right thing by bringing him to the ED.

Note: Since the "wife" is a faculty/facilitator she/he can come out of role and give the student feedback and direction as needed during or after the interaction.

Computer technician: When you think that the students are starting to pick up on the diagnosis of congestive heart failure [can be cured by lead faculty], begin coughing (as Mr. Jones).

Facilitator: Once Mr. Jones starts coughing, hand the students the emesis basin with pink, frothy sputum.

Recipe: Pink, frothy sputum can be simulated by mixing a small amount of red powdered Jell-O, ivory dish detergent, and water, shaking it vigorously, pouring off liquid, and putting pink suds in emesis basin.

Students: The students should recognize this as a cardinal sign of pulmonary edema. If they feel that they have enough data, they need to anticipate the following orders:

- Diuretic
- Narcotic analgesic
- Nitroglycerine
- EKG
- Chest X-ray
- Blood gases
- CBC, Chem 7, cardiac enzymes
- Foley catheter (strict I/O)
- Continue 100 percent oxygen per non-rebreather mask

Students: When the students feel they are ready, the **communicator** places a call to the health care provider. A prop telephone is available for the student to use. The student is expected to do the following: (If student is having difficulty, they can use the script that follows. Faculty hands card with script to **communicator**.) Using principles of SBAR (situation, background, assessment, recommendation), student accomplishes the following:

- Introduce yourself and state where you are located.
- State who the patient is and describe him.
- State chief complaints and relevant signs and symptoms.
- Provide brief history with relevant information for current status.
- Give quantitative vital signs, always include FiO_2 with pulse ox.
- Identify interventions that have been done.
- State what you think is going on with the patient.
- Ask health care provider for further orders.

Figure 1. Communication With Health Care Provider

"Dr. _____, This is [*state your name*], one of the nurses in [*state your department*].

We have a new patient, [*patient's name*], a [*age*] year-old, [*race*], [*gender*]. He came in with complaints of_____

_____, which started at [*time of onset*].

His vital signs are [*HR*], [*RR*], [*BP*], [*T*], and [*pulse ox, amount of O_2 and type of delivery*].

He has a history of _____.

On assessment, we found_____.

So far, we have [*tell what interventions you have done so far*].

I think he may have _____.

I think he needs some_____.

What else you would like for us to do?"

Restate what needs to be done, including reading back the orders.

Confirm when the health care provider will arrive to assess the patient.

Facilitator: (One of the faculty facilitators acts as the health care provider responding to the student's call.) The health care provider gives the following orders and states she/he will be down to see the patient shortly. The student should write down the orders and read them back to the health care provider. After this is done, the orders are displayed on a prewritten foam board so that they can be seen by all the students simultaneously.

The orders are as follows:

- Lasix 40mg IV stat
- Morphine 4mg IV stat
- Nitroglycerine 0.4mg/spray 2 sprays SL stat
- Normal saline at 30 ml per hour
- Stat ABG
- Stat EKG and serial EKGs
- Stat CBC and Chem 7
- Stat cardiac enzymes
- Stat portable CXR
- Foley catheter to straight drainage
- Hourly intake and output
- Continue 100 percent NRB mask

Students:
The primary nurse delegates tasks to secondary nurse (med administration, Foley, etc.) and directs communicator to call lab, x-ray, and EKG.
The resource nurse needs to look up the proper rate of administration for Lasix and MSO_4. The primary and secondary nurses administer the Lasix and morphine IV push through the peripheral IV that they placed earlier.
The communicator places a call to lab, radiology, and EKG to request stat testing.

Facilitator: State "After about 15 minutes, you get the test results on Mr. Jones."

- EKG: Sinus tachycardia, indicative of old MIs **(Give students EKG.)**
- CXR: Enlarged heart, enlarged hila with indistinct margins (perivascular edema), and prominence of veins draining the upper lobes (cephalization of flow) **(Show students CXR.)**
- Lab results: respiratory acidosis **(Show students ABG.)**

Students should recognize and state need to call results to the health care provider as soon as possible.

Facilitator: "Where do you think Mr. Jones should be transferred?"
Students should state that Mr. Jones will likely go to an intensive care unit.

SCENARIO ENDS

Debriefing

This is one of the most important aspects of simulation. It is imperative that it is done well in order to help students have the best possible synthesis experience.

Take the students outside the simulation room. Begin debriefing (see Simulation Box 4) while other simulation staff reset the room and mannequin for the next case. Distribute handouts with key points and materials for the student to take with them and review.

Remind students they are not to share information with their fellow students because

- All students should have the same opportunity to learn.
- It is best for the student to move through the case as they did, experiencing the hot seat as they did.
- To discuss the case is similar to sharing answers from a test and would be considered an Honor Code violation.