PART I. OVERVIEW

Chapter 1. An Introduction to the Report

1.1. General Overview

The Institute of Medicine's (IOM) report, *To Err is Human: Building a Safer Health System*,[1] highlighted the risks of medical care in the United States. Although its prose was measured and its examples familiar to many in the health professions (for example, the studies estimating that up to 98,000 Americans die each year from preventable medical errors were a decade old), the report shocked the sensibilities of many Americans. More importantly, the report undermined the fundamental trust that many previously had in the health care system.

The IOM report prompted a number of legislative and regulatory initiatives designed to document errors and begin the search for solutions. These initiatives were further catalyzed by a second IOM report entitled *Crossing the Quality Chasm: A New Health System for the 21st Century*,[2] which highlighted safety as one of the fundamental aims of an effective system. But Americans, who now wondered whether their next health care encounter might harm rather than help them, began to demand concerted action.

Making Health Care Safer represents an effort to determine what it is we might do in an effort to improve the safety of patients. In January 2001, the Agency for Healthcare Research and Quality (AHRQ), the Federal agency taking the lead in studying and promoting patient safety, commissioned the UCSF-Stanford Evidence-based Practice Center (EPC) to review the literature as it pertained to improving patient safety. In turn, the UCSF-Stanford EPC engaged 40 authors at 11 institutions around the United States to review more than 3000 pieces of literature regarding patient safety practices. Although AHRQ expected that this evidence-based review would have multiple audiences, the National Quality Forum (NQF)—a public-private partnership formed in the Clinton Administration to promote a national quality agenda—was particularly interested in the results as it began its task of recommending and implementing patient safety practices supported by the evidence.

A Definition of "Patient Safety Practices"

One of our first tasks was to define "patient safety practices" in a manner that would allow us and our reviewers to assess the relevant evidence. Given our task—producing a full report in less than six months—a complete review of all practices associated with improving health care quality was both impossible and off-point. Working closely with AHRQ and NQF, we chose the following definition:

> *A Patient Safety Practice is a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.*

A few elements of the definition deserve emphasis. First, our focus on processes and structure allowed us to emphasize changing the system to make it safer rather than targeting and removing individual "bad apples." We recognize that when individuals repeatedly perform poorly and are unresponsive to education and remediation, action is necessary. Nevertheless, there is virtual unanimity among patient safety experts that a focus on systemic change will be far more productive than an emphasis on finding and punishing poor performers.

Second, looking at crosscutting diseases and procedures allowed us to distinguish patient safety activities from more targeted quality improvement practices. Admittedly, this dichotomization is imprecise. All would agree that a practice that makes it less likely that a

patient will receive the wrong medication or have the wrong limb amputated is a patient safety practice. Most would also agree that practices designed to increase the use of beta-blockers in patients admitted to the hospital after myocardial infarction or to improve the technical performance of hernia repair would be quality improvement strategies rather than patient safety practices. When there was a close call, we generally chose to be inclusive. For example, we included practices designed to increase the rate of appropriate prophylaxis against venous thromboembolism, the appropriateness of pain management, and the ascertainment of patient preferences regarding end-of-life care. We recognize that these practices blur the line somewhat between safety and quality, but we believe that they are reasonable examples of ways to address potential patient safety hazards.

Third, we realized it would be impossible to review every potential safety practice and recognized that some gaps in the evidence were inevitable, so at times we reviewed illustrative examples that *might* be broadly generalizable. For example:

- Methods to avoid misread radiographs (Chapter 35); where the content could be relevant to analogous efforts to avoid misread electrocardiograms or laboratory studies
- Decreasing the risk of dangerous drugs (Chapter 9), where the focus was on anticoagulants, but similar considerations might be relevant for chemotherapy and other high-risk drugs
- Localizing care to specialized providers reviews geriatric units and intensivists (Chapters 30 and 38), but similar evidence may be relevant for the rapidly growing field of hospitalists[3-5]
- The use of ultrasound guidance for central line placement (Chapter 21); the premise (decreasing the risk of an invasive procedure through radiologic localization) may also be relevant for ultrasound guidance while performing other challenging procedures, such as thoracentesis

A Focus on Hospital Care

Most of the literature regarding medical errors has been drawn from hospital care.[6-22] For example, the two seminal studies on medical error[22,23] from which the oft-cited extrapolations of yearly deaths from medical error were derived, have highlighted the risks of inpatient care. We applaud recent studies examining the risks of errors in the ambulatory setting[24] but believe that the hospital is an appropriate initial focus for an evidence-based review because the risks associated with hospitalization are high, strategies for improvement are better documented, and the importance of patient trust is paramount.

That said, the reader will see that we allowed the evidence to take us to other sites of care. For example, although much of the literature regarding the occurrence and prevention of adverse drug events is hospital-based, more recent literature highlights outpatient issues and is included in this review. An example is the chapter on decreasing the risk of anticoagulant treatment (Chapter 9), in which two of the most promising practices involve outpatient anticoagulation clinics and patient self-monitoring at home. Similarly, strategies to prevent falls or pressure ulcers are relevant to nursing home patients as well as those in hospitals, and many studies that shed light on these issues come from the former setting.

The Evidence

Chapter 3 describes our strategy for evidence review. As in other evidence-based reviews, we set the bar high. One would not want to endorse a practice unsupported by evidence, nor withhold one substantiated by a high level of proof. In the end, we aimed to identify practices whose supporting evidence was so robust that immediate widespread implementation would lead to major improvements in patient safety. Additionally, we hoped to identify several practices whose promise merited a considerable investment in additional research, but whose evidentiary base was insufficient for immediate endorsement. The results of this effort are summarized in Part V of the Report.

Readers familiar with the state of the evidence regarding quality improvement in areas where this has been a research priority (eg, cardiovascular care) may be surprised and even disappointed by the paucity of high quality evidence for many patient safety practices. The field is young. Just as there had been little public recognition of the risks of health care prior to the first IOM report, there has been relatively little attention paid to such risks—and strategies to mitigate them—among health professionals and researchers. Nevertheless, we found a number of practices supported by high quality evidence for which widespread implementation would save many thousands of lives.

Moreover, there are important methodologic reasons why research in patient safety is particularly challenging. First is the problem of blinding. The physician who has begun to use a new computerized order entry system cannot be blinded to the intervention or its purpose. Second, it is sometimes difficult to measure important outcomes. As in aviation, enormous benefits can be reaped from analyzing "near misses" (with no ultimate harm to patients),[25,26] and yet these outcomes cannot be reliably counted in the absence of potentially obtrusive, and often very expensive observation. Third, many effective practices are multidimensional, and sorting out precisely which part of the intervention works is often quite challenging. Fourth, many of the patient safety problems that generate the most concern (wrong-site surgery, for example) are probably uncommon. This makes demonstrating the success of a "safety practice" in a statistically meaningful manner with respect to outcomes all but impossible.

Finally, establishing firm epidemiologic links between presumed (and accepted) causes and adverse events is critical, and frequently difficult. For instance, verbal orders from doctors to nurses are regarded as a cause of medication errors almost as matter of dogma, with many hospitals prohibiting or strongly discouraging this practice except in emergency situations.[27] Yet, the one study that we could identify that specifically and comprehensively addressed this issue[28] actually reported *fewer* errors among verbal medication orders compared with written medication orders. A similar relationship might be found studying other intuitively plausible "risk factors" for errors, such as "fatigue." Because many health care providers work long hours and/or late at night, analyses of errors will commonly reveal fatigued providers. The question is whether or not fatigue is over-represented among situations that lead to errors. As discussed in Chapter 46, the evidence supporting fatigue as a contributor to adverse events is surprisingly mixed. The point is not that the problem of long work-hours should be ignored, but rather that strong epidemiologic methods need to be applied before concluding that an intuitive cause of errors is in fact causal. These methodologic issues are further explored in Chapters 3 (methods for analyzing the individual practices) and 56 (methods for summarizing the overall evidence).

Improving patient safety is a team effort, and the playbook is often drawn from fields outside of health care. Most medical errors cannot be prevented by perfecting the technical work of individual doctors, nurses or pharmacists. Improving patient safety often involves the

coordinated efforts of multiple members of the health care team, who may adopt strategies from outside health care. Thus, our teams of authors and advisors included physicians, pharmacists, nurses, and experts from non-medical fields. The literature we reviewed was often drawn from journals, books, or Web sites that will not be on most doctors' reading lists. We reviewed several promising practices whose evidence came from the domains of commercial aviation, nuclear safety, and aerospace, and the disciplines of human factors engineering and organizational theory. In reviewing these practices, we tried to be flexible regarding standards of evidence. For example, the randomized trial that is appropriately hailed as the "gold standard" in health care is rarely used in aviation, which instead relies on analyses of detailed case studies and industrial engineering research approaches. (Examples and additional discussion of this issue can be found in Chapter 2.)

We also limited our discussion to the existing practices, recognizing that future technology may make the ones we reviewed obsolete. For example, much of the struggle to find safe ways to administer warfarin (Chapter 9) would be rendered moot by the development of a much safer, but equally effective oral anticoagulant that did not require monitoring. Similarly, the evidence regarding changing the flooring of rooms to decrease falls (Subchapter 26.4) indicated that present options may *decrease* the harm from falls but actually *increase* their rate. Clearly, a better surface would make falls *both* less likely and less harmful. Such a surface has not yet been tested.

Finally, we have tried to define (to the extent possible from the literature) the costs—financial, operational, and political—associated with the patient safety practices we considered. However, we have not made judgments regarding the appropriate expenditures to improve safety. These judgments, which involve complex tradeoffs between public dollars and private ones, and between saving lives by improving patient safety versus doing so by investing in other health care or non-health care practices, will obviously be critical. However, the public reaction to the IOM report, and the media and legislative responses that followed it, seem to indicate that Americans are highly concerned about the risks of medical errors and would welcome public and private investment to decrease them. It seems logical to infer that Americans value safety during a hospitalization just as highly as safety during a transcontinental flight.

The Decision to Include and Exclude Practices

The patient safety/quality interface was only one of several areas that called for judgments regarding which practices to include or exclude from the Report. In general (and quite naturally for an evidence-based review), we excluded those practices for which we found little or no supporting evidence. However, we recognize that patient safety is of great public and professional interest, and that the informed reader might expect to find certain topics in such a review. Therefore, we included several areas notwithstanding their relatively meager evidentiary base. For such high profile topics (such as bar coding to prevent misidentifications, Subchapter 43.1), we tried to fairly present the practice's background, the experience with the practice thus far, and the evidence (and gaps in the evidence) regarding its value. In many of these cases, we end by encouraging additional study or demonstration projects designed to prove whether the practices live up to their promise.

Conversely, another very different group of practices lacked evidence and were excluded from the review. These practices were characterized by their largely self-evident value (in epidemiologic terms, their "face validity"). For example, large randomized studies of the removal of concentrated potassium chloride from patient care floors surely are not necessary in order to recommend this practice as a sensible way of preventing egregious errors that should

never occur. Although some of these types of practices were not included in this "evidence-based" Report, the reader should not infer their exclusion as a lack of endorsement.

A cautionary note is in order when considering such "obviously beneficial" practices. Even an apparently straightforward practice like "signing the site" to prevent surgery or amputation of the wrong body part may lead to unexpected opportunities for error. As mentioned in Subchapter 43.2, some surgeons adopt the practice of marking the intended site, while others mark the site *to avoid*. The clinical research literature furnishes enough examples of practices that everyone "knew" to be beneficial but proved not to be (or even proved to be harmful) once good studies were conducted (antiarrhythmic therapy for ventricular ectopy[29] or hormone replacement therapy to prevent cardiac deaths,[30] for example) that it is reasonable to ask for high-quality evidence for most practices. This is particularly true when practices are expensive, complex to implement, or carry their own risks.

Other Content Issues

There may appear to some readers to be an inordinate focus on clinical issues versus more general patient safety practices. In this and other matters, we went where the evidence took us. Although more than a dozen chapters of the Report consider general safety practices that have been the focus of many patient safety experts for decades (ie, computerized order entry, simulators, crew resource management), most research on patient safety, in fact, has focused on more clinical matters. It is likely that some of this is explained by the previous "disconnect" between research in patient safety and its application. We are hopeful that the Report helps to bridge this gap. We also think it likely that clinical research has been promoted by the significant resources applied to it through Federal, foundation, and industry support. Until recently, patient safety research has had few champions, and even fewer champions with resources. The recent initiatives from AHRQ and other funders are a promising shift in this historical situation, and should yield important benefits.

The reader will notice that there is relatively little specific coverage of issues in pediatrics, obstetrics, and psychiatry. Most of the patient safety practices we reviewed have broad applicability to those fields as well as larger fields such as surgery and medicine. Much of the research in the former fields was too disease-specific to include in this volume. For example, practices to improve the safety of childbirth, although exceptionally important, were excluded because they focused on the care of patients with a single "condition," just as we excluded research focused specifically on the care of patients with pneumonia or stroke.

Readers may also be surprised by the relatively small portion of the Report devoted to the prevention of high-profile and "newsworthy" errors. Even if much of the national attention to patient safety stemmed from concerns about wrong-site surgery or transfusion mix-ups, in fact these are not the dominant patient safety problems today. If widespread use of hip protectors (Subchapter 26.5) leads to a marked decrease in injuries from patient falls, implementing this safety practice would be more important than preventing the few wrong-site surgeries each year, although the former seem far less likely to garner attention in a tabloid.

Conclusions

Making Health Care Safer represents a first effort to approach the field of patient safety through the lens of evidence-based medicine. Just as *To Err is Human* sounded a national alarm regarding patient safety and catalyzed other important commentaries regarding this vital problem, this review is a germinal effort to mine the relevant literature. Although we and the authors tried hard to include all relevant practices and to review all pertinent evidence, we

inevitably missed some of both. Moreover, our effort to rank practices (Part V), many of which have only the beginnings of an evidentiary base, was admittedly ambitious and challenging. We hope that the Report provides a template for future clinicians, researchers, and policy makers as they extend, and inevitably improve upon, our work.

1.2. How to Use this Report

Organizational Framework

This document is divided into five parts:

Part I – The overview introduces many of the methodologic, content, and policy issues.

Part II – We describe, and present the evidence regarding 2 practices that are used to report and respond to patient safety problems: incident reporting and root cause analysis. Since both these "practices" have relevance for all of the patient safety targets and practices covered in Part III, we neither grade them nor rank them.

Part III – In 45 chapters, we review the evidence regarding the utility of 79 patient safety practices. Each chapter is structured in a standard fashion, as follows:

- *Background* – of the patient safety problem and the practice;
- *Practice Description* – in which we try to present the practice at a level of detail that would allow a reader to determine the practice's applicability to their setting;
- *Prevalence and Severity of the Target Safety Problem* – Here, we try to answer the following questions: How common is the safety problem the practice is meant to address? How often does the problem lead to harm? How bad is the harm when it occurs?;
- *Opportunities for Impact* – In this section, we consider the present-day use of the patient safety practice. For example, we found that the use of "unit-dose" drug dispensing was quite common in US hospitals, and thus the opportunity to make an impact with wider dissemination of this practice was relatively low. Conversely, computerized physician order entry is still relatively uncommon, and therefore (assuming it is effective), its widespread implementation could have a far larger impact;
- *Study Designs* – We review the designs of the major studies evaluating the practice. Similarly, *Study Outcomes* looks at the kinds of outcomes (eg, adverse drug events, surgical complications, mortality) that were considered. Our criteria for grading the evidence related to both design and outcomes (more information on other methodologic issues appears in Chapter 3);
- *Evidence for Effectiveness of the Practice* – Here, the authors summarize the findings of the studies and comment on any methodologic concerns that might effect the strength of these findings. This section is often accompanied by tables summarizing the studies and their findings;

- *Potential for Harm* – Many practices that are effective in improving patient safety nonetheless carry the potential for harm. More widespread use of antibiotic prophylaxis or antibiotic-impregnated urinary or vascular catheters could prevent individual hospital-acquired infections yet breed antibiotic resistance. Increasing the use of barrier precautions could also prevent infections, but might lead caregivers to visit patients less often. These sections do not imply that harm is inevitable; rather they highlight the issues that require vigilance during the implementation of effective practices;
- *Costs and Implementation* – Here we consider the costs and other challenges of implementing the practice. We tried to uncover data related to the true costs of implementation (How much does an automatic drug dispensing machine cost a pharmacy?), but also considered some of the potential offsets when there were data available. We also considered issues of feasibility: How much behavior change would be necessary to implement the practice? Would there be major political concerns or important shifts in who pays for care or is compensated for providing it? We tried not to assign values to such issues, but rather to present them so that policy makers could consider them; and
- *Comment* – Here, the authors highlight the state of the evidence, elucidate key implementation issues, and define a potential research agenda.

Part IV – In many ways a mirror of Part II, Part IV considers the ways in which patient safety practices can be implemented. The evidence is reviewed, and some of the benefits and limitations of various strategies are analyzed. As with Part II, we neither grade nor rank these "practices" in Part V since each of these strategies can be applied to most of the patient safety targets and practices covered in Part III.

Part V – Here we analyze the practices. Using methods described in Chapter 56, we synthesize the evidence in Part III to grade and rank the patient safety practices across two major dimensions:

- *Does the evidence support implementation of the practice to improve patient safety?*
- *Does the evidence support additional research into the practice?*

Tips for Users of the Report

We envision that this evidence-based report of patient safety practices will be useful to a wide audience.

Policy makers may use its contents and recommendations to promote or fund the implementation of certain practices. Similarly, local *health care organization leaders* (including leaders of hospitals, medical groups, or integrated delivery systems) may use the data and analysis to choose which practices to consider implementing or further promoting at their institutions.

Researchers will identify a wealth of potential research opportunities. This document is, in many ways, a road map for future research into patient safety. Those who fund research, including (but not limited to) AHRQ, which sponsored this report, will find literally dozens of areas ripe for future studies. In some cases, such studies may be expensive randomized controlled trials, while other practices may require a simple meta-analysis or cost-effectiveness analysis to tip the scales toward or away from recommending a practice.

Clinicians and trainees will, we hope, find the material both interesting and relevant to their practices. One of the salutary consequences of the IOM's reports has been their impact on the attitudes of our future health care providers. We have noticed at our institutions that students and post-graduate trainees in medicine, nursing, and pharmacy are increasingly taking a systems approach to health care. Several of us have heard medical residents refer to issues as "patient safety problems" that beg for a "systems solution" over the past two years, terms that were absent from the medical ward a few years earlier. Clinicians must be part of the solutions to patient safety problems, and their increasing interest in the field is an exceedingly hopeful sign.

Finally, although not primarily written for *patients and their families*, we recognize the broad public interest in, and concern about patient safety and believe that much of the material will be compelling and potentially useful to the public. For years quality advocates have lamented the relatively small impact that "quality report cards" appear to have on patients' choices of health care providers and institutions. One study demonstrated that patients were more likely to respond to a newspaper report of an egregious error than such quality report cards.[31] These data indicate that patients may be interested in knowing whether their institutions, providers, and health plans are proactive in implementing practices that demonstrably decrease the risk of adverse events. Also, any general reader is likely to come away from this Report with heightened sensitivity to the unique challenges that the health care industry—which aims to provide compassionate, individualized care in a dynamic, organizationally and politically complex, and technologically fluid environment—faces in improving safety, and the significant strides that have already been made. Continued improvement will require the infusion of substantial resources, and the public debate about their source, quantity, and target is likely to be lively and very important.

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- **John W. Gosbee, MD, MS**, Director of Patient Safety Information Systems, Department of Veterans Affairs National Center for Patient Safety
- **Peter V. Lee, JD**, President and Chief Executive Officer, Pacific Business Group on Health
- **Arnold Milstein, MD, MPH**, Medical Director, Pacific Business Group on Health; National Health Care Thought Leader, William M. Mercer, Inc.
- **Karlene H. Roberts, PhD**, Professor, Walter A. Haas School of Business, University of California, Berkeley
- **Stephen M. Shortell, PhD**, Blue Cross of California Distinguished Professor of Health Policy and Management and Professor of Organization Behavior, University of California, Berkeley

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