Technical Review

Number 9

Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies

Volume 1—Series Overview and Methodology

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-02-0017

Prepared by:
Stanford–UCSF Evidence-based Practice Center

Kaveh G. Shojania, M.D.
Kathryn M. McDonald, M.M.
Robert M. Wachter, M.D.
Douglas K. Owens, M.D., M.S.
Series Editors

Amy J. Markowitz, J.D.
Managing Editor

AHRQ Publication No. 04-0051-1
August 2004

Suggested Citation:

Shojania KG, McDonald KM, Wachter RM, Owens DK. Closing The Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 1—Series Overview and Methodology. Technical Review 9 (Contract No. 290-02-0017 to the Stanford University–UCSF Evidence-based Practices Center). AHRQ Publication No. 04-0051-1. Rockville, MD: Agency for Healthcare Research and Quality. August 2004.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report, *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies,* was requested and funded by the Agency for Healthcare Research and Quality. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean R. Slutsky, P.A., M.S.P.H.
Acting Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Acknowledgments

During the preparation of the series volumes, Dr. Owens, Dr. Goldstein, and Dr. Nayak were supported by the Department of Veterans Affairs.

We are grateful to our many technical experts and content reviewers for their uniformly thoughtful comments.

We give special thanks to our panel of technical advisors: Jeremy Grimshaw, MBChB, PhD, University of Ottawa, Cochrane Collaboration Effective Practice and Organisation of Care Group (EPOC); Andrew Oxman, MD, MSc, Department of Health Services Research, Norwegian Directorate for Health and Social Welfare, EPOC; Russell Glasgow, PhD, Kaiser Permanente, Colorado; Martin Eccles, MD, Centre for Health Services Research, University of Newcastle upon Tyne, EPOC; Harmon Jordan, ScD, New England Medical Center Evidence-based Practice Center; and Val Lawrence, MD, MSc, The University of Texas Health Science Center at San Antonio and South Texas Veterans Health Care System; whose attentive guidance from the beginning of the project was critical to the development of the methodology and structure for the series, and who were unstinting with their assistance under unusually tight time constraints.

We are grateful to our panel of peer reviewers: Karen Adams, Institute of Medicine; Dale Bratzler, DO, MPH, Oklahoma Foundation for Medical Quality, Inc.; Lee Green, MD, MPH, University of Michigan; Norman Kaplan, MD, University of Texas, South Western Medical Center; Jerod Loeb, PhD, Joint Commission on Accreditation of Healthcare Organizations; Brian Mittman, PhD, Center for the Study of Healthcare Provider Behavior, VA Greater Los Angeles Health Care System; Peter Rudd, MD, Stanford University School of Medicine; William Rollow, MD, Centers for Medicare & Medicaid Services; Vincenza Snow, MD, American College of Physicians; William Caplan, MD, Kaiser Permanente, Patricia Barry, MD, MPH, Merck Institute of Aging and Health; Rodney Hornbake, MD, ProHealth Physicians MSO, Inc., Somerset Family Health Care; Marc Jaffe, MD, Kaiser Permanente Care Management Institute; Michelle Wong, MPH, MPP, Kaiser Permanente Care Management Institute; and Jim Zazzali, PhD, RAND Institute; who read early drafts of the chapters and provided timely and detailed comments.

We are extremely indebted to our colleagues who worked together to develop a common approach across the clinical topics. In particular, we thank Mary Goldstein, MD, MS, Judith Walsh, MD, MPH, and Sumant Ranji, MD for sharing the wisdom they gained in researching their own topics with each others' teams.

Finally, we extend our thanks to Donna Neumark, PhD for her help in reviewing articles; Alan Bostrom, PhD for statistical analyses support; and Allan Korn, MD, FACP, Blue Cross and Blue Shield Association for providing our team with important background information and contacts.

The views expressed are those of the authors, and not necessarily those of the Department of Veterans Affairs. The technical advisors and peer reviewers are not responsible for the accuracy of any of the content of this Volume.

Structured Abstract

Substantial evidence suggests that there is a wide gap between evidence-based best practices and those treatment practices actually used in day-to-day clinical medicine. To bring data to bear on this "quality gap" and the opportunities that exist to bridge it, the Agency for Healthcare Research and Quality (AHRQ) engaged the Stanford–UCSF Evidence-based Practice Center (EPC) to compile a critical analysis of the existing literature on quality improvement (QI) strategies for a selection of 20 disease and practice priorities identified in a 2003 Institute of Medicine report.

In Volume 1 of *Closing the Quality Gap*, we provide an overview of our methods and the theoretical underpinnings of the field, which we will rely on to review and analyze the literature on the quality gap in a number of the IOM-identified priority areas that will appear in subsequent volumes. We describe the genesis of the quality implementation field, providing some historical perspective on the science of translating research into practice. We then set forth our methodology: our reviews generally are restricted to studies that are likely to have strong validity (randomized controlled trials, well controlled before–after studies, and interrupted time series studies). To ensure consistency across our reviews, we introduce a taxonomy for nine QI strategies (provider reminder systems; facilitated relay of clinical data to providers; audit and feedback; provider education; patient education; promotion of self-management; patient reminders; organizational change; and financial, regulatory, or legislative incentives).

We hope the volumes in this series will be an essential source of accessible and critical analyses of the evidence regarding QI strategies that can help close the quality gap.

This page intentionally left blank

Contents

Appendixes

Summary

In early 2003, the Institute of Medicine (IOM) released its report, *Priority Areas for National Action: Transforming Health Care Quality*. The report listed 20 clinical topics for which "best practices" were strongly supported by clinical evidence. The rates at which these practices have been implemented in the United States has been disappointing low, at a cost of many thousands of lives each year.

To bring data to bear on the quality improvement opportunities articulated in the IOM's 2003 report, the Agency for Healthcare Research and Quality (AHRQ) engaged the Stanford–UCSF Evidence-based Practice Center (EPC) to perform a critical analysis of the existing literature on quality improvement strategies for a selection of the 20 disease and practice priorities noted in the IOM Report. The focus of the commissioned investigations is translating research into practice–identifying those activities that *increase the rate with which practices known to be effective are applied to patient care* in real world settings. In other words, the EPC research effort aims to facilitate narrowing the "quality gap" that is in large part responsible for suboptimal health care practices and outcomes. In addition to furthering the IOM's quality agenda, this analysis also has been prepared in support of the National Healthcare Quality Report (NHQR) (also see *National Healthcare Disparities Report)*. In this, the first volume of *Closing the Quality Gap*, the authors introduce the series and its goal, while providing methodological and theoretical overviews for the quality improvement (QI) field of study. Subsequent volumes will address the relation of QI strategies to treatment practices for a number of the 20 priority areas identified in the IOM report.

Target Audiences

Closing the Quality Gap is intended to assist a wide range of users:

- Policymakers can use the detailed evidence review to prioritize quality improvement strategies and choose how best to close the quality gaps in their organizations.
- Researchers can find detailed information about well-scrutinized areas of treatment, while learning of other areas in need of further exploration.
- Clinicians and trainees can see a broad spectrum of approaches to improving the quality of care. Some of these approaches fall within the control of individual practitioners, while others will require major systemic changes at the local level or beyond.
- Patients can learn quality improvement strategies that they can help to promote, while gaining a deeper understanding of the nature and extent of quality gaps, as well as the systemic changes necessary to close them.
- Groups and individuals charged with funding research will be able to identify high-yield areas of concern that warrant future research support.

Volume 1 consists of three chapters:

Chapter 1—reviews the genesis of the quality implementation field, providing some historical perspective on the science of translating research into practice.

Chapter 2—sets forth the carefully designed methodology used to review the vast amount of existing quality literature on particular diseases. The methodology is the result of collaborative efforts of the editorial team, in consultation with several of the undisputed experts in the field. For this project, the following terms were defined:

Quality of health care: The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Quality gap: The difference between health care processes or outcomes observed in practice, and those potentially obtainable on the basis of current professional knowledge. The difference must be attributable in whole or in part to a deficiency that could be addressed by the health care system.

Quality improvement target: The outcome, process, or structure that the QI strategy aims to influence, with the goal of reducing the quality gap.

To ensure consistency in the review and evaluation of the literature, the editors developed a taxonomy of interventions that modifies several well-established classification systems, denominating the QI strategies as follows:

1. Provider reminder systems
2. Facilitated relay of clinical data to providers
3. Audit and feedback
4. Provider education
5. Patient education
6. Promotion of self-management
7. Patient reminder systems
8. Organizational change
9. Financial, regulatory or legislative incentives

Chapter 3—provides the reader some context for the field of QI implementation with a summary of the theoretic underpinnings that may influence the development of QI interventions, and an overview of selective efforts that have been made to adopt and modify interventions from outside of health care. The authors review a selection of the major theories that may influence the two dominant and parallel tracks of QI interventions: behavioral change and transfer or diffusion of knowledge. References to a number of pertinent theoretical models are cited.

What Conclusions can be Drawn from the Report's Evidence?

The purpose of this report is to help readers assess whether the evidence suggests that a quality improvement strategy would work in their specific practice setting or with their specific patient population. Three important questions should be considered:

1. Are the studies of the strategy valid? A study has validity (sometimes called "internal validity") if its findings are likely to be true in the population in which the study was performed. The primary determinant of validity is the design and conduct of the study.

2. For each quality improvement strategy that has been evaluated in multiple studies with sufficient validity, does the weight of evidence indicate that the strategy is effective?
3. Can the conclusions of a body of evidence be applied to a specific practice setting or population of interest?

Except where noted, the review is restricted to studies that are likely to have strong validity, (e.g., randomized controlled trials, well-designed and controlled before-after studies, and interrupted time series studies). The authors thought it important to find and analyze studies whose research methodologies were most likely to provide scientifically correct answers. When the same QI strategies have been evaluated in more than one study, assessing the weight of the evidence and whether it favors the strategy can be a complex matter. To help readers make this assessment, the findings of studies are summarized in tables showing the range of results for different strategies.

Remarkably, despite the vast stakes—after all, the concern here is identifying which techniques have been shown to promote the adoption of evidence-based "best practices"—there has been remarkably little information about the most effective ways to translate research into practice. Even in the case of common disorders such as diabetes, hypertension, and cancer care—areas in which research *has* demonstrated some best practices that can save tens of thousands of lives—there has been only modest systematic study of the techniques and strategies that most successfully close the quality gap. Moreover, in the few areas that have benefited from such studies, little consideration has been given to how practices may be "crosscutting" (i.e., how a practice that closes the quality gap in asthma, might be applicable to congestive heart failure).

Closing the gaps will require new resources and focus from caregivers and institutions. Ultimately, pressure from patients (brought to bear through market choices, regulators, policymakers, or others) is crucial if we are to succeed.

It is AHRQ's hope that the *Closing the Quality Gap* series will become an essential source of accessible and critical analyses of the evidence supporting techniques for implementing state-of-the-art best practices, while stimulating ideas for ongoing quality improvement activity nationally, in individual health systems, and among individual caregivers.

This page intentionally left blank

Chapter 1. An Introduction to the Report

Robert M. Wachter, M.D.
University of California, San Francisco

Douglas K. Owens, M.D., M.S.
VA Palo Alto Health Care System
and Stanford University

The Genesis of *Closing the Quality Gap*

Knowing is not enough; we must apply.
Willing is not enough; we must do.
— Johann Wolfgang Von Goethe (1749-1832)

In early 2003, the Institute of Medicine (IOM) released its report, *Priority Areas for National Action: Transforming Health Care Quality*.[1] The report listed 20 clinical topics for which best practice treatment guidelines are strongly supported by clinical evidence. Unfortunately, the report and a substantial quantity of other scientific literature show best practice implementation rates in the United States have been disappointing low, and at an annual cost of many thousands of lives.

To bring data to bear on the quality improvement opportunities laid out in the IOM's 2003 report, the Agency for Healthcare Research and Quality (AHRQ) asked the Stanford–UCSF Evidence-based Practice Center (EPC) to perform a critical analysis of the existing literature on quality improvement strategies for a number of the 20 disease and treatment priorities noted in the IOM Report. Rather than concentrating on the specific clinical practices that appear to improve health outcomes, these analyses focus on the effort of translating research into practice–identifying those activities that *increase the rate at which effective practices are applied to patient care* in real world settings. The overarching goal is one of narrowing the quality gap that is largely responsible for suboptimal health care practices and outcomes. This work also supports the recently released *National Healthcare Quality Report* (NHQR)[2] —and its companion document, the *National Healthcare Disparities Report* (NHDR).[3] Based upon earlier recommendations of the IOM,[4] Congress called upon AHRQ to deliver an annual report on the state of health care in the United States. The NHQR is intended to corroborate or refute widespread concerns related to health care quality, to document whether health care quality is stable, improving, or declining over time, and to provide national benchmarks with which individual states, health plans, and providers may compare their relative performance.

This is the first volume in a series of reports intended to support these goals. A carefully designed methodology will be applied to the scientific literature for a number of medical conditions characterized by the IOM as high-level threats to health and longevity. It is AHRQ's hope that the series will stimulate ideas for ongoing quality improvement activity nationally, as well as in individual health systems and among individual caregivers.

Origins of the Quality Movement

Although humans have long been intrigued and moved by the complex science of healing others, the science of measuring and improving the quality of delivered care is a relatively recent undertaking. Boston surgeon Ernest A. Codman (1869–1940) began his "end results system" a century ago, to track surgical outcomes and to improve surgical practice.[5] Codman's work in this area ultimately led to the creation of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Despite Codman's pioneering work and several other individuals and organizations whose efforts extended through the middle of the 20th Century, the science of health care quality improvement truly took root only a generation ago. Several forces catalyzed this transformation. First, medicine transcended its status as an anecdotal, non-evidence-based enterprise to one in which good data led to the discovery of improved treatment practices. For example, in the mid-1960s, 100 clinical trials were published each year. Thirty years later, that number had grown to more than 10,000.[6,7]

Second, as the public's interest and investment in the "miracles" of modern medicine grew—particularly in high technology specialties such as cardiac surgery and transplantation—so, too, did the public's demand for greater provider accountability and positive patient outcomes. Although public awareness of patient safety and quality increased with the IOM's seminal publication in 2000 of *To Err is Human: Building a Safer Health Care System,*[8] and its broader, 2001 indictment of health care quality (*Crossing the Quality Chasm*[4]) the trend had already been established. In an increasingly consumerist society, people had become less inclined to simply trust that their caregivers would deliver the highest quality care. And the public's skepticism only grew with the cost-driven growth of managed care.

Third, the expense of medical technology and the highly trained personnel needed to deliver that technology required the expansion of third-party payment systems, many of which were employer-based. These costs became a disproportionately large part of annual operating budgets and so employers, accustomed to making purchasing decisions based on *value* (quality and cost), found themselves without any information from the quality dimension of this equation. Their unwillingness to take it on faith that medicine's "product" was of the highest quality only grew with the published evidence of huge regional variations in the numbers of common procedures (coronary bypass grafting, hysterectomies, trans-urethral prostate resections) that could not be explained by differences in patient populations nor justified by differences in outcomes.[9,10] Other studies showed unacceptably high rates of "inappropriate" surgical procedures such as carotid endarterectomy,[11] further fueling the skepticism regarding the quality of health care in America and increasing demands for accountability.[12-17]

These pressures were mounting during the same time that tools for measuring the quality of evidence supporting clinical practice, such as clinical epidemiology, decision- and cost-effectiveness-analysis, meta-analysis, and the like, were becoming more robust. Driven in part by sizable congressional allocations to the National Institutes of Health and by private investments on the part of pharmaceutical companies and others, the clinical research knowledge base grew as well. The use of computer-assisted health care management systems led to the creation of large databases that could be mined to provide information on the quality of care, as large and complex clinical trials became commonplace. Before long, specialties such as cardiology, for example, were transformed. Cardiologists witnessed a shift in the cultural context, their focus

drawn away from the art of medicine and redirected toward the dozens of regularly published clinical trials and emerging evidence on best practice treatments and heart disease prevention. The probability of an American death by heart disease fell by 56 percent between 1950 and 1996. Although many factors contributed to this decline, much of the success is attributable to advances in clinical care and medical science.[18]

By the mid-1990s, the powerful influences of clinical treatment information, skepticism of the medical community's ability to ensure high-quality health care, increased consumer and purchaser knowledge, and the science of quality measurement had come together. More and more studies revealed large gaps between the findings of scientific studies and their practical implementation, even in areas of medicine where the optimal clinical approach was assured. Several large and recent studies have confirmed sizable quality of care gaps in areas spanning preventive medicine, acute and chronic care, and care of elders.[19,20-22] These and other studies emphasized the notion that research into quality health care does not, in itself, ensure the clinical patient will receive the highest quality care. A new area of inquiry—how best to translate research into practice—was born.[23-26]

Translating Research into Practice: What do we Know?

There are many reasons for the gaps that exist between the best, evidence-based understanding of high quality treatment practices, and the actual practices themselves.

First, there may be a gap in the dissemination of knowledge. The large and growing number of clinical trials underway at any given time makes it impossible for any individual physician or system of care to stay fully abreast. There is an inevitable time lag between the publication of studies that demonstrate an effective practice and its implementation. There is sometimes a need for a consensus to emerge among specialists, or a diffusion from specialists to generalists. For example, a 1994 study by Ayanian showed that cardiologists were about 10 absolute percentage points more likely to prescribe therapies known to be effective, and less likely (by roughly the same margin) to prescribe ineffective therapy, than were their generalist peers.[27] Similar lags have been demonstrated in the management of a variety of conditions,[28] ranging from peptic ulcer disease[29] to heart failure.[30]

Second, providers may be aware of a best practice, but fail to implement it because of skepticism surrounding the cost effectiveness of the practice (in terms of dollars or time needed to educate patients or adapt work processes). Or, they may have reservations regarding their treatment environment and the systems support (people or equipment) or changes in organizational culture needed to implement the practice. For example, new recommendations designed to provide improved glucose control in ICU patients[31] would mandate an increase in ICU nurse staffing to facilitate more frequent blood glucose checks. The director of critical care services at the University of California, San Francisco estimates that such increased monitoring would consume an additional 2 hours per ICU nurse shift for a typical nurse caring for two patients (Michael Gropper, MD, personal communication, 2003). Not surprisingly, many ICUs have yet to adopt this practice, despite clear and compelling evidence of the clinical benefits.

Finally, while the treatment practice may have been proven effective in a special research setting, it may not be applicable to an individual provider's setting. Clinical trials differ in many ways from real-life practice: staff members are attentive to the research protocols, personnel with specialized training may have been hired to provide additional support or patient education,

patient selection may be related to the research protocol, and additional safety measures may be built into the trial. In addition, research studies are often carried out in specialized settings (e.g., a Veterans Affairs hospital or a large academic medical center) that may bear little resemblance to the smaller treatment setting of a physician considering the practice. This gap between efficacy (how well the practice works in the research environment) and effectiveness (how well it works in clinical practice–generalized to include a wide range of treatment settings, with providers who may not be committed to or expert in its application, and a broader array of patients) has been well appreciated in recent years.[12-17]

As the quality gap has become more widely acknowledged, investigators have focused on its genesis and possible strategies for closing it. In one early analysis, Greco and Eisenberg[32] described six possible interventions to improve uptake (adoption) of improved treatment practices: education, feedback, participation by physicians in efforts to bring about change, administrative rules, financial incentives, and financial penalties.

In addition to those interventions that focus largely on the clinical behavior of individual providers (mostly physicians), more attention is being given to systematic changes in the practice environment, some of which (e.g., computerized rules and checklists, automatic stop orders) may bypass physicians entirely. A parallel movement is focusing on patients as the guardians of their own health care quality. One example cited frequently in the realm of patient safety involves patients asking their providers if they had washed their hands prior to the patient encounter.[33]

Whatever the method used to achieve the desired change, there is little doubt that the movement to base accountability and competition on metrics of quality has just begun. Business coalitions including the Pacific Business Group on Health and the Leapfrog Group are partnering with accreditation groups such as JCAHO to develop new quality-of-care standards. These standards will be made available to the public and can be used as the foundation for purchasing or payment decisions. The National Committee for Quality Assurance (NCQA) publishes its own "Report Card" for use by government agencies, employers, and consumers. Although the evidence regarding report card documents and their ability to characterize and improve overall health care quality is decidedly mixed,[34-38] public reporting and the desire to avoid negative publicity has made certain hospitals and providers eager to receive good "grades." As the case for improved quality in health care grows, so too does the realization that the best way to improve patient outcomes is a strict adherence to well-researched and respected quality improvement practices–to translate research into practice.

The Theoretic Underpinnings of Quality Improvement Efforts

Medicine has a long history of investigating what works in the clinical realm, and why. At the same time, we have a fairly limited understanding of the causal mechanisms of interventions to improve health care quality. Theories abound with regard to changing the behavior of patients, clinicians, and organizations for the better. These theories often are drawn from studies that try to isolate the effect of a single varied element or combinations of setting, interventions, and targets for change. The challenge for researchers rests in the accurate interpretation of this diverse literature regarding implementation.

In an effort to provide the reader with some context relative to the field of quality improvement (QI) implementation, this report offers a brief summary of the theoretical underpinnings that influence the development of QI interventions, as well as identifying selective

efforts that have been made to adopt and modify interventions from outside of health care. Readers interested in QI theory discussions of greater depth are encouraged to spend some time with Chapter 3, which reviews a selection of the major theories thought to influence the two dominant and parallel tracks of QI interventions: behavioral change, and the transfer or diffusion of knowledge. References to a number of pertinent theoretical models also are provided in this chapter.

An overarching theory for closing the quality gap may be neither feasible, nor desirable. Existing theories, including those from disciplines outside of health care, however, may be marshaled to design interventions for health care protocols in need of modification. Such theories have been applied in many ways—often borrowing techniques from industry such as those promoted by Juran and Deming[39-43] —with varying degrees of success. The methods generally emphasize 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.

The mixed results produced by industry-oriented quality improvement programs (such as Total Quality Management [TQM] and Continuous Quality Improvement [CQI]) have taught managers and others the need to exercise caution before assuming that strategies drawn from other industries automatically will work in health care settings, and demonstrated that additional attention that must be given to the forces that promote desired behavioral changes among front-line workers.[44-46] These forces are an outgrowth of human needs and desires: the altruism of most health care professionals, their desire for success and peer respect, their preference for avoiding embarrassment, and the goal of financial independence, to name but a few. These inspirations have prompted a more recent movement, in which the traditional quality improvement sensibilities of programs such as TQM or CQI are coupled with more modern approaches to behavior modification, such as performance auditing and feedback. An audit often will measure provider adherence to a specific process or treatment practice, and the providers being studied will receive comparative data after the fact about their performance and how they stack up against their peers. In other types of audits, providers might receive financial rewards for their strict adherence to desired behaviors, or information regarding their performance and standing might be forwarded on to their patients (who can influence non-conforming providers to make the appropriate behavioral change, or choose to seek care elsewhere).

Remarkably, considering the enormous stakes, there has been little information written about the most effective ways to translate research into practice. Even for common disorders like diabetes, hypertension, and cancer care—areas in which research has successfully demonstrated that some best practices can save tens of thousands of lives—there has been only modest systematic study of the techniques and strategies shown to close the quality gap. Moreover, in those few areas that have benefited from such studies, little consideration has been given to crosscutting practices (i.e., how a practice that closes the quality gap in asthma, might be applicable to congestive heart failure).

What Conclusions can be Drawn from the Report's Evidence?

This report is intended to help readers assess whether the available evidence suggests that a quality improvement strategy would work in their specific practice setting, or, within their specific patient population. Three important questions should be considered:

1. Are the studies of the strategy *valid*? A study has validity (sometimes called *internal validity*) if its findings are likely to be true in the population on which the study was based. The primary determinant of validity is the design and conduct of the study.
2. For the quality improvement strategies that have been evaluated in multiple studies with sufficient validity, does the evidence indicate that the strategy is *effective*?
3. Are the conclusions of a body of evidence applicable to a practice setting or population of interest?

Careful attention has been paid to the design of each included study (Chapter 2), as a means of assisting readers to better judge study validity. Except where noted, the review has been restricted to studies that are likely to have strong validity, i.e., randomized controlled trials, well controlled before–after studies, and interrupted-time-series studies. This has been done to acknowledge an important tension in the field of quality improvement. Given the challenges and constraints of studying change in complex organizations, some authorities consider some of the most relevant QI work to be that performed "in the trenches," by front-line workers taking advantage of available resources to answer important, practical questions using simple designs (e.g., uncontrolled before-and-after studies). This point of view has relevance. However, in a report of this type, the authors placed a priority on finding and analyzing those studies with research methodologies most likely to give scientifically correct answers: randomized controlled studies, controlled before-and-after studies, and interrupted-time-series studies. They did so with the recognition that the relatively strict criteria may have led to the exclusion of some studies with potentially relevant findings.

When specific QI strategies have been evaluated in the course of multiple studies, deciding if the weight of the evidence favors the strategy can be a complex decision. To help readers make this assessment, the authors have used tables to indicate the range of results for different strategies. In those instances where studies were sufficiently similar in their design and sample size to justify combining the results, the authors used quantitative methods of analysis to synthesize their findings. When it was judged imprudent to combine studies quantitatively, the researchers made every attempt to highlight important findings and, when possible, they noted whether the findings are consistent across studies. The methods used in the course of these analyses are described in greater detail in Chapter 2.

Perhaps the most difficult challenge facing the authors of this report and its readers concerns the applicability of a study's results to a particular treatment setting or a patient population other than that used in the study itself. Studies vary in terms of the disease process considered, the population sample, the type of quality improvement intervention scrutinized, the behavior addressed by the intervention, and the time frame of the study. Each of these factors affects the applicability (sometimes called "generalizability") of the study. For example, if a study showed that audit and feedback improved prescribing practices for hypertension in a managed care treatment setting, would these findings hold true in a fee-for-service practice? Would they hold

true for diabetes care? If audit and feedback was effective in a general medicine clinic, would the same improvement strategy prove equally effective for a specialty clinic?

Caution is warranted with respect to any study's results and their applicability across settings or diseases, as the specific conditions of any user's practice are certain to differ from those of the study population. The factors with the greatest effect on the applicability of study findings are not yet known, but the final evidence report of the series will describe the EPC's findings and experience in the hope that the reader will be able to evaluate any common findings across different disease processes.

The Organizational Framework of this Series

Volume 1 contains this introduction to the series, the evidence-based methodology that unifies and underlies each of the treatment condition reports in the series (Chapter 2), and the theories thought to influence QI and implementation (Chapter 3).

Volumes 2 and 3 will review the evidence regarding the effectiveness of QI implementation practices in the treatment of diabetes and hypertension, respectively. These volumes, and those to follow, will feature the same detailed organizational framework:

Introduction – The authors identify the general background and clinical context for the disease or condition, they illustrate the primary quality gap(s) for the topic, and provide a means of benchmarking outcomes for these problems. The best treatment practices also are provided, as are the strategies for quality improvement.

Methodology – The scope of material reviewed for the topic is delimited, noting studies that have been excluded, and specifying the primary outcomes of interest. Some information pertaining to the methodologic process and analysis appears in the Methods section of Volume 1 as well as in Volume 2 (Diabetes) and Volume 3 (Hypertension). This redundancy was planned for the reader's convenience, since each of the volumes dealing with priority conditions may be read as a stand-alone analysis.

Findings Overview – A summary of the reviewed literature is provided, along with two separate analyses: one delineated by outcome and one by quality improvement strategy. An Appendix for each volume provides tables of included studies and results.

Discussion – An analysis will be included for each of the studied priority conditions, with a list of the strategies best supported by the available evidence, as well as obvious gaps and suggestions for future research.

Subsequent volumes in the series, to be produced over the next two years, will consider the evidence behind QI practices for a select number of conditions from the IOM's 2003 quality report. Evidence for the impact of individual QI practices in specific diseases or care settings will be considered in condition- or setting-specific volumes. Global analysis of the QI practices across diseases or settings will likely be addressed in the final volume in the series. The last volume also may be used to describe broad themes that emerge from the project. Finally, attempts will be made to quantify and prioritize the benefits of the various QI strategies, to the extent that the published evidence permits.

This page intentionally left blank

Chapter 2. Evidence-based Review Methodology for the *Closing the Quality Gap* Series

Kaveh G. Shojania, M.D.
University of California, San Francisco

Kathryn M. McDonald, M.M.
Stanford University

Douglas K. Owens, M.D., M.S.
VA Palo Alto Health Care System
and Stanford University

Definition and Scope

The Stanford University–UCSF Evidence-based Practice Center (EPC) performed a comprehensive review of the evidence relating to a broad range of quality improvement (QI) strategies and their utility in a variety of clinical areas. The topic areas were chosen from a group of 20 priority conditions identified by the IOM[1] (see Appendix A). For this project, the authors defined the following terms:

Quality of health care: The degree to which health services for individuals and patient populations increase the likelihood of desirable health outcomes and are consistent with current professional knowledge.[47]

Quality gap: The difference between health care processes or outcomes observed in practice, and those thought to be achievable with the most current and effective professional knowledge. The difference must be attributable in whole or in part to a deficiency that could be addressed by the health care system. An example of a process-level quality gap for hypertension involves the 62 percent of clinical visits during which physicians failed to introduce evidence-based, guideline-concordant drug therapy to patients with a systolic blood pressure of 140mm/HG or higher.[48]

An example of an outcome-level quality gap for myocardial infarctions involves a disparity in survival rates. Despite numerous new therapies that have substantially decreased mortality over the past 25 years, survival gains have occurred mainly in males and in younger patients, with less gain in women and the elderly.[49] The resolution of such outcome gaps generally entails detailed analyses of relevant treatment and care processes, in an effort to explain their genesis and identify targets for action.

Quality improvement (QI) strategy: Any intervention aimed at reducing the quality gap for a group of patients representative of those encountered in routine practice. For the purposes of their literature search, the authors considered a study to include a QI strategy evaluation if any of the following applied:

- The intervention targeted implementation of a particular process of care (or set of processes) believed to benefit patients with the priority condition(s); i.e., interventions

designed to improve provider adherence to a clinical best practice guideline, or those intended to increase the proportion of patients who received recommended care.

- The intervention targeted implementation of a structural or organizational feature believed to benefit patients with the priority condition; i.e., interventions that changed the care provider, added supplemental personnel, or made clinical information systems part of the treatment protocol.
- The intervention attempted to improve outcomes for a broad and relatively unselected group of patients with the priority condition; i.e., interventions designed to improve the delivery of care for all patients with diabetes or hypertension at a specific clinic.
- The intervention targeted a subset of patients that typically is excluded from clinical research; i.e., frail elders, minorities, the economically disadvantaged, or those with multiple comorbid conditions.
- The intervention involved any of the specific QI strategies falling within a taxonomy of approaches to QI that the authors developed, based on evaluations of various quality improvement interventions[50-59] and authoritative definitions[60] (see below for taxonomy).

Quality improvement target: The outcome, process, or structure that the QI strategy is intended to influence, with the goal of reducing the quality gap. A target typically would be a measure of disease control, including direct health outcomes (morbidity or mortality), or intermediate outcomes proven to influence direct outcomes (such as blood pressure or hemoglobin A_{1C} control). Targets also may involve adherence to accepted processes of care, either by clinicians (i.e., guideline recommendations and performance measures) or by patients (i.e., adherence to prescribed medications, recommended self-management).

Taxonomy of Quality Improvement Strategies

To ensure consistency in their review and evaluation of the literature, the authors developed a taxonomy that modifies several well-established classification systems.[50-54] A recent and systematic review of disease management studies combined QI strategies and targets, classifying interventions as: provider education, provider feedback, provider reminders, patient education, patient reminders, and patient financial incentives.[54] The Cochrane EPOC data collection instrument uses four broad classifications (professional interventions, organizational interventions, financial interventions, and regulatory interventions), each of which has detailed subcategories. An alternative taxonomy, described in a recent systematic review of interventions to promote immunization and cancer screening,[52] specifies three dimensions for characterizing QI strategies – the *type* of QI strategy (e.g., education, audit and feedback, organizational changes, financial incentives), *mediators* of the intervention (e.g., use of local opinion leaders, involvement of top management, identification of barriers to change), and *target audience* (e.g., patients, providers, health care delivery systems). The authors of this series modified the various taxonomies to better facilitate their review of the evidence.

Types of QI Strategies

Nine types of QI strategies are outlined below, along with key substrategies. These categories are broad, and, in some cases, combine multiple interventions. The authors explored this heterogeneity in their analyses to assess the possibility of making inferences and judgments about the success of the strategy as a whole, or whether further subdivision would be needed.

Where relevant, the analyses also take into consideration the fact that many interventions are multifaceted and employ more than one type of QI strategy.

1. **Provider reminder systems**—the investigators defined a reminder system as any patient- or clinical encounter-specific information, provided verbally, in writing, or by computer, to prompt a clinician to recall information, or intended to prompt consideration of a specific process of care (i.e., "This patient last underwent screening mammography 3 years ago"). The reminder also may include information prompting the clinician to follow evidence-based care recommendations (e.g., to make medication adjustments, or to order appropriate screening tests). The phrase "clinical encounter-specific" in the definition serves to distinguish reminder systems from audit and feedback, where clinicians typically receive performance summaries relative to a process or outcome of care spanning multiple encounters (e.g., all Type 2 diabetic patients seen by the clinician during the past 6 months).

2. **Facilitated relay of clinical data to providers**—used to describe the transfer of clinical information collected directly from patients and relayed to the provider, in instances where the data are not generally collected during a patient visit, or using some format other than the existing local medical record system (i.e., the telephone transmission of a patient's blood pressure measurements, from a specialist's office). The EPOC group uses the term "patient mediated" to describe such interventions, but the authors regard the above label as more descriptive. Some overlap with provider reminder systems was expected, but the strategies were kept separate at the abstraction stage. This decision allowed for the possibility that the data could be subsequently analyzed with and without collapsing the two strategies.

3. **Audit and feedback**—the researchers defined audit and feedback as any summary of clinical performance for health care providers or institutions, performed for a specific period of time and reported either publicly or confidentially to the clinician or institution (e.g., the percentage of a provider's patients who achieved or did not achieve some clinical target, such as blood pressure or HbA_{1c} control over a certain period). Benchmarking is a term referring to the provision of performance data from institutions or providers regarded as leaders in the field. These data serve as performance targets for other providers and institutions. The authors included benchmarking as a type of audit and feedback, so long as local data were provided for comparison with the benchmark data.

4. **Provider education**—used to describe a variety of interventions including educational workshops, meetings (e.g., traditional Continuing Medical Education [CME]), lectures (in person or computer-based), educational outreach visits (by a trained representative who meets with providers in their practice settings to disseminate information with the intent of changing the providers' practice). The same term also is used to describe the distribution of educational materials (electronically published or printed clinical practice guidelines and audio-visual materials). The investigators further captured information about the intensity (i.e., duration and number of educational sessions) and format (i.e., lectures delivered live, via teleconference, or pre-recorded) in a free-text mode, for each of these substrategies. Early plans to capture these and other predictors in a structured form were abandoned after the authors and their technical advisors agreed the judgments

were too subjective. This was due in large part to a relative lack of detail surrounding the interventions in the vast majority of studies.

5. **Patient education**—this strategy is centered on in-person patient education, either individually or as part of a group or community, and through the introduction of print or audio-visual educational materials. Patient education may be the sole component of a particular quality improvement strategy, or it can be one part of a multifaceted QI strategy. It should be noted that the authors evaluated only those strategies in which patient education was regarded as one component of a multifaceted strategy. A future volume in this series may address the topic of patient education as a singular intervention, along with its relative effects on a variety of chronic diseases.

6. **Promotion of self-management**—this strategy includes the distribution of materials (i.e., devices for blood pressure or glucose self-monitoring) or access to a resource that enhances the patients' ability to manage their condition, the communication of useful clinical data to the patient (e.g., most recent HbA_{1c} or lipid panel levels), or followup phone calls from the provider to the patient, with recommended adjustments to care. The authors expected some overlap with regard to patient education (strategy 5) and patient reminders (strategy 7). They elected to keep the strategies separate at the abstraction stage, to allow for the possibility that the data could be analyzed after the fact, with and without collapsing the two strategies.

7. **Patient reminders**—used to define any effort directed by providers toward patients that encourages them to keep appointments or adhere to other aspects of the self-management of their condition.

8. **Organizational change**—this strategy included any intervention having features consistent with at least one of the following descriptions, each of which represents a substrategy of organizational change that was abstracted for incorporation in the analysis:
   a) Disease management or case management – the coordination of assessment, treatment, and referrals by a person or multidisciplinary team in collaboration with, or supplementary to, the primary care provider.
   b) Team or personnel changes – adding new members to a treatment team (e.g., the addition of a diabetes nurse, a clinical pharmacist, or a nutritionist to a clinical practice), creating multidisciplinary teams within a practice, or revising the roles of existing team members (e.g., a clinic nurse is given a more active role in patient management), or the simple addition of more nurses, pharmacists, or physicians to a clinical setting.
   c) Communications, case discussions, and the exchange of treatment information between distant health professionals (i.e., telemedicine).
   d) Total Quality Management (TQM) or Continuous Quality Improvement (CQI) techniques for measuring quality problems, designing interventions and their implementation, along with process re-measurements.
   e) Changes in medical records systems—adopting improved office technology (e.g., computer-based records, patient tracking systems).

Although the definition used for this strategy is consistent with prior reviews,[52] the authors recognized the potential heterogeneity of included interventions and accordingly planned to analyze this strategy with respect to the aforementioned substrategies.

9. **Financial, regulatory or legislative incentives—**this strategy encompassed any intervention having features consistent with at least one of the following descriptions:
   a) Positive or negative financial incentives directed at providers (e.g., regarding adherence to some process of care or achievement of target patient outcome).
   b) Positive or negative financial incentives directed at patients.
   c) System-wide changes in reimbursement (e.g., capitation, prospective payment, shift from fee-for-service to salary).
   d) Changes to provider licensure requirements.
   e) Changes to institutional accreditation requirements.

The authors further abstracted information about the use of clinical information systems, including their role in identifying eligible study participants for QI interventions, for generating clinical reminders, for enabling decision support, and their ability to cultivate data for audit and feedback.

Table 1 presents the major types of QI strategies in the first column, with examples of corresponding substrategies in the second column. The table illustrates the manner in which some QI strategies and substrategies target a single audience, while others attempt to influence multiple audiences, such as patients and health care delivery systems. Many QI strategies evaluated in the literature combine substrategies and audience targets, a situation that makes for challenging analyses of effectiveness. Such combinations often limit the ability of researchers to interpret the active component(s) of a particular intervention.

Table 1. Taxonomy of QI 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
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

QI strategy	Examples
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
Promotion of self-management	• Materials and devices promoting self-management
Patient reminder systems	• 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:* • Co-payments 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)

Identification of Quality Improvement Strategies for Evaluation

The medical conditions selected for evaluation were taken from the IOM National Priorities report,[1] and were based on the priorities of stakeholders, the quality of evidence in relation to the usefulness of QI strategies, the expertise of the EPC, and available resources. As described in the Introduction to this volume, the selected topics will be analyzed in a series of volumes to be published over the course of the next two years. The final volume may be used to examine crosscutting analyses of selected QI strategies for many of the disease topics presented in the series.

Search Strategy

The authors initially reviewed QI strategies for hypertension and diabetes to help formulate their methodologic approach. They searched the MEDLINE® database from 1980-present, the Cochrane databases, and the Cochrane registry for the selected topics. The general search strategy was consistent across these two topics. Appendix B illustrates the search strings for hypertension. They searched terms relevant to care coordination and disease management, quality improvement (including Total Quality Management and Continuous Quality Improvement), continuing medical education, educational outreach, audit and feedback, financial incentives, information technologies, telemedicine, and the specific condition under consideration (e.g., hypertension). Additional searches were undertaken for systematic reviews and manual searches also were done, when appropriate, for relevant references. The bibliographies of all articles that met final inclusion criteria were scanned by hand for the project, as were the bibliographies for all relevant systematic reviews and meta-analyses. In cases where no systematic review was found to exist for a given topic, the authors searched the bibliographies of traditional (narrative) review articles, editorials, and news items that appeared to describe QI studies involving outpatient diabetic care.

These searches were supplemented with reviews of citations from the Cochrane EPOC registry of quality improvement strategies. Each of the Collaborative Review Groups within the Cochrane Collaboration works to prepare and maintain systematic reviews of the prevention, treatment, and rehabilitation of a particular health problem or groups of problems, known as the 'scope' of the group. EPOC's mandate is the systematic review of educational, behavioral, financial, organizational, and regulatory interventions designed to improve health professional practice and the organization of health care services, using the most statistically reliable methods, and across all clinical areas.

The EPOC registry has been developed using a highly sensitive search strategy to identify studies within EPOC's scope. The registry is updated quarterly and is derived from a search of more than 200,000 citations in the MEDLINE, EMBASE®, and CINAHL® databases, last updated prior to this report on June 14, 2003, August 6, 2002, and May 28, 2003, respectively. As of this writing, the registry contains approximately 2,500 studies, with another 3,000 studies pending full text assessment. The registry includes the full bibliographic reference (including MEDLINE index terms) and details the type of study, interventions considered, and targeted behavior. With the assistance of EPOC, the authors developed searches within the registry using the applicable clinical area MESH terms.

This approach differs from EPOC in one significant respect: it is EPOC policy to exclude interventions that do not involve provider or organizational change (e.g., patient education, self-management, and behavior change). In part because of this difference in scope, the authors conducted independent MEDLINE and hand searches for the first two priority conditions: diabetes and hypertension.

Inclusion and Exclusion Criteria

To begin, teams consisting of one or two senior reviewers (including an editor), trained two or more junior reviewers (junior faculty, fellows, and research assistants) to perform literature searches, conduct content reviews, and abstract data. The searches undertaken by these individuals revealed several thousand abstract titles for each priority condition. Stage 1 centered on the triage process for the article titles and/or abstracts (see Appendix C—triage forms), to determine if an article described an actual QI strategy. At this stage of the review process, randomized controlled trials, quasi-randomized trials, controlled before–after studies, interrupted time series, and before–after comparisons all were considered evaluations. A senior reviewer confirmed exclusion decisions using a random sample of 500 citations from the articles excluded at Stage 1–roughly a 20% sample. If the exclusion sample revealed any articles that should have been passed on for a full-text review, all the excluded citations were re-reviewed. The investigators included studies that examined the use of single or multiple QI strategies, with one exception: studies that used only patient education interventions were excluded because these studies likely will become the focus of a subsequent review. Studies were identified as relevant to quality improvement for this project if any one of the following applied:

1. The intervention was designed to increase the proportion of patients receiving recommended processes of care (e.g., those demonstrated to improve outcomes for patients with the condition of interest), including aspects of diagnosis and screening, therapeutic interventions, and patient education or counseling.

2. The intervention implemented organizational or structural features likely to benefit patients with the condition of interest.

3. The intervention attempted to improve outcomes for a broad and relatively unselected group of patients with the condition(s) of interest [e.g., "all patients with diabetes (or asthma, hypertension, etc.] who receive care at a clinic").

4. The intervention targeted a subset of patients that is typically excluded from clinical research (i.e., frail elderly, minorities, homeless).

5. The intervention involved any of the specific QI strategies or sub-strategies noted in Table 1: provider reminder systems, facilitated relay, audit and feedback, provider educational interventions, patient educational interventions, promotion of self-management, patient reminders, organizational change, and financial, regulatory, or legislative incentives and interventions.

The authors set out to assess QI strategy effectiveness. The inclusion/exclusion criteria did not consider whether there was an established evidence-based guideline for the priority condition being studied. Nor did they review the evidence for the underlying quality improvement target. For example, the reviewers did not attempt to correlate the evidence for tight blood pressure

control with improved diabetes outcomes. Rather, they examined the evidence for QI interventions that have a positive effect on blood pressure control.

In Stage 2, a senior reviewer reconfirmed the description of a QI strategy in each included report and identified the study design (see Appendix C—triage forms). Determinations were made with regard to the study designs suitable for Stage 3 abstraction, based on the availability of the highest quality studies for that priority condition. Any study that was not excluded in Stage 2, on the basis of the title or abstract, was advanced to Stage 3 and a full text review.

In fact, the articles that remained part of the study at Stage 3 were scrutinized independently by two reviewers. Each reviewer abstracted information from the complete article about the QI strategy employed, the study design, and the outcomes evaluated (see Appendix D—Stage 3 abstraction forms). The forms used for the abstractions were tailored to each of the priority conditions, while still containing some common elements. Given the data available in the published literature, an emphasis was placed on information relevant to the effectiveness of the strategy and the aspects of study design most pertinent to the applicability of the study. The goals of health care quality (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity), outlined in the IOM's Quality Chasm report[4], also served to guide the reviewers. Unfortunately, most of these dimensions generally are not reported in studies assessing the efficacy of quality improvement strategies. Comparative data has been included, where available.

The purpose of Stage 3 was to ensure the exclusion of articles that were deemed to be something other than evaluations of QI strategies, and to allow an assessment of the amount and types of evidence available for a given priority condition. This information guided decisions regarding the breadth of the analysis to be undertaken, and how best to create discrete substrategies for synthesis. Any conflicts that arose in Stage 3 were resolved by consensus opinion between a junior reviewer and a senior reviewer.

Once the study designs and QI strategies were identified for a specific priority condition, articles meeting these final criteria underwent Stage 4 review. A junior reviewer conducted a detailed abstraction of relevant data (e.g., patient population, QI strategy, outcomes) from all included articles within the defined scope (see Appendix D—Stage 4 abstraction forms). A senior reviewer further confirmed the accuracy of the data abstraction.

Types of Evidence Assessed in the Review

The highest quality evidence available was used to assess the value of the QI strategies. Each of the study designs for the different QI strategies was assessed with respect to the conditions under consideration (i.e., hypertension). The reviewers also assessed important features of study conduct and analysis including concealment of allocation, patient blinding, provider blinding, and the unit of analysis relation to the unit of randomization. The hierarchy of study designs in Table 2 was used to guide the selection of study types for detailed data abstraction. Randomized controlled trials were considered the most persuasive source of evidence and so were deemed Level 1. If there were few or no randomized trials for a given strategy, the researchers evaluated Level 2 studies. Additionally, Level 2 studies also were reviewed to determine if findings about QI strategies were consistent across different study designs. Upon completing their initial literature review for each priority condition, the authors determined if sufficient studies existed meeting either Level 1 or Level 2 criteria. If they did, no detailed review of the study designs was performed at Level 3 (see Table 2). This is because biases commonly appear in Level 3

studies that make interpretation difficult, despite any insights they might provide with regard to applicability (e.g., external validity). Level 4 evidence was excluded; as such, no uncontrolled studies were considered. The studies also were catagorized by types of outcomes measured. Studies that did not report any of the outcome types specified in Table 3 also were excluded.

Table 2. Hierarchy of study designs

Level 1. Randomized controlled trials

Level 2. Controlled Before–After (CBA)—contemporaneous observation periods for control and intervention groups before and after an intervention

Interrupted time series (ITS)—well-defined time period for intervention implementation and at least three time points both before and after intervention

Quasi-randomized trials—contained at least two cohorts of patients assembled prospectively based on an allocation procedure that was non-random, but arbitrary, in the sense of bearing no apparent connection to patient or provider factors that might affect intervention outcome (e.g. alternation, date of birth, even/odd character of provider or patient identification)

Level 3. Observational studies with controls—includes before-after and time series not meeting strict definitions of CBA and ITS (above), case–control studies, cohort studies with controls.

Level 4. Observational studies without controls (e.g., cohort studies without controls and case series)

Table 3. Outcomes relevant to inclusion criteria*

	Measures of Disease Identification	Measures of Disease Control	Measures of Provider Adherence	Measures of Patient Adherence
Included studies reported one of more of the outcomes presented here	Proportion of eligible patients receiving appropriate screening (i.e., blood pressure measurements, cancer screening)	Clinical outcomes Intermediate outcomes with established connections to clinical outcomes (e.g., HbA_{1c}, blood pressure, lipid levels)	Performance of specific processes of care with established connections to patient outcomes Adherence to well-recognized practice guidelines (e.g., from professional societies)	Biochemical assays (e.g., blood or urine drug levels, urine cotinine for smoking cessation) Pharmacy data (e.g., refilled prescriptions) Home or office pill counts Patient interviews

*Measures of provider knowledge, patient understanding, self-efficacy, or other intermediate outcomes were included only when they accompanied outcomes listed in the above table. For instance, a study reporting a measure of patient adherence with care as well as changes in patient understanding, self-efficacy, or empowerment would be included. Similarly, articles reporting only measures of satisfaction with care or resource use were not included unless they also reported measures of disease identification, disease control, or provider or patient adherence.

Evaluation of Quality Improvement Strategies

Most of the reported information addressed QI strategy effectiveness. There was a paucity of available data on the safety, equity, and applicability of the various approaches.

A number of factors may influence the success of a QI strategy. Table 4 summarizes many of these factors and organizes them into three categories. Relatively little information on the features of the QI target was obtainable, due to time restrictions. This is a potential limitation of the analysis. The authors have noted in the table those factors for which information was obtained, as well as those factors included in the synthesis.

Table 4. Features that may affect success of QI interventions

Features of the Study	Features of the QI Intervention	Features of the QI Target
Study setting √ Study period √ Country (√√ US vs. non-US) __ Financial/organizational structure of health care system √ Type of clinical setting (e.g., general vs. specialty clinic, community-based, work site intervention) √ patient population (e.g., specific disease being studied (diabetes vs. hypertension vs. asthma, etc.), early vs. advanced illness, significant comorbid conditions, underserved, poor adherence) √ magnitude of local quality gap *Study methodology* √√ Trial design (e.g., RCT, quasi-RCT, CBA, ITS)† √√ Concealment of allocation √√ Blinding (patients, providers) √√ Agreement in unit of randomization and unit of analysis	*Type of QI strategy* √√ Broad category of QI strategy (e.g., patient education, provide education, audit & feedback, etc.) √√ Number of QI strategies employed in the intervention * Intensity of QI strategy (e.g., number of educational sessions, frequency of audit & feedback cycles, extent of case management) __ Involvement of top management and other forms of institutional support * Format in which QI strategy delivered (e.g., face-to-face, dissemination of printed materials) √√ Use of an information system	*Content* __ Attitude of clinicians toward target (driven in turn by guideline complexity, evidence base, concordance with existing practice) __ Complexity of action required by provider (e.g., making a referral, ordering a test, adjustment of medication regimen, performing specific aspects of history or physical) __ Baseline level of adherence with target __ Difficulty in achieving target (e.g., achieving a specific goal such as blood pressure below a certain value vs. process performance irrespective of outcome)

† RCT = randomized controlled trial; CBA = controlled before–after study; ITS = interrupted time series.
__ Indicates no information collected
* Indicates information captured in text answers by reviewers rather than structured format
√ Indicates data collected relevant to this feature
√√ Indicates data collected and included in summary analysis, when feasible for a given topic

Quantitative Synthesis of Quality Improvement Strategies

Quantitative evaluations of the QI effect were performed for the various strategies, when possible. These evaluations were done only in situations when: 1) a sufficient number of studies with similar outcomes were available, and 2) the studies were sufficiently homogeneous in their design and population to provide a valid quantitative sample.

Calculation of summary effect for studies. In addition to the descriptive and qualitative investigations, two additional forms of analysis were planned for inclusion in the review. The first involved calculation of the median effect for outcomes within a given category (i.e., all provider adherence outcomes reported by a given study) so that studies with the same features could be compared using a common metric. Following the method employed in a recent systematic review of strategies for guideline implementation,[61] researchers identified for each study the adherence outcome that indicated the median improvement attributable to the intervention. For example, if a study reported one outcome involving adherence to a guideline for checking HbA_{1c}, another relating to managing cardiovascular risk factors, and another for delivery of patient education, a calculation of the net improvement attributable to the intervention for each outcome then would be done. The net improvements then were ranked for all of the outcomes and the median net improvement was used as a summary measure for the study.

The net improvement in adherence was calculated as (Post-intervention adherence – Pre-intervention adherence)$_{\text{Study group}}$ – (Post-intervention adherence–Pre-intervention adherence)$_{\text{Control group}}$. Outcomes were not combined for measures of disease control, so for example, the authors simply reported the net reduction in HbA_{1c}, systolic blood pressure (SBP) or diastolic blood pressure (DBP) attributable to the intervention.

For instance, the net reduction in SBP attributable to the intervention was calculated as:

(Post-intervention SBP – Pre-intervention SBP)$_{\text{Study group}}$ – (Post-intervention SBP – Pre-intervention SBP)$_{\text{Control group.}}$

To characterize the impact of a particular type of QI strategy (i.e., provider education) or study feature (i.e., trial design), a calculation was made of the median effect achieved in studies with the feature of interest. For instance, all trials with interventions that included some aspect of provider education and also reported a change in mean SBP for the study groups were identified. Next, the median net reduction in SBP for these trials was computed and compared to the median effect for all trials, as well as the median effect for trials with interventions having no component of provider education. The median improvement in adherence across different QI types was compared similarly.

The use of median effects, rather than average effects, prevented the skewing of summary measures based on outliers with particularly large or small effect sizes. This was regarded as particularly important because, if publication bias were present, small studies with relatively large effect sizes would more likely be published than small studies with more modest effect size. Thought was given to a weighted median, with weights based on sample size, to avoid giving equal weight to all studies regardless of size. Weighted medians are not as straightforward as weighted means, especially when attempting to preserve the original significance of the effect size (e.g., the observed reduction in HbA_{1c} or SBP in the units used for those outcomes). So

rather than attempting a weighting function, the authors chose instead to examine the median effect sizes using different strata of study sample size (e.g., comparing the median effect among studies with sample sizes in the lowest quartile vs. those in the highest quartile, or lower half vs. upper half).

Adjustments for unit of analysis errors. The "clustering effect," in which the unit of analysis and unit of allocation differ (i.e., providers or clinics randomized, but patient level outcomes analyzed) was anticipated in a significant number of studies. The significance of clustering is that patients within a cluster are not independent (e.g., patients at one clinic resemble one another in more ways than they resemble patients at other sites, or those cared for by other providers in the trial). Unit-of-analysis errors do not affect point estimates for effect sizes, but they can have a spurious narrowing effect on the associated confidence interval, causing potentially false-positive trial results.[62-69] To prevent the same false precision in this analysis, an effective sample size* was calculated for each study for the meta-regressions described below. Moreover, the degree to which investigators acknowledged or accounted for cluster effects did not affect the analysis, apart from the fact that investigators who did consider cluster effects in the design or analysis of their trial were more likely to report data such as the number of providers randomized, rather than reporting only the total numbers of patients in each group. The same investigators also might provide more technical details, such as values for the intra-cluster coefficient (ICC).[70-72]

Meta-regression Analyses

For the more involved quantitative analyses—meta-regression analysis of included studies—the investigators used a more conventional measure of effect size, defined as the difference between the mean values for the intervention and control arms, divided by the pooled estimate of groups within the standard deviation.† The researchers constructed these formal effect sizes, as well as the above median effect measures, such that a positive result always reflected improvement (e.g., a positive reduction in average HbA_{1c} or a positive improvement in adherence).

The regression models aimed to evaluate the relative effectiveness of different intervention components and the impact of study features such as trial design and study period. Specifically, the investigators constructed regression models using the pre-intervention effect size (ES_{Pre}) as a predictor variable. Initially, each methodological feature or QI strategy was modeled with ES_{Pre} to evaluate its effect on the post-intervention effect size (ES_{Post}); subsequently, the researchers developed multivariate models using multiple components as an individual feature's covariates, in order to independently assess the effect of an individual feature after adjustment for other components. Linear regression was carried out as $Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2$, with $X_1 = ES_{pre}$ and the dependent variable, Y, corresponding to the outcome of interest—a measure of disease control such as $HbA_{1c,}$ or the summary measure of adherence outcome described above. The approach retained ES_{pre} as a predictor in all analyses because baseline differences between the study and

---

* Effective N = (km) / (1 + (m-1)r) where k is the number of clusters and m is the number of observations per cluster and r is the intra-cluster coefficient. When r = 0, then N = km. When r = 1, then N = k

† Effect size = $(\bar{X}_I - \bar{X}_C) / S_p$ where $\bar{X}_I$ is the mean for the intervention group, $\bar{X}_C$ is the mean for the control group and S_p is the pooled-within-groups standard deviation, which is calculated from: $S_p^2 = ((N_I - 1) S_I^2 + (N_C - 1) S_C^2) / (N_I + N_C - 2)$. N_I and N_C are the intervention and control sample sizes and S_I and S_C are the intervention and control standard deviations.

control groups were expected to act as important covariates, even when these differences did not meet conventional thresholds for statistical significance.

Chapter 3. Toward a Theoretic Basis for Quality Improvement Interventions

Kathryn M. McDonald, M.M.
Stanford University

Ian D. Graham, Ph.D.
University of Ottawa
and Ottawa Health Research Institute

Jeremy Grimshaw M.B.Ch.B. Ph.D. FRCGP
Ottawa Health Research Institute
and University of Ottawa

Introduction

While medicine has a long history of investigating what works and why, we have a fairly limited understanding of the causal mechanisms of interventions to improve health care quality. *Implementation research* has been defined as the scientific study of methods to promote the uptake of research findings for the purpose of improving quality of care.[73] It includes the study of factors that influence the behavior of health care professionals and organizations, and the interventions that enable them to use research findings more effectively. Closing the quality gap relies on implementation research to create effective quality improvement (QI) interventions. Implementation research is referred to by many names, including action research, research utilization, practice guidelines implementation research, diffusion of innovation, translating research into practice, quality improvement research, knowledge translation, knowledge transfer, knowledge mobilization, and knowledge exchange. Research has followed two primary and related tracks: transfer or diffusion of knowledge and behavioral change.

Researchers and analysts from diverse disciplines have studied variables that influence the diffusion of innovations. In addition, numerous theories of behavioral change have been developed from a variety of perspectives-- psychology, sociology, economics, marketing, education, organizational behavior, and others. In QI, theories abound regarding ways to change the behavior of patients, clinicians, and organizations. However, these "parts" are not integrated into one overarching "whole." Most theories are descriptive, and do not predict the components that are required for effective design and implementation of quality improvement strategies. What are the important variables in the sequence of steps that will result in improved quality? How do these variables interact? Which variables are likely to matter, and under what circumstances? The application of theory to quality improvement strategies may be analogous to the use of biologic plausibility in designing new clinical treatments; a process by which researchers determine the most likely target for a treatment, and interpret study results accordingly. Developing a theory that helps to explain and predict a particular set of behaviors would allow QI implementers to zero in on an appropriate target for change, and craft the intervention to effect that change.

Development of theories with greater predictive value also would help researchers to design interventions to overcome barriers to behavioral change. Barriers to change may stymie even the most laudable (and seemingly obvious) effort to correct a health care quality problem. Ongoing

attempts to enhance clinicians' compliance with standard hand hygiene practice is a case in point.[74] Barriers to change exist at each stage in the causal pathway of noncompliance, from the psychological, to the cognitive, to the physical layout, across diverse clinical settings.

For hand hygiene, or any intervention to be effective it must be tailored to the target behavior or process, as well as to the environment itself. Cognitive theory suggests that clinicians may simply be unaware of the consequences of hygiene noncompliance, while adult-learning theorists would argue that clinicians must experience the negative consequences of their action before their behavior will change.[75] Behaviorists might suggest an intervention designed to provide feedback and reinforcement, while social theory adherents and organizational theorists would turn their attention to the culture of the organization that fails to support compliance, or to disseminate an appropriate "message," to adopt the vernacular of marketing theorists.[76] All of these are credible suppositions. Without an understanding of the theoretical construct(s) that explain mechanisms of change, efforts are likely to be scattershot, challenging even the most enthusiastic QI implementer to transfer innovations into practice efficiently and consistently.

As the hand hygiene example illustrates, numerous descriptive theories—and some predictive theories—are available. Unfortunately, they have been put to little use in the field. A literature review of surveys of physician behavior identified nearly 300 barriers to physician adherence with clinical practice guidelines, sorted into seven general categories, and further classified according to behavioral and other theories.[77] However, a recent review of guideline implementation efforts reveals that of the 235 included studies, merely 10% of the authors provided an underlying theoretical rationale for the particular intervention they had selected.[78]

For readers with an interest in QI's formative and ongoing theoretical discussion, this chapter introduces a general hierarchy that organizes various levels of theory from the macro to the micro. The authors then introduce selective examples of the theories that some researchers in the field of QI have considered as they design interventions to modify interactions among individual patients, health care providers, and the organizations they function within. The reader should note that this selective overview renders only a sampling of the numerous theoretical schools of thought from which health care quality improvement strategies are or could be designed. A comprehensive review of the entire body of theoretic work in the field of QI exceeds the scope of this review. In addition, the omission of any particular theoretic basis (and the inclusion of others) does not imply that one lacks importance or should not be accorded due consideration. Rather, the selection presented reflects the combined expertise of the EPC's technical advisors, and represents a variety of some of the more commonly utilized theoretic underpinnings that inform or show promise for QI efforts in the field of health care. Sources for more in-depth coverage of the theoretical models discussed, and others, are noted.

Hierarchy of Theories and Models

A theory describes and explains what is observed and why it happens. Various taxonomies, including the one used for the QI reviews of diabetes (*Closing the Quality Gap*, Vol. 2) and hypertension (*Closing the Quality Gap*, Vol. 3), answer the question of "what" strategies could be used to try to change behavior or transfer knowledge. Theories expand on the "what" question by addressing "how" and "why" these QI strategies or their components might or might not be effective, and under what conditions ("when" and "where"). Thus, theories provide a framework for interpreting a study's findings in its own setting, and potentially, in other settings. A model can be conceptual, as described below, or action-oriented with process steps to provide an

approach to QI. Following is a selection of models and theories that have been used to design some quality improvement strategies, or which may be useful in future work. Given the rudimentary state of the art and science of implementation research it is helpful to review what is sometimes referred to as the structural hierarchy of knowledge, or the levels of theory from the most abstract to the most specific.[77]

The terms *conceptual models, conceptual frameworks*, and *conceptual systems* often are used synonymously and represent global ideas about a phenomenon. They are used to clarify, describe, and organize ideas,[78] and could be viewed as the top level of the hierarchy. It should be noted, however, that conceptual models/frameworks and theories vary in their levels of abstraction and a continuum exists within the structural hierarchy of knowledge. Boundaries between conceptual models and levels of theory sometimes overlap, making it difficult to clearly differentiate among them within the hierarchical structure.

A *theory* is an organized, heuristic, coherent, and systematic set of statements related to significant questions that are communicated in a meaningful whole.[79] It describes observations, summarizes current evidence, proposes explanations, and yields testable hypotheses—all within specific assumptions and constraints. Theories can be described in terms of their scope, with wider scopes reflecting generally higher levels of abstraction in the knowledge hierarchy.

A *grand or macro theory* is a very broad theory that provides a general framework for the nature and goals of a discipline. Grand theories are non-specific and are made up of relatively abstract concepts that lack operational definitions and relatively abstract propositions that are not amenable to direct empirical testing.[80,81] They tend to be developed through thoughtful and insightful appraisal of existing ideas, or creative leaps beyond existing knowledge. While widely applicable, grand theoretical statements lack the detail that is necessary to fully understand the relationships between constructs and variables in specific situations. A *mid-range theory* is more limited in scope, addresses specific phenomena, and is intended to guide empirical inquiry as well as action or practice. It encompasses a limited number of concepts and a limited aspect of the real world. Mid-range theories are made up of relatively concrete concepts that are operationally defined and can be empirically tested. They are less abstract than grand theory and more abstract than empirical generalizations or micro theory.[82] A *micro, practice, or situation-specific theory* (sometimes referred to as *prescriptive theory*) has the narrowest range of interest, and focuses on specific phenomena that reflect clinical practice, and that are limited to specific populations or to a particular field of practice.

At all levels, the purpose of theory is to organize and communicate information parsimoniously and clearly, in order to describe, discover, and predict phenomena seen in the world. Whether a theory is "good" or not depends on both its ability to withstand efforts to disprove it (i.e., "falsifiability"), and its usefulness.[83] In the subsequent descriptions of selected theories, organized roughly by their level in the hierarchy, no attempt has been made to evaluate the theories, apart from the commentary on their potential applicability to QI strategies.

Conceptual Models and Grand Theories of Implementation Phenomena

Conceptual models and grand theories of implementation phenomena are essentially models or theories of change. Change theories/models may be classified as either classical or planned.[78]

Classical Theories of Change

Classical theories/models of change (sometimes referred to as descriptive or normative theories) are passive; they explain or describe the naturalistic process of change or diffusion of innovation. Perhaps the most prominent example of a classical theory of change is Everett Rogers' *diffusion of innovation theory.*[84-85] Some of the better known observations deriving from Rogers' work are the innovation-decision process, which describes how potential adopters' perceptions of the attributes or characteristics of an innovation influence diffusion of the innovation, and the relationship between adopter types and diffusion. The innovation-decision process consists of five stages that potential adopters pass through as they decide to adopt an innovation. These stages are: knowledge (becoming aware of the innovation), persuasion (developing positive attitudes toward the innovation), decision (making a cognitive decision to adopt the innovation—i.e., developing an intention to adopt), implementation (using the innovation), and confirmation (continuing to use the innovation, adapting the innovation, or abandoning it).

Rogers posited that innovations are more quickly adopted when they are compatible with current values, beliefs, and ways of doing things; are seen to be more advantageous than the current practice (relative advantage); are easy to do or use (low complexity); are observed by others to be in use (observability); and can be easily tested before being formally adopted (trialability). Another important contribution of Rogers' work has been the observation that potential adopters may fall into one of a number of adopter types, which relate to diffusion: innovators (the fastest adopter group, venturesome, cosmopolitan, socially disconnected), early adopters (opinion leaders, respected, locally well connected, self-conscious experimenters), early majority (deliberate, local observers, have watched early adopters), late majority (skeptical, more conservative, wait for majority's adoption of the innovation before adopting it themselves), and laggards (traditionalists, socially isolated, slowest to change). Readers should also consider Jonathan Lomas's *Coordinated Implementation Model,*[86-87] another implementation theory that is more descriptive in nature and focuses explicitly on the medical context. For example, the Lomas model proposes that better knowledge transfer occurs when passive continuing medical education is replaced with active dissemination that takes into consideration a broad range of interacting factors that may promote or hinder adoption (e.g., economic, personal, administrative, and community-based incentives).[88]

Limitations of Classical Theories of Change

While classical theories/models of change may help to identify potential determinants of change, they provide little information on the best way to either accelerate or hinder natural diffusion (e.g., they provide no direction for operationalizing opinion leaders). For this reason, QI implementers and researchers tend to be more interested in planned change theories/models, which are specifically intended as guides, or to cause change.[78]

Planned Models of Change

A planned change model/theory is a set of logically interrelated concepts that explain, in a systematic way, the means by which planned change occurs. These models predict how various forces in an environment will react in specified change situations, and help QI implementers control variables that increase or decrease the likelihood that change will occur.[89-90] Planned

change, in this context, refers to deliberate (not haphazard) efforts to engineer change in groups that vary in size and setting. Those who use planned change theories/models may work with individuals, but their objective is to alter ways of doing things in social systems. Examples of planned change models/theories are Green's Precede-Proceed model,[91-92] the social marketing model, Berwick's rules for dissemination,[93] and the Ottawa Model of Research Use,[94] to name several.

Precede–proceed. Precede–Proceed specifies the steps that precede an intervention and suggests ways to proceed with its implementation, including subsequent evaluation.[91] In the *precede* stages, the implementer first specifies the problem and then identifies the factors that contribute to it. These factors are categorized theoretically as predisposing, enabling, or reinforcing, and then rated in terms of importance and amenability to change. Predisposing factors include attitudes, beliefs, and perceptions, all of which provide the impetus for change. Enabling factors include the resources, facilities, and skills that must be present for change to actually occur. Reinforcing factors include rewards or incentives, such as positive feedback, that encourage change.[92] The key *proceed* stages are implementation and evaluation of the intervention. The evaluation stage examines the degree to which the protocol was implemented, and the effect the intervention had on behavior change, and on predisposing, enabling, and reinforcing factors.

Social Marketing. Social marketing is a planning model that consists of several stages: [95] *planning and strategy,* when research is conducted with the target group and resources available for the intervention are assessed; *selecting the relevant channels and materials for intervention,* when specifications of the program structure and relevant outcomes are made, and the target group is 'segmented' to create homogeneous subgroups for tailoring messages and distribution methods; *developing and piloting materials with the target audience* to determine their relevance, comprehensibility, and likely impact; and finally, *implementation, evaluation, and feedback* after which the intervention may be refined. Social marketing has largely focused on bringing about health behavior change at the community level, but has also been used as the basis for some other quality improvement strategies. For example the principles for academic detailing proposed by Soumerai and Avorn[96] are based upon social marketing approaches. In academic detailing, implementers conduct interviews to investigate baseline knowledge and motivations for current practice; focus programs on specific categories of physicians as well as opinion leaders; define clear educational and behavioral objectives; establish credibility through a respected organizational identity, reference authoritative and unbiased sources of information, and present both sides of controversial issues; stimulate active physician participation in educational interactions; use concise graphic educational materials; highlight and repeat the essential messages; and provide positive reinforcement for improved practices in followup visits.

Donald Berwick's Rules for Dissemination. While not proposed as a model *per se*, Berwick[93] has proposed a series of seven 'rules' for translating research into practice, largely derived from the theoretical work of Rogers and Van de Ven.[85-97] The seven rules require an implementer to: 1) find sound innovations, 2) find and support innovators, 3) invest in early adopters, 4) make early adopter activity observable, 5) trust and enable reinvention, 6) create slack for change, and 7) lead by example. The IOM National Priority Report (which provides the topic areas for this Series) reflects the first rule, in that the IOM committee identified clinical topics for which sound, evidence-based innovations exist, which could be implemented more broadly. This Series could be viewed as fulfilling the second rule, by finding and reviewing the research that innovators have reported.

Ottawa Model of Health Care Research Use. The Ottawa Model of Research Use[94-98] offers a comprehensive, interdisciplinary framework of elements that affect the process of health care knowledge transfer, and is derived from published literature. Although not explicitly linked to Donabedian's germinal work describing health care quality production in terms of structure, process, and outcomes,[99] the model captures these characteristics, along with important social factors. The elements considered central to the *research use* process are: the evidence-base of the innovation, potential adopters, practice environment, strategies for transferring the evidence into practice, the use of the evidence, and outcomes of the process (e.g., related to patient health, practitioner issues, and economic implications). A particular advantage of the model is that it may be applied at any level in the delivery of care (e.g., individual professional or team behavior change, hospital behavioral change, health care system change), and that the patient is incorporated as a key component of each element. The model is dynamic, meaning that each element is assumed to influence and be influenced by the others (e.g., depicted by double arrows that create multiple loops in Figure 1). Finally, in planning research transfer activities, the model relies on a process of assessment, monitoring, and evaluation (AME) of each element before, during, and after the decision is made to promote an innovation (broadly defined as research evidence that is new to the potential adopter). In brief, the model directs QI implementers to conduct a barriers assessment of the evidence-based recommendations, the potential adopters, and practice environment to determine factors that might be expected to hinder or support the uptake of the recommendations. Next, this information is used to select and tailor interventions to overcome the anticipated barriers or enhance the supports. The introduction of the interventions is then monitored, to ensure that they are being delivered as expected, are addressing the identified barriers, and that unexpected barriers have not emerged since the time of introduction that must now be addressed. Monitoring the adoption of the recommendations during the implementation phase can help determine whether the dose of intervention has been sufficient to bring about the desired change in practice, or whether more of the same or new interventions may be required. Finally, the impact of the implementation process is evaluated and the iterative process begins again. Figure 1 summarizes the key features of the model, with the QI strategies' elements bolded to emphasize the focus of this report.

Limitations of planned change models. Planned change models provide broad frameworks for planning implementation activities, but are less helpful when considering which specific interventions to use. This may be due to the fact that these theories are as yet insufficient to relate specific intervention components to a predicted effect on knowledge transfer or behavior. In addition, potentially relevant theories have not yet been validated for health care professional or organizational change.

Mid-range Theories

Mid-range theories are potentially more predictive of behavior and behavioral change at different levels. They are commonly discipline-specific, however, and their applicability to individual health behaviors and/or health care professional behavior has not been well tested in many instances.

Ferlie and Shortell[100] have suggested several levels at which interventions to improve the quality of health care might operate: the individual health professional and health care groups or teams; organizations providing health care; and the larger health care system or environment in which individual organizations are embedded. Different theories will be relevant to interventions

at different levels, for example, psychological theories will be more relevant to interventions directed at individuals and teams, while theories of organizational change will be more relevant to interventions directed at hospitals and other organizations. A full scientific rationale for interventions to improve quality requires exploration of theories relevant to interventions directed at each of these levels.

Social Psychological Theories

Individual health behaviors and health care professional behaviors are forms of human behavior that are influenced at the level of the health care system, the health care organization, the individual provider, and by the characteristics of clinical best practices. Theories of human behavior that have been successfully adopted in similar settings may provide a basis for developing a theoretical basis for understanding health care professional and organizational behavior.

Social influence theories. Social influence theory recognizes the importance of shared beliefs and assumptions, group norms, and organizational culture as determinants of individual and professional behavior. Social influence interventions attempt to promote behavioral change by influencing group perspectives. Mittman and colleagues[101] have proposed a classification scheme of potential social influence interventions for practice guideline dissemination and implementation that depends on the size of the target audience, and includes educational outreach and opinion leaders.

Motivational theories (including social cognition models). These theories propose that motivation determines behavior, and therefore the best predictors of behavior are factors that predict or determine motivation (or intention). Examples include Albert Bandura's *social cognitive theory*,[102] and the *theory of planned behavior*[103]. Bandura's social cognitive theory[102] proposes that behavior is determined by incentives and three kinds of expectancies (situation-outcome expectancies, outcome expectancies, and self-efficacy expectancies). Self-efficacy expectancies are beliefs about one's ability to perform the behavior (e.g., I can stop smoking) and have been found to be the most important construct in empirical studies[104]as well as a consistent predictor of behavioral change.[105] The theory of planned behavior (TPB) proposes that the strength of an individual's intention (or motivation) to engage in a behavior, and the degree of control they feel they have over that behavior (perceived behavioral control), are the proximal determinants of engaging in it.[103] The theory of planned behavior also proposes that intention strength is determined by three variables: attitudes towards the behavior (a product of beliefs about its consequences and evaluations of those consequences), subjective norms (a product of perceptions of the views of other individuals or groups about the behavior, and the strength of the individual's desire to gain approval of these groups), and perceived behavioral control (a function of beliefs about factors likely to facilitate or inhibit the behavior— these might include organizational constraints and patient preferences). The TPB has been shown to predict a range of individual health related behaviors with some success. Recent meta-analyses have suggested that the TPB can account for approximately 30% of the variance in health behavior.[106] The application of TPB to our understanding of providers' adherence to evidence-based advice about their practice has been limited. However, early studies suggest that it is a useful, systematic tool to identify barriers to, and facilitators of, change and is helpful in selecting appropriate forms of intervention.[107-108]

Action theories. These theories may include motivational elements, but postulate that other factors are necessary to predict behavior. Examples include operant conditioning and implementation intentions. *Operant conditioning* proposes that behaviors that have positive consequences for the individual (such as remuneration) are likely to be repeated, whereas those that have unpleasant consequences will become less frequent.[109] The principle that positive consequences promote repetition of behavior is well established and has been widely and successfully used to understand behavior and behavioral change. As rewarded behaviors are repeated, and may become "habitual," the frequency of past behavior can be a powerful predictor of future behavior. Gollwitzer[110] distinguishes between *goal intentions* (conceptually similar to intentions within the theory of planned behavior) and *implementation intentions,* which are explicit plans about when and where a goal intention will be achieved. Gollwitzer argues that by creating an implementation intention, people effectively transfer control of the behavior to the environment—establishing cues to action. This is a relatively new concept in health behavior research, however, experimental studies suggest that people who have formulated plans like these are more likely to translate their intentions into action than those who have not.[111] For example, women are told to specify where and when they will perform breast self-examination, and subsequently are found to have followed through more frequently than those with no plan regarding their intention to implement.[111] While studies thus far have utilized this theory for patient behavior change, it may be just as applicable to provider behavior change (e.g., a provider education QI strategy might incorporate a step that asks the clinician to formulate a plan for implementing a change in practice).[112]

Stage theories. These theories propose that at a given point in time, individuals are at different stages in a linear progression toward behavioral change (for example, an awareness stage occurs before an action stage), and that predictors of behavior must account for the different stages of progression. Examples include the *transtheoretical model of change*[113] and the *precaution–adoption process model.*[114] From a stage theory perspective, interventions to facilitate change will be most effective if they are tailored to the stage the individual has reached within this process. Stage theories have been widely used to develop interventions in behaviors such as smoking cessation.[114] Despite their face validity and (relatively) widespread use, a recent systematic review found that there was little evidence that interventions based on stage theories were more effective than non-stage theory interventions.[115]

Organizational Theories

To understand organizational change theories, it is helpful to define organizational behavior, and to present some background on organizational theory on a macro level. Organizational behavior is the study of individual and group attitudes and actions within an organizational setting, and describes how the resultant behavior affects the goals of the organization. Macro theories regarding how organizations function and behave fall into three major typologies: 1) *rational system theories,* which focus on the internal structures and processes of an organization, 2) *natural-system theories*, which also focus on internal workings, but emphasize the organization as a social system, noting the importance of unplanned processes and events, human relations, and integration of individual and organizational goals, and 3) *open-system theories,* which emphasize the ways in which an organization's environment relates to its structure and behavior.[116] Shortell posits that the health care system can be best understood in light of all three of these theories, because of its complex inner, social, and external structures.[117-118]

Organizational change theories, particularly the rational system models, may be most directly applicable to managing and achieving change within the health care organization and its environment. Alternatively, institutional models (described below) likely also apply to prominent QI strategies. The following section describes these mid-range models generally in terms of definition, important variables, perspective on organizational change, and strategies for change within organizations.[118-119]

Rational models. These models emphasize four stages in the process of organizational change: *awareness* of a problem or quality gap, *identification* of action to solve the problem or narrow a gap, *implementation* of the action, and finally *institutionalization,* where all relevant parties accept the change. At each stage, the models adopt three perspectives of the change process, any of which may need to be addressed, depending upon circumstances. First, the *behavioral perspective* assesses the manner in which issues connect to attitudes, culture, values, and norms within the organization. The *structural perspective* focuses on the design of activities and roles of individuals and work groups, considerations of power and influence, and variables such as complexity, centralization and formalization. Finally, the *contingency perspective* considers the interactions between behavior and structure, as well as the particular timing and circumstances of the target change. Kalunzy and colleagues[120] diagram factors influencing a change process in three dimensions, with a spiral through time showing the stages from recognition through institutionalization, with each twist in the spiral affected differentially by personnel, processes, and structure of the organization, as well as the attributes of the change. For example, at the implementation stage of an innovation that is costly or has widespread consequences for the organization, each of the factors—personnel, process, and structure—are likely to be influential. At the earlier problem recognition phase, only personnel may be involved, regardless of the nature of the change. Throughout all phases, an organization is likely to be influenced by internal and external pressure for change, as well as potential examples from other organizations about intervention possibilities.

Institutional models. In contrast to rational models, which assume that management has the freedom to implement change according to specific economic and strategic interests of the organization, institutional models specify that legitimacy seeking behaviors of organizations drive the implementation of organizational change. Legitimacy is acquired relative to the norms of the time and industry for each organization. These models may be particularly pertinent to QI because they emphasize the role of social factors including pressures to conform from outside of an organization (e.g., regulatory bodies, professional organizations). One illustration of how institutional theory explains important factors in the adoption and implementation of a QI strategy involves Total Quality Management (TQM), an organizational intervention encompassing a range of philosophies and activities. Institutional theorists hypothesize that as TQM has become more accepted, the reason for its adoption, and therefore the style of implementation is motivated by a need for legitimacy, as opposed to a strategic or economic imperative. The menu of TQM philosophies includes commitment to identifying, meeting, and then exceeding the needs of both internal and external stakeholders; continuous improvement, including raising standards; structured, problem-solving processes using statistical and other tools; and employee empowerment to improve quality, including training across all levels, functions, and areas of an organization. Activities associated with TQM include assessments of community needs; benchmarking performance; training in principles and methods of TQM; brainstorming; use of cause and effect diagrams (also known as Ishakawa or "Fishbone" diagrams), control charts, and other analytic tools. Health care organizations have either adopted their own versions of TQM, or followed a standard approach named for its progenitors (e.g.,

Juran, with its emphasis on quality audits, *Crosby,* with a focus on training, or *Deming*, with an orientation toward statistical and process tools). Westphal and colleagues[121] examined Total Quality Management programs introduced in standard or customized ways over an eight year time period to determine if implementation of this QI strategy differed depending on timing. They observed that earlier adopters customized the form of TQM in ways that improved organizational performance, as expected in a rational system theory, while later adopters more often used standardized TQM programs, apparently motivated by external factors such as accreditation ratings, and fitting with precepts of institutional theory. Thus, both the form and consequences of a particular QI strategy are influenced by the timing of its implementation, and the organization's place, relative to the health care industry as a whole.

Iles and Sutherland[122] conducted a comprehensive review of several decades of organizational change theories for the British National Health Services. They provide summaries of a large number of models, and cluster them around a small number of key questions for implementation of quality improvement strategies. The organizing questions or topics for each cluster of theories, and the specific theories and models examined in the review are shown in Figure 2.

According to this review, most of the evidentiary base for organizational theories in the health care sector is comprised of case studies, with only one cohort study on TQM examining the link between the strategy and the effect on health care quality.[123] Several case studies also examine the link between the particular theory and health outcomes, but most focus on other outcomes (e.g., job security, cost-competitiveness, position, etc.). Generally, the organizational literature related to promoting change, or "change management" is descriptive and infrequently applied to the health care setting. It is certainly conceivable that the type of evidence useful in the management area may differ from that applied to clinical practice. The complexity of health service delivery and organization may require alternative methods for assessing what qualifies as evidence. Ultimately, however, more evaluative research in this area may be useful to those implementing quality improvement strategies by highlighting potential levers for change.

Other Discipline-Based Theories

A number of other disciplines have contributed theories to patient, provider, and organizational behavior change. For example, *adult learning theory* from educational research, emphasizes the role of intrinsic personal motivation,[124] and creates interventions based on consensus development and problem-based learning.[125] Provider education strategies that incorporate these approaches may be more likely to work than those that do not address intrinsic motivation. In contrast, *marketing approaches* have been used to promote health to the general public,[126] as well as to target physician or organizational change. The advent of direct-to-consumer marketing is providing a natural experiment to determine the significance of marketing theories.

Economic theories provide insight about the policies and funding mechanisms that may contribute to efficiency (e.g., avoiding waste in achieving quality) and equity (e.g., providing the same quality regardless of individual patient characteristics). Value or quality-based purchasing activity in the U.S. marketplace is an example of a QI strategy derived from economic theory. This approach is intended to have either a direct influence on the decisions of consumers or health care organizations by using payment incentives, or an indirect influence by reducing asymmetric information between different stakeholders in a market (e.g., health plans and

consumers).[127] Theories drawn from economics therefore play a role in considerations about designing policies to increase incentives for quality.

Micro or Situation-specific Theory

As a relatively new field of inquiry, micro theories of knowledge translation and behavior change have yet to be articulated in relation to health care. These theories, should they eventually be developed, would predict the uptake of a specific behavior by a particular health professional group or subgroup when exposed to a given intervention (e.g., audit and feedback may be effective for changing radiologic ordering behavior of family physicians, but may not influence nurses' use of compression bandaging guidelines).

Conclusion

Transferring knowledge, diffusing innovation, changing behavior, or getting the system to do the "right thing," are different ways of stating the ultimate objective: to close quality gaps. Concurrent consideration of theory and actual implementation practice may yield mutually useful results. Figure 3 depicts a conceptual framework of the interactions among various mid-range theories, and incorporates some of the factors that may predictably bring about change. The applicability of these theories to behavior change and knowledge transfer at the individual health, health care professional, and organizational level remains uncertain. There are considerable challenges to the development of interventions based upon these theories. To improve our understanding of the causal mechanisms, effect modifiers, and applicability of a variety of QI strategies, QI implementers and researchers may benefit from working together to rigorously develop and test predictive theories of professional and organizational theory at the mid-range and practice levels. Insight about why a QI strategy fails or succeeds may be more easily accomplished when theory and implementation are tested side by side.

Chapter 3 Figures:

Figure 1. Ottawa Model of Research Use (Logan and Graham, 2003)

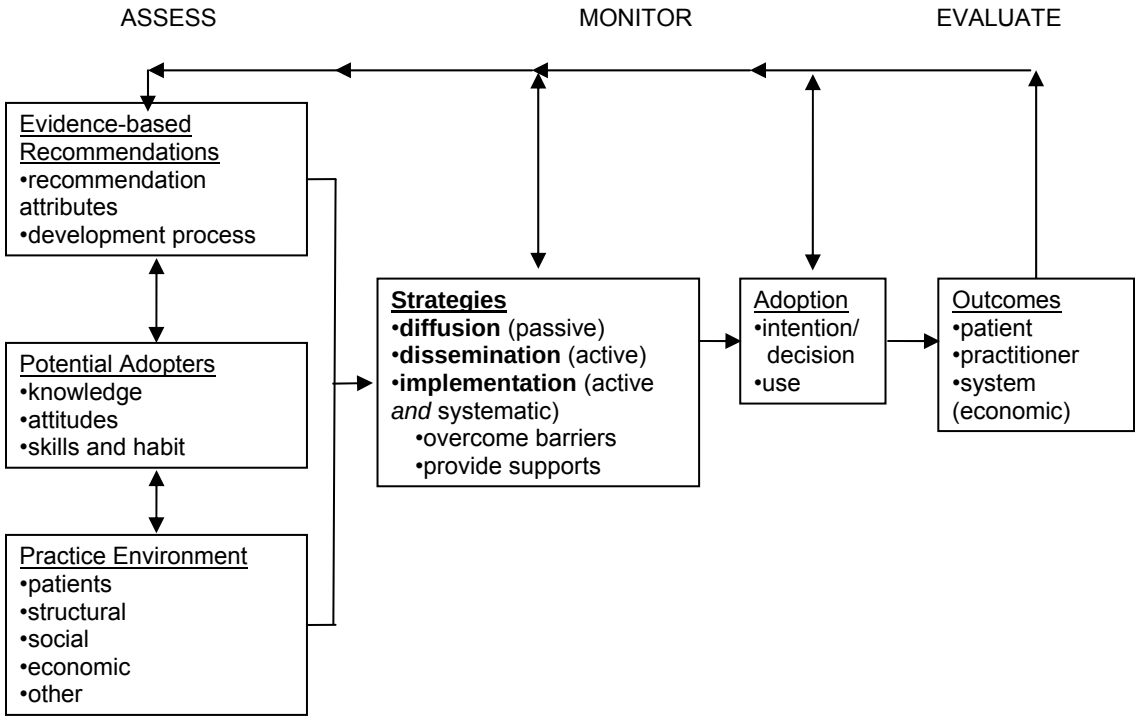


Figure 2. Organizational theories examined for evidence (adapted from Iles and Sutherland)

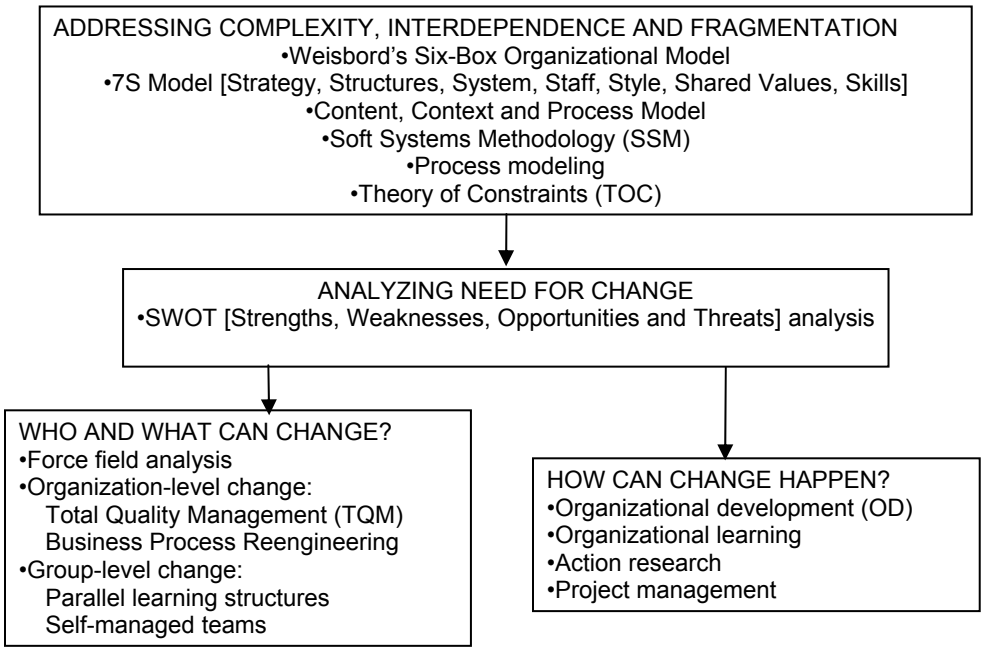
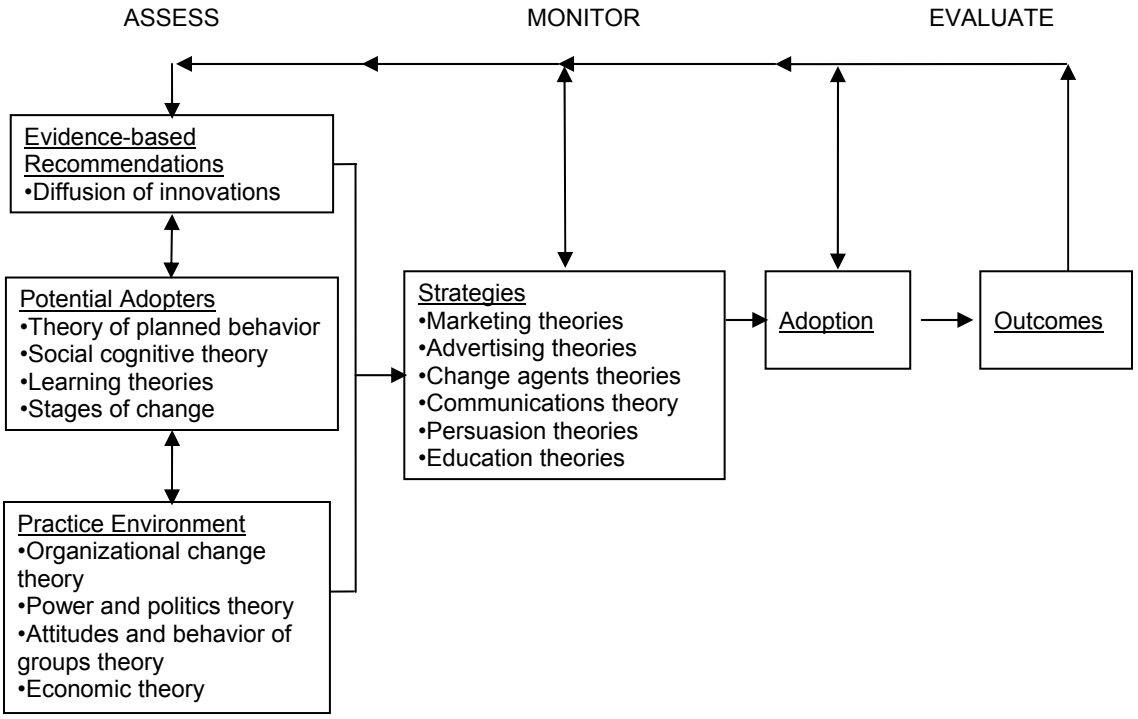


Figure 3. Examples of theories that could begin to populate the Ottawa Model of Research Use



Chapter 3 Notes

1. We would like to acknowledge the many collaborators who have contributed to our understanding in this area, in particular Martin Eccles, Professor of Clinical Effectiveness, University of Newcastle upon Tyne, UK; Marie Johnston, Professor of Psychology, University of Aberdeen, Scotland; Jo Logan, Associate Professor, School of Nursing, Faculty of Health Sciences, University of Ottawa, Canada; Dr Anne Walker, formerly Senior Research Fellow, Health Services Research Unit, University of Aberdeen, Scotland.

Appendixes

This page intentionally left blank

Appendix A

National Priority Areas Summary with Key Associated Goals

This page intentionally left blank

Appendix A: National Priority Areas Summary with Key Associated Goals

Care coordination (cross-cutting area)—About 60 million Americans live with multiple chronic conditions, such as hypertension and diabetes. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Children with special health care needs—Children with a chronic physical, developmental, behavioral, or emotional condition, or an increased risk of developing one, require more than the typical level of pediatric care. This vulnerable population requires caregivers to work closely with families to develop and coordinate care plans.

Diabetes—Diabetes is the fifth-leading cause of death in America, predisposing people to serious, long-term medical complications, including heart disease, hypertension, and blindness. There are several well-known and effective models for improving the delivery of care, with the goal of preventing progression through early and proper management.

End of life with advanced organ system failure—Heart, lung, and liver failures account for about one-fifth of all fatalities in America. Care should minimize symptoms and reduce the rate of exacerbations of organ malfunction. Improving care requires continuity of care over time and across settings, close monitoring, and rapid responses.

Evidence-based cancer screening—Cancer is the second-leading cause of death in the United States. Screening can significantly reduce death rates for several forms of cancer, especially colorectal and cervical cancer. Goals should be to increase the number of people who receive screenings and to provide timely followup.

Frailty associated with old age—With more Americans living longer, more people will experience the multiple mental and physical health challenges associated with advanced age. Health care efforts should focus on preventing falls and pressure ulcers, maximizing function, and developing advanced care plans.

Hypertension—Although this disease affects one in four adults in the United States, nearly a third of people with high blood pressure are undiagnosed. Untreated hypertension can lead to life-threatening complications, including stroke, heart attack, and kidney failure. Interventions should emphasize early detection and management.

Immunization—Timely vaccination could prevent the deaths of about 300 children and between 50,000 and 70,000 adults annually. Influenza and pneumonia account for most of the adult deaths. Vaccination efforts should target nursing-home residents, who are susceptible to contagious illnesses because of advanced age and close living quarters. Also, new strategies should be developed to reach out to black and Hispanic adults, as well as low-income, inner-city children – populations that tend to have lower-than-average immunization rates.

Ischemic heart disease—Ischemic, or coronary, heart disease, is the leading cause of death among adults in the United States. Efforts should focus on preventing heart disease and reducing recurrence of heart attacks through promotion of healthy lifestyle changes and use of cholesterol-lowering drugs, surgery, and timely administration of medications after a heart attack. In addition, efforts should ensure that those with heart disease are functioning at their greatest capacity.

Major depression—Treatment rates for depression are significantly lower than those for many other chronic conditions; fewer than half of individuals with depression are correctly diagnosed. National rates of screening and treatment should be improved.

Medication management—Efforts should focus on preventing medication errors, particularly through greater use of computer technology. In addition, educational interventions that warn physicians and patients about problems associated with overuse of antibiotics have been successful.

Nosocomial infections—Hospital-acquired infections kill nearly 90,000 patients in the United States each year, and cost an additional $5 billion to treat. Wider implementation of the nosocomial infection guidelines from the Centers for Disease Control and Prevention would save more than 40,000 lives annually, reduce infection rates by up to 50 percent, and save nearly $2.75 billion each year.

Obesity (emerging area)—Each year more than 300,000 deaths can be attributed to obesity. The condition eventually could become the nation's single most preventable cause of premature death and disability. Changes in social norms and national policies to promote physical activity and healthy diets are essential. Effective national strategies for obesity prevention, treatment, and control will require a combination of public health and clinical interventions.

Pain control in advanced cancer—Twenty percent of Americans die from cancer, often after months of painful, progressive illness. Effective pain control programs have been developed. Efforts should emphasize cooperation in protocols across care settings, advance planning for changes in settings as well as heightened pain, and public education regarding the merits of opioid medications in this area.

Pregnancy and childbirth—The quality of prenatal care and care related to labor and delivery should be enhanced to boost the long-term health of women and their children. Some key goals should be to increase the number of women who start prenatal care in the first trimester and to screen more pregnant women for sexually transmitted diseases.

Self-management/health literacy (cross-cutting area)—Public and private entities should systematically provide educational programs and interventions that boost patients' skills and confidence in managing and assessing their health problems. Higher levels of health literacy allow people to understand and act on health care information.

Severe and persistent mental illness—The quality of mental health care in the public sector, including state hospitals, community mental-health centers, and various federal and state programs should be improved. The federal government should play a larger role to assure higher standards of care across states.

Stroke—Stroke is the third-leading cause of death in the United States. Efforts should focus on seamlessly integrating care across health care settings and clinical disciplines. Beginning rehabilitation as soon as possible after a stroke also helps patients regain their abilities.

Tobacco-dependence treatment in adults—Tobacco use and dependence are the nation's most preventable causes of disease and death. Many successful efforts to improve health care in this area have used multilayered interventions that include systems to remind caregivers to discuss tobacco use with patients, as well as provider-education programs centered on best practices.

Adapted from National Academy of Medicine Press Release, January 7, 2003 “Officials Should Target 20 Key Areas to Transform Health Care System” http://www4.nas.edu/news.nsf/isbn/0309085438?OpenDocument; accessed April 11, 2003.

Appendix B: Search Strategy Exemplar: Quality Improvement and Hypertension

This page intentionally left blank

Appendix B: Search Strategy Exemplar: Quality Improvement and Hypertension

I. MEDLINE search

Search		Search String	Citations[‡]
#1	Care coord, Disease Mx, etc.	Disease Management [mh] OR Patient Care Planning [mh] OR Patient-Centered Care [mh] OR Primary Health Care [mh] OR Progressive Patient Care [mh] OR Critical Pathways [mh] OR Delivery of Health Care, Integrated [mh] OR Health Services Accessibility [mh] OR Managed Care Programs [mh] OR Product Line Management [mh] OR Patient Care Team [mh] OR Patient-Centered Care [mh] OR Behavior Control [mh] OR Counseling [mh] OR Health Promotion [mh] OR Patient Compliance [mh] OR After-Hours Care [mh] OR ((coordination [ti] OR coordinated [ti] OR Multifactorial [ti] OR Multi-factorial [ti] OR Multicomponent [ti] OR Multi-component [ti] OR multidisciplinary [ti] OR multi-disciplinary [ti] OR interdisciplinary [ti] OR inter-disciplinary [ti] OR integrated [ti] OR community-based [ti] OR organized [ti]) AND (care [ti] OR approach [ti] OR intervention [ti] OR strategy [ti] OR strategies [ti] OR management [ti] OR managing [ti] OR center* [ti] OR clinic*[ti])) OR Organization and Administration [mh]	683,000
#2	TQM, CQI	Total Quality Management [mh] OR Quality control [mh] OR TQM [ti] OR CQI [ti] OR (quality [ti] AND (continuous [ti] OR total [ti]) AND (management [ti] OR improvement [ti]))	28,087
#3	CME, educ outreach	Education, Continuing [mh] OR (Education [ti] AND Continuing [ti] AND (medical [ti] OR professional* [ti] OR nursing [ti] OR physician* [ti] OR nurse* [ti])) OR (outreach [ti] AND (visit*[ti] OR educational [ti]) OR (academic [ti] AND detailing [ti]))	35,276
#4		Diffusion of Innovation [mh] OR (Diffusion [ti] AND (Innovation [ti] OR technology [ti]))	4,889
#5	Audit, feedback financial incentive	Medical audit [mh] OR ((Audit [ti] OR feedback [ti] OR compliance [ti] OR adherence [ti] OR training [ti]) AND (improvement* [ti] OR improving [ti] OR improves [ti] OR improve [ti] OR guideline* [ti] OR practice* [ti] OR medical [ti] OR provider* [ti] OR physician* [ti] OR nurse* [ti] OR clinician* [ti] OR practice guidelines [mh] OR academic [ti] OR visit* [ti])) OR Reminder Systems [mh] OR Reminder* [ti] OR ((financial [ti] OR economic [ti] OR physician* [ti] OR patient*) AND incentive* [ti]) OR Reimbursement Mechanisms [mh]	36,852

[‡] Numbers of citations reflect search results from July 8, 2003

#6	IT, telemed	Medical Informatics [mh] OR computer [ti] OR (decision [ti] AND support [ti]) OR Telemedicine[mh] OR Telemedicine [ti] OR telecommunication* [ti] OR Internet [mh] OR web [ti] OR modem [ti] OR telephone* [ti] OR telephone [mh]	306,703
#7		#1 OR #2 OR #3 OR #4 OR #5 OR #6	988,356
#8		#7 AND (Hypertension [mh] OR Hypertension [ti] OR (blood [ti] AND pressure [ti]))	7,574
#9		#8 AND (systematic review search string[§] OR original research string[**])	3,698
#10		#9 Limit to English	3,144
#11		#10 Limit to Pub since 1980	2,942
#12	Main result	#11 BUTNOT (editorial [pt] OR comment [pt] OR letter [pt])	2,842
#13	Additional yield of journal search	(#8 AND Journal Search String [††]) BUTNOT (#9 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	220

[§] ((meta-analysis [pt] OR meta-analysis [tw] OR metaanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti] OR Decision Support Techniques [mh]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti]))) BUTNOT (case report [mh] OR case* [ti] OR report [ti] OR editorial [pt] OR comment [pt] OR letter [pt]) → 38,865 MEDLINE records

[**] Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR impact [ti] OR effectiveness [ti] OR Evaluation [ti] OR Studies [ti] OR study [ti] Comparative [ti] OR Feasibility [ti] OR Program [ti] OR Design [ti] OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh] —> 2,551,486 MEDLINE records

[††] N Engl J Med [ta] OR JAMA [ta] OR Ann Intern Med [ta] OR Am J Med [ta] OR Arch Intern Med [ta] OR J Gen Intern Med [ta] OR BMJ [ta] OR Lancet [ta] OR CMAJ [ta] OR Clin Invest Med [ta] OR Arch Fam Med [ta] OR J Fam Pract [ta] OR Fam Pract [ta] OR Ann Med [ta] OR Br J Gen Pract [ta] OR J Intern Med [ta] OR Med J Aust [ta] OR South Med J [ta] OR West J Med [ta] OR Aust N Z J Med [ta] OR Med Care [ta] OR Health Serv Res [ta] OR Inquiry [ta] OR Milbank Q [ta] OR Health Aff (Millwood) [ta] OR Health Care Financ Rev [ta] OR Med Care Res Rev [ta] OR eff clin pract [ta] OR eval health prof [ta] OR Jt Comm J Qual Improv [ta] OR Qual Saf Health Care [ta] OR Int J Qual Health Care [mh] OR Qual Health Care [ta] OR Qual Health Res [ta] OR Rep Med Guidel Outcomes Res [ta] OR Am J Manag Care [ta] OR Am J Med Qual [ta] OR J Contin Educ Health Prof [ta] OR Prev Med [ta] OR Am J Prev Med [ta] OR Patient Educ Couns [ta] OR Ann Behav Med [ta] OR J Hum Hypertens [ta] OR Hypertension [ta] OR Am J Hypertens [ta] OR Clin Exp Hypertens [ta] OR J Clin Hypertens [ta] OR J Hypertens [ta] OR Am J Cardiol [ta] OR Am Heart J [ta] OR circulation [ta] OR J AM Coll Cardiol [ta] OR Can J Cardiol [ta] OR Heart Lung [ta]

#14	Additional yield of author search	(#8 AND author search[‡‡]) BUTNOT (#13 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	29
#14			3,070 references total (322 of these were same as in the Diabetes search)

[‡‡] (Berwick D [au] OR berlowitz d [au] OR davis d [au] OR kiefe c [au] OR wagner e [au] OR glasgow r [au] OR boddenheimer t [au] OR Hulscher M [au] OR grol r [au] OR grimshaw j [au] OR haynes b [au] OR haynes rb [au] OR sackett d [au] OR goldberg h [au] OR Hirsch I [au] OR nash d [au] OR roper w [au] OR weingarten s [au]) --> 6,401

This page intentionally left blank

Appendix C: Article Review Triage Forms (Exemplar: Diabetes)

This page intentionally left blank

Appendix C: Article Review Triage Forms (Exemplar: Diabetes)

Note: Items in *Italics* are topic-specific

Diabetes Triage Forms

Stage 1:

1. Does the article report or evaluate the results of an intervention (whether performed by the investigators or not)?
   - o Yes
   - o No **<exclusionary answer>**
   - o Can't Tell

2. Does the article involve quality improvement or a QI strategy?
   - o Yes - involves quality improvement or a QI strategy
   - o Yes - systematic review of evaluations of a QI strategy
   - o No **<exclusionary answer>**
   - o Can't Tell

Stage 2:

1. Should this article proceed to article abstraction stage for this topic?
   - o Yes - evaluates a QI strategy involving diabetes
   - o *No - focused on diabetes in pregnancy, Type I DM only, screening for/preventing diabetes, hospital care only* **<exclusionary answer>**
   - o No - but involves other EPC topic(s) **<exclusionary answer>**
   - o No - not an evaluation or not QI **<exclusionary answer>**
   - o Can't tell - need article
   - o No - but useful background article **<exclusionary answer>**

2. What type of study design was used?
   - o RCT or quasi-RCT
   - o Prospective clinical trial, CBA* or ITS **
   - o Cohort study; before-after or time series not meeting CBA* or ITS** definitions **<exclusionary answer for this topic>**
   - o Observational (e.g., cross-section, case-control) **<exclusionary answer>**
   - o Can't tell (need article)
   - o Systematic review or meta-analysis
   - o Economic or decision analysis, modeling **<exclusionary answer>**
   - o Non-research (commentary, review, news) **<exclusionary answer>**
   - o Qualitative research (e.g., focus groups) **<exclusionary answer>**
   - o Guideline or consensus statement **<exclusionary answer>**

This page intentionally left blank

Appendix D: Full Article Review Abstraction Forms Stages 3 and 4 (Exemplar: Diabetes)

This page intentionally left blank

Appendix D: Full Article Review Abstraction Forms Stages 3 and 4 (Exemplar: Diabetes)

Note: Items in *Italics* are topic-specific

Stage 3:

1. Does this article merit abstraction at Level 3?
   - o Yes
   - o No – not QI or not an evaluation of a QI strategy **<exclusionary answer>**
   - o No – study design below Level 2 **<exclusionary answer>**
   - o *No - excluded topic (focused only on pregnancy, Type I DM, or screening)* **<exclusionary answer>**
   - o No – no eligible outcomes* **<exclusionary answer>**

*Eligible outcomes include measure of disease control, provider adherence, or patient adherence. Excluded are: measures of provider or patient understanding, satisfaction, self-efficacy; costs and resource use. Also excluded are articles reporting no outcomes specifically related to diabetes (e.g. smoking only).

2. Does this article present data overlapping with another article?
   - o Exclude this article as a duplicate publication (identify included citation being duplicated) **<exclusionary answer>**
   - o Include this article, but obtain listed citation to help with abstraction (e.g., separate methods paper; identify required citation)
   - o No or N/A

3. What category of study question is addressed by the article?
   - o *Can screening for or awareness of diabetes be improved?*
   - o *Can provider treatment of diabetes be improved? (e.g., increased adherence to recommended care)?*
   - o *Can patient glycemic control or diabetic complications be improved?*
   - o *Can patient adherence, education or self management be improved?*
   - o Not sure or Other (describe)
   - o N/A

4. Describe the QI strategy used and its salient features.

5. Did the QI strategy involve a provider reminder system* or facilitated relay of clinical data ** back to providers?
   - o Chart based reminder system* for providers
   - o Computer based reminder* or decision support for providers
   - o Facilitated relay of clinical data to providers**
   - o Not sure
   - o No or N/A

* Patient or provider encounter specific information, provided verbally, on paper or on a computer screen, which is intended to prompt provider to recall information (e.g., the last time the patient had a HbA_{1c} checked and its value, the last time the patient underwent screening colonoscopy and the result).

** Clinical information collected directly from patients and given to the provider using some format other than the conventional chart system.

6. Did the QI strategy involve provider audit and feedback*?
   - o Confidential feedback to individual provider
   - o Non-confidential feedback to provider and colleagues in same clinic or institution
   - o Public reporting of performance data
   - o Benchmarking**
   - o Not sure or other
   - o No or N/A

*Any summary of clinical performance of health care over a specified period of time. E.g., the percentage of a provider's patients who have achieved or have not achieved some clinical target (e.g., BP or HbA_{1c} in certain range), have or have not been offered some diagnostic test.

**Benchmarking refers to the provision of performance data from institutions or providers regarded as "leaders in the field." These data provide targets for other providers and institutions to emulate.

7. Did the QI strategy involve provider education?
   - o Educational workshops, meetings (e.g., traditional CME), lectures (live or computer based)
   - o Educational outreach visits (Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice)
   - o Distribution of educational materials (Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications)
   - o Not sure or other
   - o No or N/A

8. Did the QI strategy involve patient education or promote self-management?
   - o In-person patient education individually or as a part of a group or community
   - o Distribution of printed or audio-visual educational materials
   - o Patient reminders (e.g., to keep appointments or comply with other aspect of care)
   - o Provision of clinical data back to the patient *(e.g., your most recent HbA1c or lipid panel was such and such)*
   - o Distribution of materials or access to a resource that enhances patients' ability to manage their condition
   - o Not sure or other
   - o No or N/A

9. Did the QI strategy involve organizational change?
   - o Case management, disease management --coordination of assessment, treatment and arrangement for referrals by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider
   - o Adding new members to team *(e.g., adding a diabetes nurse, clinical pharmacist, or nutritionist to clinic)* or creating multidisciplinary teams (creation of a new team of health professionals of different disciplines or additions of new members to the team who work together to care for patients)
   - o Communication and case discussion between distant health professionals (e.g., telemedicine)
   - o TQM/CQI - cycles of measurement of quality problems, design of interventions, implementation and re-measurement
   - o Changes in medical records systems -- e.g. changing from paper to computerized records, patient tracking systems
   - o Revision of professional roles ('professional substitution', 'boundary encroachment') - the shifting of roles among health professionals (e.g., nurse midwives providing obstetrical care)
   - o Increased staffing without changes in roles (e.g., adding more nurses)
   - o Skill mix changes (changes in types or qualifications of personnel - e.g., changing from LVN to RN or RN to NP, but also changing from GP to specialist)
   - o Not sure or other
   - o No or N/A

10. Did the QI strategy involve financial, regulatory or legislative incentives or actions?
   - o Positive or negative financial incentives directed at providers
   - o Positive or negative financial incentives directed at patients
   - o System-wide changes in reimbursement (e.g., capitation, prospective payment, shift from fee for service to salary)
   - o Changes to provider licensure requirements
   - o Changes to institutional accreditation requirements
   - o Not sure or other
   - o No or N/A

11. Did a clinical information system play a role in design or implementation of intervention (regardless of QI strategy type)?
   - o Identification and/or group allocation of eligible patients or providers
   - o Reminders generated by existing clinical information system
   - o Decision support at point of care (e.g., for provider order entry)
   - o Facilitated communication between providers (e.g., generated emails between members of care team)
   - o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
   - o Not sure or Other
   - o No or N/A

12. Who or what was targeted by the intervention?
   - o Patients
   - o Providers (i.e., individual clinicians)
   - o Ambulatory clinics or practices

- o Inpatient units or hospitals
- o Public health systems, healthcare delivery systems, policy makers
- o Not sure or Other
- o N/A

13. Among the target group, what was the number of participants? (i.e., study size)

14. What type of study design was used?
    - o RCT or quasi-RCT
    - o Prospective clinical trial, CBA* or ITS**
    - o Cohort study, retrospective before-after, or time series not meeting ITS definition** **<exclusionary answer for this topic>**
    - o Not sure or other
    - o N/A

*Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgment that control represents a comparable group or setting

** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND at least three time points both before and after

15. What were the outcome types?
    - o Measure of disease control (clinical outcomes, *HbA1c, glucose control, lipids*)
    - o Provider adherence (adherence to a guideline or recommended practice)
    - o Patient adherence
    - o Patient or provider understanding, self-efficacy, empowerment **<exclusionary answer for this topic>**
    - o Not sure or other
    - o N/A

16. What specific measures of disease control were used?
    - o *Serum glucose values (mean or percent of patients in certain range) HbA1c (mean or percent of patients in certain range)*
    - o *Cardiovascular risk factor modification (hyperlipidemia, hypertension, smoking cessation)*
    - o *Microvascular complications (retinopathy, neuropathy, microalbuminuria, foot ulcers)*
    - o *Macrovascular complications (MI, stroke, renal failure, amputation)*
    - o Not sure or other
    - o None or N/A

17. For studies reporting measures of clinician adherence, what specific measures were used?
    - o *Adherence to guideline targets for assessment of glycemic control (e.g., measuring HbA1c at certain intervals)*
    - o *Adherence to recommended screening practices for ophthalmologic complications (e.g., performance of or referral for dilated retinal exam)*
    - o *Adherence to recommended screening practices for renal complications (e.g., checking urine microalbumin)*
    - o *Adherence to recommended screening practices for neuropathy or foot complications (e.g., performance of or referral for foot examination)*
    - o *Adherence to treatment choices for achieving glycemic control (e.g., medication choices)*
    - o *Adherence to guideline targets for managing blood pressure or cardiovascular disease*
    - o *Adherence to recommendations for patient education or counseling re: diet, exercise, smoking, or other lifestyle factors*
    - o Not sure or other
    - o N/A

18. For studies reporting measures of patient adherence, how was adherence assessed?
    - o Laboratory confirmation (e.g., detection of drug or metabolite in blood or urine; including biochemical assays for smoking cessation)
    - o Pharmacy data (e.g., filled or refilled prescriptions)
    - o Specially designed dispensers that record medication use
    - o Home medication counts
    - o Office medication counts (e.g., patients bring in bottles with unused pills)
    - o Patient self report (via interview or survey)
    - o Not sure or other
    - o N/A

Stage 4:

1. Does abstraction of this study require information from methods or results reported in other citations.
   - o Yes (specify)
   - o No

2. Does the article report data for more than one comparison (i.e., should it be abstracted as more than one study)?
   - o Yes (specify which comparison is being abstracted here and which others will be abstracted elsewhere)
   - o No

A) Study Setting and Participants

3. In what country did the study take place?
   - o US only
   - o Non-US (specify)

4. Were the dates of the study period reported?
   - o Yes – give dates exactly as indicated in paper
   - o No – indicate duration of study in month or years if reported.

5. In what setting did the study intervention take place?
   - o Primary care clinic
   - o Specialist clinic (e.g. diabetes or endocrinology practice)
   - o Community
   - o Multiple or Other (describe)
   - o Not stated or not clear

6. Were INCLUDED patients selected on the basis of any of the following?
   - o *Poor compliance with medications or clinic attendance (describe)*
   - o *Poor glycemic control (describe)*
   - o *Presence of specific comorbid conditions or illnesses (specify/describe – e.g., HTN, hyperlipidemia, coronary artery disease, obesity, tobacco use)*
   - o *Presence of specific diabetic complications (specify/describe – e.g., renal failure, albuminuria, neuropathy, retinopathy)*
   - o Other (explain)
   - o None of above
   - o Not applicable (no patient involvement in study – e.g., study of provider-based intervention and provider outcomes only).

7. What type of care was provided to the control population?
   - o No intervention or usual care
   - o Some form of low intensity intervention (describe)
   - o No true control – just two or more different types of intervention (discuss with other reviewers; study may need to be excluded)

B) Study Design

8. What was the study design?
   - o Randomized trial – state method of randomization if described and any descriptive phrases (e.g., “randomly assigned”)
   - o Quasi randomly trial – state basis for treatment allocation (e.g., alternating patients, calendar date, even or odd identification numbers)
   - o Controlled before-after study

9. Did the study have a cross over design? (Patients randomized to a sequence of interventions such as treatment A followed by treatment B in one group B in one group and treatment B followed by treatment A in the other group).
   - o Yes (describe)
   - o No
   - o Not sure – clarify with other review

10. What was the unit of randomization or treatment allocation?
    - o Patient
    - o Episode of care
    - o Clinic day
    - o Provider
    - o Practice
    - o Firm (describe)

- o Institution
- o Community
- o Other

11. For the unit of treatment allocation (above), state sample size in each group (If sample size differs for outcomes, detail differences in "Not stated or not clear" text box):
    - o Control group
    - o Intervention group
    - o Not stated or not clear (explain)

12. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient outcomes analyzed, state sample size in each group: (Use text box for "Not applicable" if sample size for any outcomes reported is different-give details)
    - o Control group
    - o Intervention group
    - o Not stated or not clear

13. If unit of analysis differed from unit of treatment allocation, did authors acknowledge this issue and/or make appropriate adjustments?
    - o Yes (describe)
    - o No
    - o Not applicable (unit of analysis did not differ from unit of treatment allocation)

14. Was the adequate concealment of treatment allocation?
    - o Yes – (unit of allocation was institution, team or professional and any random process explicitly described, e.g., use of random number tables, OR unit of allocation was patient or episode of care and some form of centralized randomization scheme or sealed, opaque, serially numbered envelopes used)
    - o Not clear (only partially meets above criteria) or not stated – specify which
    - o No – inadequate concealment (enrollment of patient in alternation or through use of even/odd identifying numbers OR unit of allocation was patient or episode of care and reported use of any allocation process that is entirely transparent before assignment (e.g., open list of random numbers) OR allocation was altered by investigators, professionals or patients)

15. Were patients blind to intervention/treatments allocation?
    - o Yes
    - o No
    - o Not sure (explain)
    - o Not applicable (patients not actively involved in study – e.g., provider-focused intervention with patient level data obtained retrospectively from charts)

16. Were providers blind to intervention/treatment allocation?
    - o Yes
    - o No
    - o Not sure (explain)
    - o Not applicable – (explain)

17. Do any methodologic aspects of the study design not captured above seriously undermine appropriateness of inclusion?
    - o Yes (explain)
    - o No (use text box to document any non-fatal, but still noteworthy methodological features)

C) Quality Improvement Attributes of Intervention

18. Did the study involve PATIENT Education?
    - o Yes (describe what was taught, where it occurred, duration and frequency of sessions)
    - o No

19. Did the intervention include access to a resource or provision of a device that promoted Patient Self-Management? (excluding patient reminder systems)
    - o Yes (describe)
    - o No

20. Did the intervention involve a PATIENT REMINDER system?
    - o Yes (specify target of reminder – appointments, compliance with meds or recommendations for self-care)
    - o No

21. Did the intervention involve PROVIDER education?
    - o Yes (describe nature of education, who administered the education, how often did it occur, etc)
    - o No

22. Did the intervention involve a PROVIDER REMINDER system?
    - o Yes (describe content of reminders and how delivered)
    - o No

23. Did the intervention involve a Facilitated Relay of clinical information to providers?
    - o Yes (describe type of information – e.g., recent glucose or HbA1c, and method of relaying information)
    - o No

24. Did the intervention involve provider AUDIT and FEEDBACK?
    - o Yes (describe what was fed back, how often, etc)
    - o No

25. Did the intervention involve ORGANIZATIONAL Change (e.g., disease or case management, creation of multidisciplinary teams or expansion of professional roles, TQM/CQI, telemedicine, change in medical record system)?
    - o Yes
    - o No

26. If the intervention involved Disease Management or Case Management, which of the following apply?
    - o Intervention specifically described as involving "case management" or "disease management"
    - o Someone other than physician actively participated in ongoing patient management using guidelines or systematic approach to care (protocols/algorithms to guide practitioner and patient decisions in specific clinical circumstances (specify type of person playing role of case manager)
    - o Person or system actively tracked, scheduled and coordinated patients' appointments
    - o Other basis for describing intervention as disease/case management (describe)
    - o Not applicable – no component of disease/case management

27. Did intervention involve changes to make up of healthcare team or roles of providers?
    - o Yes – Creation of multidisciplinary team, addition of new team member, expansion of roles, automatic referral for periodic visit with specific provider type (e.g., podiatrist or ophthalmologist)
    - o *Revision/expansion of roles or "shared care" (e.g., nurse or pharmacist operated actively managed medications without consulting physician)*
    - o Other (describe)
    - o No changes to team/personnel

28. Did the intervention involve changes to medical records systems?
    - o Change from paper to computerized records
    - o Implementation of computerized provider order entry (CPOE)
    - o New patient tracking system
    - o Other (describe)
    - o Not applicable – No change to medical record system

29. Did intervention involve any type of organizational change not captured by above questions?
    - o Yes (describe)
    - o No

30. Did a clinical information system play a role in design or implementation of intervention?
    - o Identification and/or group allocation of eligible patients or providers
    - o Reminders generated by existing clinical information system
    - o Decision support at point of care (e.g., for provider order entry)
    - o Facilitated communication between providers (e.g., generated emails between members of care team)
    - o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
    - o Other
    - o No role for a clinical information system

D) Results

31. For unit of treatment allocation (e.g., clinics, providers, patients), were results reported for at least 80% of participants?
    - o Yes (state %)
    - o No (state %)
    - o Not stated

32. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient level outcomes analyzed), were results reported for at least 80% of participants?
    - o Yes (state %)
    - o No (state %)
    - o Not stated or not clear
    - o Not applicable (unit of analysis same as unit of treatment allocation)

Measures of Disease Control

33. Did the study report outcomes involving measures of disease control?
    - o *Yes*
    - o *No*

34. Did one measure of disease control involve HbA1c reported as mean and standard deviation in intervention and control groups?
    - o *Yes*
    - o *No*

35. For the outcome of disease control involving mean HbA1c, provide the following information for patients in CONTROL group; indicate not reported by typing "NR"
    - o *Mean HbA1c before intervention*
    - o *Standard deviation for HbA1c before intervention*
    - o *Mean HbA1c after intervention*
    - o *Mean difference between pre- and post-intervention HbA1c values*
    - o *Standard deviation for difference between pre- and post-intervention HbA1c values*
    - o *Not applicable (no measure of HbA1c)*

36. For the outcome of disease control involving mean HbA1c, provide the following information for INTERVENTION group; indicate not reported by typing "NR"
    - o *Mean HbA1c value before intervention*
    - o *Standard deviation for HbA1c before intervention*
    - o *Mean HbA1c value after intervention*
    - o *Standard deviation for HbA1c after intervention*
    - o *Mean difference between pre- and post-intervention HbA1c values*
    - o *Standard deviation for difference between pre- and post-intervention HbA1c values*
    - o *Not applicable (no measure of HbA1c)*

37. Did study report any measures of disease control involving HbA1c outcomes not captured above (e.g. median HbA1c or % of patients with HbA1c in certain range)?
    - o *Yes (describe)*
    - o *No*

38. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in CONTROL group (indicate not reported by typing NR)
    - o *pre-intervention SBP (state mean and standard deviation)*
    - o *post-intervention SBP (state mean and standard deviation)*
    - o *difference between pre- and post-intervention values (state mean and SD)*
    - o *Not applicable - no disease control outcomes involving SBP as mean and SD*

39. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)
    - o *pre-intervention SBP (state mean and standard deviation)*
    - o *post-intervention SBP (state mean and standard deviation)*
    - o *difference between pre- and post-intervention values (state mean and SD)*
    - o *Not applicable - no disease control outcomes involving SBP as mean and SD*

40. For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in the CONTROL group (indicate not reported by typing NR)
    - o *pre-intervention DBP (state mean and standard deviation)*
    - o *post-intervention DBP (state mean and standard deviation)*
    - o *difference between pre- and post-intervention values (state mean and SD)*
    - o *Not applicable - no disease control outcomes involving DBP as mean and SD*

41. For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)
- *pre-intervention DBP (state mean and standard deviation)*
- *post-intervention DBP (state mean and standard deviation)*
- *difference between pre- and post-intervention values (state mean and SD)*
- *Not applicable - no disease control outcomes involving DBP as mean and SD*

42. Did study report any measures of disease control involving blood pressure outcomes not captured above (e.g. median SBP/DBP or % patients with BP in certain range)?
- *Yes (describe)*
- *No*

43. Indicate results for measures of disease control no captured above:
- *Serum blood glucose*
- *Other CV risk factor (e.g. total cholesterol, HDL-C, LDL-C, triglyceride, lipid, smoking, weight)*
- *Microalbuminuria or renal failure*
- *Other microvascular complications (e.g. foot lesions, retinopathy, neuropathy)*
- *Clinical outcomes (e.g. mortality, MI, stroke, amputation)*
- *Other (explain)*
- *Not applicable - no other outcomes of disease control*

Measures of clinician adherence

44. Did the study report outcomes related to clinician adherence?
- *Yes*
- *No – none reported or none in usable form (explain)*

ADHERENCE TO GUIDELINES FOR ASSESSING GLYCEMIC CONTROL USING HBA1C

45. Did one of the outcomes of clinician adherence involve proportion of patient with HbA1c measure at least once during a certain time period?
- *Yes*
- *No – none reported or none in usable form (explain)*

46. For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with HbA1c checked according to stated definition); indicate not reported by typing NR
- *pre-intervention adherence (% patients)*
- *post-intervention adherence (% patients)*
- *difference between pre- and post-intervention values (% patients)*
- *Not applicable - no adherence outcome involving measurement of HbA1c in this format*

47. For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for intervention group:
- *pre-intervention adherence (% patients)*
- *post-intervention adherence (% patients)*
- *difference between pre- and post-intervention values (% patients)*
- *Not applicable - no adherence outcome involving measurement of HbA1c in this format*

48. Did study report any outcomes of clinician adherence involving checking HbA1c that are not captured above?
- *Yes (describe; give results)*
- *No*

ADHERENCE TO OTHER GUIDELINES INVOLVING PERFORMANCE OF LABORATORY TESTS

49. Did the article report outcomes for change in clinician adherence to a guideline for obtaining any lab measurements other than HbA1c?
- *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
- *No - none reported or none in usable form*

50. For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with other lab values checked according to stated definition); indicate not reported by typing NR
- *pre-intervention adherence (% patients)*
- *post-intervention adherence (% patients)*

- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving measurement of other lab values in this format*

51. For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for intervention group:
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving measurement of other lab values in this format*

52. Were there any adherence outcomes for obtaining lab measurements not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)
- o *Yes (list)*
- o *No*

ADHERENCE TO GUIDELINES FOR ASSESSMENT OR MANAGEMENT OF HYPERTENSION AND/OR CORONARY ARTERY DISEASE

53. Did the article report outcomes for change in clinician adherence to a guideline for assessment or management of HTN and/or CAD?
- o *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
- o *No - none reported or none in usable form*

54. For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with stated guideline performed); indicate not reported by typing NR
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format*

55. For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for intervention group:
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format*

56. Were there any adherence outcomes for assesment or management of HTN and/OR CAD not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)
- o *Yes (list)*
- o *No*

ADHERENCE TO GUIDELINES FOR ASSESSMENT OF DIABETIC COMPLICATIONS INVOLVING THE EYE OR FOOT

57. Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of foot exam?
- o *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
- o *No - none reported or none in usable form*

58. For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with feet checked according to stated definition); indicate not reported by typing NR
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving referral for or performance of foot exam in this format*

59. For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for intervention group:
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving referral for or performance of foot exam in this format*

60. Were there any adherence outcomes for referral for or performance of foot exam not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)
- o *Yes (describe)*
- o *No*

61. Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of eye exam?
- o *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
- o *No - none reported or none in usable form*

62. For the adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with eyes checked according to stated definition); indicate not reported by typing NR
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving referral for or performance of eye exam in this format*

63. For adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for intervention group:
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving referral for or performance of eye exam in this format*

64. Were there any adherence outcomes for referral for or performance of eye exam not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)
- o *Yes (describe)*
- o *No*

ADHERENCE TO GUIDELINES FOR PATIENT COUNSELING OR DELIVERY OF PATIENT EDUCATION

65. Did the article report outcomes for change in clinician adherence to a guideline for patient counseling or delivering of patient education?
- o *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
- o *No - none reported or none in usable form*

66. For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group counseled or educated according to stated definition); indicate not reported by typing NR
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving patient education or counseling in this format*

67. For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for intervention group:
- o *pre-intervention adherence (% patients)*
- o *post-intervention adherence (% patients)*
- o *difference between pre- and post-intervention values (% patients)*
- o *Not applicable - no adherence outcome involving patient education or counseling in this format*

68. Were there any adherence outcomes for patient education or counseling not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)
- o *Yes*
- o *No*

69. Did the article report outcomes for change in clinician adherence to any OTHER guideline?

- o *Yes (describe and give results)*
- o *No*

Patient compliance outcomes

70. Describe results for any outcomes involving patient compliance

- o *Compliance with self-care measures (e.g. self-monitoring of blood glucose), complying with diet or exercise, keeping appointments*
- o *Compliance with medications*
- o *Other (describe)*
- o *No patient compliance outcomes*
- o *Not sure (explain)*

71. Use textbox to state any important study features or results not captured above.

72. Has a senior reviewer checked this Level 4 abstraction?

- o Yes - completely (indicate which senior reviewer)
- o Partially (indicate where re-review was left off, i.e. question #)
- o No (indicate any important questions/comments for senior reviewer)
- o Not applicable (first reviewer is a senior reviewer)

References

1. Priority Areas for National Action: Transforming Health Care Quality. Washington, DC: National Academy Press; 2003.
2. National Healthcare Quality Report: Update. Rockville, MD: Agency for Healthcare Research and Quality; 2002 June. Report No.: 02-P028.
3. National Healthcare Disparities Report. Background. 2002 November; Available from: http://www.ahrq.gov/qual/nhdr02/nhdrprelim.htm. Accessed 2003.
4. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
5. Mallon B, Mallon W. Ernest Amory Codman: The End Result of a Life in Medicine. Philadelphia: WB Saunders; 2000.
6. Dickersin K, Rennie D. Registering clinical trials. JAMA 2003;290(4):516-23.
7. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. JAMA 1998;280(11):1000-5.
8. Kohn L, Corrigan J, Donaldson M, Committee on Quality of Health Care in America IoM, editors. To Err Is Human: Building a Safer Health System. Washington, D.C.: National Academy Press; 1999.
9. Wennberg J, Gittelsohn A. Variations in medical care among small areas. Sci Am 1982;246(4):120-34.
10. Wennberg J, Gittelsohn A. Small area variations in health care delivery. Science 1973;182(117):1102-8.
11. Merrick NJ, Brook RH, Fink A, Solomon DH. Use of carotid endarterectomy in five California Veterans Administration medical centers. JAMA 1986;256(18):2531-5.
12. Brook RH, Lohr KN. Efficacy, effectiveness, variations, and quality. Boundary-crossing research. Med Care 1985;23(5):710-22.
13. Roper WL, Winkenwerder W, Hackbarth GM, Krakauer H. Effectiveness in health care. An initiative to evaluate and improve medical practice. N Engl J Med 1988;319(18):1197-202.
14. Krumholz HM, Radford MJ, Wang Y, Chen J, Heiat A, Marciniak TA. National use and effectiveness of beta-blockers for the treatment of elderly patients after acute myocardial infarction: National Cooperative Cardiovascular Project. JAMA 1998;280(7):623-9.
15. Wennberg DE, Lucas FL, Birkmeyer JD, Bredenberg CE, Fisher ES. Variation in carotid endarterectomy mortality in the Medicare population: trial hospitals, volume, and patient characteristics. JAMA 1998;279(16):1278-81.
16. Katzan IL, Furlan AJ, Lloyd LE, Frank JI, Harper DL, Hinchey JA, et al. Use of tissue-type plasminogen activator for acute ischemic stroke: the Cleveland area experience. JAMA 2000;283(9):1151-8.
17. Flum DR, Morris A, Koepsell T, Dellinger EP. Has misdiagnosis of appendicitis decreased over time? A population-based analysis. JAMA 2001;286(14):1748-53.
18. Decline in deaths from heart disease and stroke—United States, 1900-1999.

MMWR Morb Mortal Wkly Rep 1999;48(30):649-56.

19. Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in the United States? Milbank Q 1998;76(4):517-63, 509.

20. Jencks SF, Cuerdon T, Burwen DR, Fleming B, Houck PM, Kussmaul AE, et al. Quality of medical care delivered to Medicare beneficiaries: A profile at state and national levels. JAMA 2000;284(13):1670-6.

21. Wenger N, Solomon D, Roth C, MacLean C, Saliba D, Kamberg C, et al. The quality of medical care provided to vulnerable community-dwelling older patients. Ann Intern Med 2003;139(9):740-747.

22. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The quality of health care delivered to adults in the United States. N Engl J Med 2003;348(26):2635-45.

23. Leape LL. Translating medical science into medical practice. Do we need a national medical standards board? JAMA 1995;273(19):1534-7.

24. Davis DA, Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. CMAJ 1997;157(4):408-16.

25. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. BMJ 1998;317(7156):465-8.

26. Grol R, Grimshaw J. Evidence-based implementation of evidence-based medicine. Jt Comm J Qual Improv 1999;25(10):503-13.

27. Ayanian JZ, Hauptman PJ, Guadagnoli E, Antman EM, Pashos CL, McNeil BJ. Knowledge and practices of generalist and specialist physicians regarding drug therapy for acute myocardial infarction. N Engl J Med 1994;331(17):1136-42.

28. Donohoe MT. Comparing generalist and specialty care: discrepancies, deficiencies, and excesses. Arch Intern Med 1998;158(15):1596-608.

29. Breuer T, Goodman KJ, Malaty HM, Sudhop T, Graham DY. How do clinicians practicing in the U.S. manage Helicobacter pylori- related gastrointestinal diseases? A comparison of primary care and specialist physicians. Am J Gastroenterol 1998;93(4):553-61.

30. Chin MH, Friedmann PD, Cassel CK, Lang RM. Differences in generalist and specialist physicians' knowledge and use of angiotensin-converting enzyme inhibitors for congestive heart failure. J Gen Intern Med 1997;12(9):523-30.

31. van den Berghe G, Wouters P, Weekers F, Verwaest C, Bruyninckx F, Schetz M, et al. Intensive insulin therapy in the critically ill patients. N Engl J Med 2001;345(19):1359-67.

32. Greco PJ, Eisenberg JM. Changing physicians' practices. N Engl J Med 1993;329(17):1271-3.

33. 20 Tips to Help Prevent Medical Errors. Patient Fact Sheet [online]. AHRQ Publication No. 00-P038. 2000 February [cited 2003 November 30]; Available from: http://www.ahrq.gov/consumer/20tips.htm.

34. Mehrotra A, Bodenheimer T, Dudley RA. Employers' efforts to measure and improve hospital quality: determinants

of success. Health Aff (Millwood) 2003;22(2):60-71.

35. Krumholz HM, Rathore SS, Chen J, Wang Y, Radford MJ. Evaluation of a consumer-oriented internet health care report card: the risk of quality ratings based on mortality data. JAMA 2002;287(10):1277-87.

36. Gandhi TK, Francis EC, Puopolo AL, Burstin HR, Haas JS, Brennan TA. Inconsistent report cards: assessing the comparability of various measures of the quality of ambulatory care. Med Care 2002;40(2):155-65.

37. Poses RM, McClish DK, Smith WR, Huber EC, Clemo FL, Schmitt BP, et al. Results of report cards for patients with congestive heart failure depend on the method used to adjust for severity. Ann Intern Med 2000;133(1):10-20.

38. Hofer TP, Hayward RA, Greenfield S, Wagner EH, Kaplan SH, Manning WG. The unreliability of individual physician "report cards" for assessing the costs and quality of care of a chronic disease. JAMA 1999;281(22):2098-105.

39. Deming W. Out of the Crisis: Quality, Productivity and Competitive Position. New York: Cambridge University Press; 1982.

40. Deming W. Sample Design in Business Research (Wiley Classics Library). Hoboken, NJ: John Wiley & Sons Inc; 1990.

41. Juran J. Quality Control Handbook. New York: McGraw-Hill; 1951.

42. Managerial Breakthrough: The Classic Book on Improving Management Performance/30th Anniversary Edition. revised ed. New York: McGraw-Hill; 1995.

43. Quality Planning and Analysis: From Product Development Through Use. 4th ed. New York: McGraw-Hill; 1993.

44. Blumenthal D, Kilo CM. A report card on continuous quality improvement. Milbank Q 1998;76(4):625-48, 511.

45. Gerowitz MB. Do TQM interventions change management culture? Findings and implications. Qual Manag Health Care 1998;6(3):1-11.

46. Shortell SM, Bennett CL, Byck GR. Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. Milbank Q 1998;76(4):593-624, 510.

47. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. N Engl J Med 1990;322(10):707-12.

48. Oliveria SA, Lapuerta P, McCarthy BD, L'Italien GJ, Berlowitz DR, Asch SM. Physician-related barriers to the effective management of uncontrolled hypertension. Arch Intern Med 2002;162(4):413-20.

49. Roger VL, Jacobsen SJ, Weston SA, Goraya TY, Killian J, Reeder GS, et al. Trends in the incidence and survival of patients with hospitalized myocardial infarction, Olmsted County, Minnesota, 1979 to 1994. Ann Intern Med 2002;136(5):341-8.

50. Ellis P, Robinson P, Ciliska D, Armour T, Raina P, Brouwers M, et al. Diffusion and Dissemination of Evidence-based Cancer Control Interventions. Evidence Report/Technology Assessment No. 79 (Prepared by the McMaster University Evidence-based Practice Center under contract no. 290-97-0017). AHRQ Publication No. 03-E032. Rockville, MD: Agency for Healthcare Research and Quality; 2003 May.

51. Grimshaw JM, Shirran L, Thomas R, Mowatt G, Fraser C, Bero L, et al. Changing provider behavior: an overview of systematic reviews of

interventions. Med Care 2001;39(8 Suppl 2):II2-45.

52. Stone EG, Morton SC, Hulscher ME, Maglione MA, Roth EA, Grimshaw JM, et al. Interventions that increase use of adult immunization and cancer screening services: a meta-analysis. Ann Intern Med 2002;136(9):641-51.

53. Stafford RS. Alternative strategies for controlling rising cesarean section rates. JAMA 1990;263(5):683-7.

54. Weingarten SR, Henning JM, Badamgarav E, Knight K, Hasselblad V, Gano A, Jr., et al. Interventions used in disease management programmes for patients with chronic illness—which ones work? Meta-analysis of published reports. BMJ 2002;325(7370):925.

55. Thomson O'Brien MA, Oxman AD, Davis DA, Haynes RB, Freemantle N, Harvey EL. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2000(2):CD000409.

56. Thomson O'Brien MA, Oxman AD, Davis DA, Haynes RB, Freemantle N, Harvey EL. Audit and feedback versus alternative strategies: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2000(2):CD000260.

57. Thomson O'Brien MA, Oxman AD, Davis DA, Haynes RB, Freemantle N, Harvey EL. Audit and feedback: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2000(2):CD000259.

58. Thomson O'Brien MA, Oxman AD, Haynes RB, Davis DA, Freemantle N, Harvey EL. Local opinion leaders: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2000(2):CD000125.

59. Thomson O'Brien MA, Freemantle N, Oxman AD, Wolf F, Davis DA, Herrin J. Continuing education meetings and workshops: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2001(2):CD003030.

60. Alderson P, Bero L, Grilli R, Grimshaw J, McAuley L, Oxman A, et al., editors. Effective Practice and Organisation of Care Group. Oxford: Update Software; 2003.

61. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess 2004 Feb;8(6):iii-iv, 1-72.

62. Kerry SM, Bland JM. Sample size in cluster randomisation. BMJ 1998;316(7130):549.

63. Kerry SM, Bland JM. The intracluster correlation coefficient in cluster randomisation. BMJ 1998;316(7142):1455.

64. Campbell MK, Mollison J, Grimshaw JM. Cluster trials in implementation research: estimation of intracluster correlation coefficients and sample size. Stat Med 2001;20(3):391-9.

65. Torgerson DJ. Contamination in trials: is cluster randomisation the answer? BMJ 2001;322(7282):355-7.

66. Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. Stat Med 2002;21(19):2971-80.

67. Donner A, Piaggio G, Villar J. Statistical methods for the meta-analysis of cluster randomization trials. Stat Methods Med Res 2001;10(5):325-38.

68. Donner A, Piaggio G, Villar J. Meta-analyses of cluster randomization trials. Power considerations. Eval Health Prof 2003;26(3):340-51.

69. Localio AR, Berlin JA, Ten Have TR, Kimmel SE. Adjustments for center in multicenter studies: an overview. Ann Intern Med 2001;135(2):112-23.

70. Frijling BD, Lobo CM, Hulscher ME, Akkermans RP, Braspenning JC, Prins A, et al. Multifaceted support to improve clinical decision making in diabetes care: a randomized controlled trial in general practice. Diabet Med 2002;19(10):836-42.

71. Kinmonth AL, Woodcock A, Griffin S, Spiegal N, Campbell MJ. Randomised controlled trial of patient centered care of diabetes in general practice: impact on current wellbeing and future disease risk. The Diabetes Care From Diagnosis Research Team. BMJ 1998;317(7167):1202-8.

72. Meigs JB, Cagliero E, Dubey A, Murphy-Sheehy P, Gildesgame C, Chueh H, et al. A controlled trial of web-based diabetes disease management: the MGH diabetes primary care improvement project. Diabetes Care 2003;26(3):750-7.

73. Foy R, Eccles M, Grimshaw J. Why does primary care need more implementation research? Fam Pract 2001;18(4):353-5.

74. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362:1225-30.

75. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement.[comment]. JAMA 1999;282(15):1458-65.

76. Davies P, Walker A, Grimshaw J. Theories of behaviour change in studies of guideline implementation. Proceedings of the British Psychological Society 2003;11:120.

77. Logan J, Graham ID. The Ottawa Model of Research Use: revisions, reflections, prospects (unpublished). 2003.

78. Tiffany CR, Johnson Lutjens L. Planned change theories for nursing. Review, analysis and implications. Thousand Oaks, CA: Sage; 1997.

79. Meleis A. Theoretical nursing. Development and progress. 3rd ed. New York: Lippincott; 1997.

80. Merton R. Social theory and social structure. New York: Free Press; 1968.

81. Fawcett J. Analysis and evaluation of contemporary nursing knowledge: Nursing models and theories. Philadelphia: FA Davis; 2000.

82. Smith MJ, Liehre PR. Introduction: middle range theory and the ladder of abstraction. In: Smith MJ, Liehre PR, editors. Middle range theory for nursing. New York: Springer; 2003. p. 1-24.

83. Bacharach SB. Organizational theories: some criteria for evaluation. The Academy of Management Review 1989;14(4):496-515.

84. Rogers E. Diffusion of innovations. 3rd ed. New York: Free Press; 1983.

85. Rogers E. Diffusion of innovations. 4th ed. New York: Free Press; 1995.

86. Lomas J. Retailing research: increasing the role of evidence in clinical services for childbirth. Milbank Q 1993;71(3):439-475.

87. Lomas J. Teaching old (and not so old) docs new tricks: effective ways to implement research findings. In: Dunn E, Norton P, Stewart M, Tudiver F, Bass M, editors. Disseminating research/changing practice. Thousand Oaks, CA: Sage; 1994. p. 1-18.

88. Lomas J. Medicine in context: a neglected perspective in medical

education. Acad Med 1994;69(10 Suppl):S95-101.

89. Tiffany CR. Analysis of planned change theories. Nurs Manage 1994;25:60-2.

90. Tiffany CR, Cheatham AB, Doornbos D, Loudermelt L, Momadi GG. Planned change theory: survey of nursing periodical literature. Nurs Manage 1994;25(7):54-9.

91. Green L, Kreuter M, Deeds S, Patridge, K. Health education planning: a diagnostic approach. Mountain View, CA: Mayfield Publishing; 1980.

92. Green L, Kreuter M. Health promotion planning: an educational and environmental approach. Mountain View, CA: Mayfield Publishing; 1991.

93. Berwick DM. Disseminating innovations in health care.[comment]. JAMA 2003;289(15):1969-75.

94. Logan J, Graham ID. Toward a comprehensive interdisciplinary model of health care research use. Sci Commun 1998;20(2):227-46.

95. Kotler P. Social marketing of health behavior. In: Frederiksen L, Solomon L, Brehony K, editors. Marketing health behavior: principles, techniques and applications. New York: Plenum Press; 1983.

96. Soumerai SB, Avorn J. Principles of educational outreach ('academic detailing') to improve clinical decision making. JAMA 1990;263(4):549-56.

97. Schroeder R, Van de Ven A, Scudder G, Rolley D. Managing innovation and change processes: findings form the Minnesota Innovation Research Program. Agribusiness Manage 1986;2:501-523.

98. Graham K, Logan J. Using the Ottawa Model of Research Use to implement a skin care program. 2003.

99. Donabedian A. The quality of care. How can it be assessed? JAMA 1988;260(12):1743-8.

100. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q 2001;79(2):281-315.

101. Mittman BS, Tonesk X, Jacobson PD. Implementing clinical practice guidelines: social influence strategies and practitioner behavior change. QRB 1992;18(12):413-22.

102. Bandura A. Self-efficacy: toward a unifying theory of behavioral change.[comment]. Psychol Rev 1977;84(2):191-215.

103. Ajzen I. The theory of planned behaviour. Organizational Behaviour and Human Decision Process 1991;50:179-211.

104. Wallston K. Hocus-pocus, the focus isn't strictly on locus: Rotter's social learning theory modified for health. Cognit Ther Res 1992;16:183-99.

105. Conner M, Norman P. Health behaviour. In: Johnston D, Johnston M, editors. Comprehensive Clinical Psychology, vol. 8: Health Psychology. Oxford: Pergamon; 1998. p.1-38.

106. Godin G, Kok G. The theory of planned behavior: a review of its applications to health-related behaviors. Am J Health Promot 1996;11(2):87-98.

107. Godin G, Naccache H, Morel S, Ebacher MF. Determinants of nurses' adherence to universal precautions for venipunctures. AJIC 2000;28(5):359-64.

108. Walker A, Grimshaw J, Armstrong E. Salient beliefs and intentions to prescribe antibiotics for patients with a sore throat. Br J Health Psychol 2001;6:347-60.

109. Blackman D. Operant conditioning: an experimental analysis of behaviour. London: Methuen; 1974.

110. Gollwitzer P. Goal achievement: the role of intentions. In: Stroebe W, Hewstone M, editors. European review of social psychology. Chichester, UK: Wiley; 1993. p. 141-85.

111. Orbell S, Hodgkins S, Sheeran P. Implementation intentions and the theory of planned behaviour. Pers Soc Psychol Bull 1997;23:945-54.

112. Mazmanian PE, Daffron SR, Johnson RE, Davis DA, Kantrowitz MP. Information about barriers to planned change: a randomized controlled trial involving continuing medical education lectures and commitment to change. Acad Med 1998;73(8):882-6.

113. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consul Clin Psychol 1983;51(3):390-5.

114. Prochaska JO, DiClemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. Health Psychol 1993;12(5):399-405.

115. Reimsma R, Pattenden J, Bridle C, Sowden A, Mather L, Walker A. A systematic review of the effectiveness of interventions based on a stages to change approach to promote individual behaviour change. Health Technol Assess 2002;6(24).

116. Scott WR. Organizations: rational, natural and open systems. 4th ed. Upper Saddle River, NJ: Prentice Hill; 1998.

117. Shortell SM, Kaluzny AD. Organization theory and health care management. In: Shortell SM, Kaluzny AD, editors. Health care management: a text in organization theory and behavior. New York: John Wiley and Sons; 1988.

118. Shortell SM, Kaluzny AD. Health care management: organization, design, and behavior. 3rd ed. Albany, NY: Delmar Publishers Inc.; 1994.

119. Kaluzny AD, Hernandez SR. Organizational change and innovation. In: Shortell SM, Kaluzny AD, editors. Health care management: a text in organization theory and behavior. 2nd ed. New York: John Wiley and Sons; 1988.

120. Shortell SM, Kaluzny AD. Health care management: a text in organization theory and behavior. 2nd ed. New York: John Wiley and Sons; 1988.

121. Westphal JD, Gulati R, Shortell SM. Customization or conformity? An institutional and network perspective on the content and consequences of TQM adoption. Adm Sci Q 1997;42(2):366-94.

122. Iles V, Sutherland K. Managing change in the NHS. Organisational change: a review for health care managers, professionals, and researchers. London: NCCSDO; 2001.

123. Shortell SM, Jones RH, Rademaker AW, Gillies RR, Dranove DS, Hughes EF, et al. Assessing the impact of total quality management and organizational culture on multiple outcomes of care for coronary artery bypass graft surgery patients. Med Care 2000;38(2):207-17.

124. Fox R, Mazmanian P, Putnam R. Changing and learning in the lives of physicians. New York: Praeger; 1989.

125. Grol R. Personal paper. Beliefs and evidence in changing clinical practice. BMJ 1997;315(7105):418-21.

126. Kotler P, Roberto E. Social marketing: Strategies for changing public behavior. New York: Free Press; 1989.

127. Scanlon DP, Chernew M, Doty HE. Evaluating the impact of value-based purchasing: a guide for purchasers. Rockville, MD: Agency for Healthcare Research and Quality; 2002 May. AHRQ Publication No. 02-002