



# The Science and Practice of Improving Health Care



# Through the Quality Kaleidoscope: Reflections on the Science and Practice of Improving Health Care Quality

## Closing the Quality Gap: Revisiting the State of the Science

### Structured Abstract

**Background.** The United States devotes significant resources to health care, yet quality is often lacking. In 2004, the Agency for Healthcare Research and Quality launched a collection of evidence reports on quality improvement (QI) opportunities and strategies related to chronic conditions, practice areas, and cross-cutting priorities. This new Closing the Quality Gap series expands the topics examined and marshals the knowledge of eight Evidence-based Practice Centers (EPCs) to synthesize lessons learned and to advance the state of QI science.

**Series topics.** The eight topics are: effectiveness of bundled payment programs, effectiveness of the patient-centered medical home, QI strategies to address health disparities, effectiveness of medication adherence interventions, effectiveness of public reporting, prevention of healthcare-associated infections, QI measurement of outcomes for people with disabilities, and health care and palliative care for patients with advanced and serious illness.

**Data sources and review methods.** Each EPC conducted a systematic review of the peer-reviewed literature. Topic search strategies are available in the individual topic reports. This methods report relies on the final topic reports to highlight common lessons, identify implications for future systematic reviews of complex QI topics, and recommend next steps to advance the QI field.

**Results.** The series collectively assessed the evidence across quality levers and various populations, interventions, outcomes, settings, and contexts. Various approaches were taken to analyze the evidence in meaningful ways for key audiences. The challenges across reports informed approaches for future reviews, including use of logic models, approaches to defining and searching for complex health care interventions, assessment of individual study quality and strength of evidence, meaningful synthesis, and methods for synthesis. Directions for future QI research include the role of systematic review to advance the field, consistent measurement, consistent and complete reporting, a focus on health, understanding of context, and development of a common lexicon for QI intervention.

**Conclusions.** In their innovative review of these complex topics, EPCs faced several common challenges, including difficulty in synthesizing the evidence due to heterogeneity in choice of outcomes measures; limited ability to draw conclusions due to weaknesses in study design and incomplete reporting; and difficulty applying traditional systematic review methods to the multifaceted, context-dependent, systems-level interventions typical of the QI field. Future research will be strengthened by consistent use of a core set of outcomes measures, more robust study designs, more complete reporting of intervention characteristics and contextual factors, and development of additional systematic review methods specific to the QI field.

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# Orientation to the Report

This report examines eight Closing the Quality Gap series topics in order to provide guidance for the future of quality improvement science and practice. It assumes a diverse readership. As a result, the report is organized into chapters and appendixes that may be read separately, depending on a particular reader's interests. The main body is geared toward those interested in the state of quality improvement science and is based on reflections across topics in the series. The report also includes substantive appendixes summarizing findings from each of the topic reports in the series, highlighting key messages for different audiences (patients/consumers and their caregivers, clinicians and health care professionals, leaders of health delivery organizations, and policymakers), and identifying lessons for the research community.

This orientation is meant to facilitate customized navigation of the report, with the goal of meeting the different needs of the potentially diverse readers of this report and the series.

**Introduction to the Series.** The first chapter summarizes the rationale and background for this collection of evidence reports; outlines its framework, Key Questions, and the topic selection process; and provides health care quality context for the series.

**Synthesis Across Topics and Implications.** An indepth discussion of the series as a whole may be found in the second through fourth chapters, including common lessons across topics (second chapter), lessons learned to guide future systematic reviews (third chapter), and implications for the future of the quality improvement field (fourth chapter). Use these sections for integrated thinking about research, practice, and policy aimed at improving the quality of health care. The fifth chapter discusses concluding thoughts.

**Highlights From Series Topic Reviews.** Appendix A contains a summary of each series topic, including highlights from each report, organized by topic and Key Question. Definitions of topic concepts are also included. Use this section to get a sense of what was found from each report or decide whether a particular topic is of interest. A summary across the series is described in a companion report.<sup>1</sup>

**Messages for Key Audiences.** Appendix B highlights take-home messages from each series topic for each of four key audiences: patients/consumers and their caregivers (Table B-1), clinicians and health care professionals (Table B-2), leaders of health delivery organizations (Table B-3), and policymakers (Table B-4).

**Messages To Guide Future Research.** Appendix C highlights, for each of the topics, research gaps (Table C-1), take-home messages for researchers (Table C-2), and take-home messages for research funders (Table C-3). It is intended to help guide future research, especially in ways of practical use to key audiences. Further discussion of future research needs may be found in the third and fourth chapters.

# Introduction to the Series Development

## Problem and Motivation for Series

Despite the significant resources devoted toward health care, high-quality high-value care in the United States remains elusive, with half of patients, on average, receiving suboptimal care.<sup>2-4</sup> Yet quality is improvable.<sup>5,6</sup>

The challenge in achieving quality is conceptual as well as practical. Although most patients have an intuitive sense of what constitutes high-quality care, quality is complex conceptually because it must encompass many different attributes and perspectives (e.g., patient, family, provider, health system, society). The Institute of Medicine (IOM) defined six key dimensions of high-quality care: that it be safe, effective, patient centered, timely, efficient, and equitable.<sup>6</sup> In practical terms, the health care system consists of complex interrelations among people (patients, their caregivers, and providers); organizations (clinics, hospitals, insurers, payers, etc.); technologies (pharmaceuticals, devices, imaging, etc.); and processes (diagnostic workups, treatments, procedures, admissions, discharges, visits, referrals, surveillance, etc.). While challenging to study, these systems must be understood in order to guide effective improvement efforts.

Medical science studies the human body system carefully to understand biologic cause and effect, with the aim of curing or ameliorating illness. Similarly, social science applied to health systems studies the complex web of health services to understand interactions and behaviors, with the aim of improving policy and practice in ways that translate into better health for a society's population. A key question in both medical and health services science concerns the ways that altering one part of a system—either the human body or the health system—produces desired results. The pursuit of better health and health care quality challenges the research field to bridge the gap between medical thinking and social science thinking.

This combined science for improving quality started with early data-driven health care professionals (Semmelweis, Nightingale, Codman)<sup>7-9</sup> and built further with conceptual developments for quality measurement (i.e., Donabedian's structure, process, and outcome framework).<sup>10</sup> Accompanying a focus on measurement, the science of intervention has its own set of potentially applicable theories of behavior change and diffusion of knowledge.<sup>11,12</sup> Intentionally building quality into the health system gained momentum with tools and principles adapted from manufacturing practice (e.g., Shewhart's statistical process control charts, Juran's Total Quality Management, Demings' Continuous Quality Improvement).<sup>13-16</sup> Subsequently, attention expanded to patient safety and high reliability organization ("HRO") thinking,<sup>17-20</sup> then broadened to "implementation science" and "service innovation,"<sup>21,22</sup> including recent concepts of "deimplementation" (removing what is no longer effective practice and organization)<sup>23,24</sup> and improvement leadership methods.<sup>25</sup> This short synopsis of scientific thinking highlights evidence domains pertinent to improving quality—people working to improve quality, data/measurement, evaluation tools, theories/frameworks, interventions, time effects—that weave through this report.

With such an important aim (high-quality health care) and with such a complex target (the health care system), the series offers the expertise of systematic reviewers of the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers (EPCs), who have gathered and synthesized what is known and what remains to be understood across a range of health care quality topics. This report describes the approach undergirding the series and extends the individual topic-level analysis, viewing the evidence through the multiple lenses of the eight



series topics, key stakeholder perspectives (patients, clinicians, health care delivery organizations, and policymakers), and three key quality levers (information, incentives, and infrastructure). Like a kaleidoscope that creates new images through multiple reflections, viewing the quality improvement (QI) field across topics and through multiple perspectives provides a novel view, highlighting complexity and revealing patterns that emerge only through cross-topic synthesis. This report aims to serve as that kaleidoscope, ultimately providing guidance for the future of QI science and practice.

## **Context: Previous Series**

Following an IOM study in 2003 that identified high-priority QI opportunities,<sup>5</sup> AHRQ in 2004 launched a collection of evidence reports to guide QI efforts targeting those areas. Culminating in 2007, that series—Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies—summarized evidence about QI strategies related to diabetes, asthma, hypertension, prevention of healthcare-associated infections, antibiotic prescribing behavior, and care coordination.<sup>8,26-31</sup>

Like its predecessor, this new Closing the Quality Gap series aims to assemble the evidence about effective strategies to close the “quality gap” between what is known to be high-quality evidence-based care and what patients experience on a day-to-day basis. This series not only expands the topic terrain beyond that covered in the initial collection, but also marshals the knowledge of eight EPCs, with the goal of applying and advancing the state of the science for improving the health care system for the benefit of all patients.

## **Closing the Quality Gap Series Response to the Problem**

Both the previous and current Closing the Quality Gap series are intended to inform multiple audiences and serve multiple uses. For example, while leaders of health delivery organizations may be most interested in evidence about effective strategies to improve particular aspects of care, policymakers may care most about how particular strategies can be used to address multiple improvement targets. Both groups may be interested in the resource implications of various improvement strategies. The research community may be most interested in evidence gaps. Clinicians, patients, and their advocates may find value in identifying areas for improvement that fall within their control and understanding more broadly the evidence for quality gaps and QI. All readers of these reports might expect a deeper understanding of the nature and extent of quality gaps, as well as both targeted and systemic changes necessary to close them.

In addition, this series culminates with two reports developed by the series overview investigators—a summary report intended to show how topics relate and complement each other, which is accompanied by the topic executive summaries,<sup>1</sup> and this methods report synthesizing lessons learned that cut across the topics, with the goal of describing the state of the science of QI and the implications for each of the targeted audiences. Thus, this new series is titled: “Closing the Quality Gap: Revisiting the State of the Science.”

## **Topic Selection**

The leaders of AHRQ portfolios on comparative effectiveness, prevention and care management, value, health information technology, patient safety, and innovation nominated topics for inclusion in the Closing the Quality Gap series. In selecting topics, they considered:

- The ability to focus and clarify the topic area
- Relevance to QI and a systems approach
- Amenability to systematic review
- Low likelihood of duplication and/or overlap with other known or ongoing work
- Relevance and potential impact in improving care
- Fit of the topics as a whole in reflecting the AHRQ portfolios.
- Relevance to system and delivery reform provisions in health care reform legislation under the Patient Protection and Affordable Care Act (ACA)<sup>32</sup>

Consistent with AHRQ's mission, particular consideration was given to relevance with respect to current trends in health care and the potential for high impact on patient outcomes. Emphasis was also placed on topics that would provide information for rewarding high-quality care through measurement and reporting, key tenets of the ACA legislation. To be selected for the series, topics needed to be "ripe" for systematic review, which is a tool to build a knowledge base and inform decisionmaking.

## Topics

AHRQ selected eight topics for the current series, which reflect its priorities and portfolios:

- Effects of bundled payment systems on health care spending and quality of care (Bundled Payment), by the RAND EPC<sup>33</sup>
- Patient-centered medical home (PCMH), by the Duke EPC<sup>34</sup>
- QI interventions to address health disparities (Disparities), by the Vanderbilt EPC<sup>35</sup>
- Comparative effectiveness of medication adherence interventions (Medication Adherence), by the RTI International-University of North Carolina EPC<sup>36</sup>
- Public reporting as a QI strategy (Public Reporting), by the Oregon EPC<sup>37</sup>
- Prevention of healthcare-associated infections (HAI), by the Blue Cross and Blue Shield Association Technology Evaluation Center EPC<sup>38</sup>
- QI measurement of outcomes for people with disabilities (Disability Outcomes), by the Minnesota EPC<sup>39</sup>
- Interventions to improve health care and palliative care for advanced and serious illness (Palliative Care), by the Johns Hopkins EPC<sup>40</sup>

In "Priority Areas for National Action: Transforming Health Care Quality," the IOM used a systematic process and available evidence to identify 20 priority areas for focusing efforts to improve health care quality in the United States.<sup>5</sup> These 20 areas informed the clinical topic areas of the original Closing the Quality Gap series and are relevant to the topics of this new series. Like the IOM priorities, the Closing the Quality Gap series topics include clinical topic areas, populations of interest, setting types, and cross-cutting strategies, and also collectively extend across the full spectrum of health care. In addition, the topic areas touch on the further recommendations of the IOM committee regarding disparities, measures development, and evidence review.

The topics of the Closing the Quality Gap series are also relevant to ongoing initiatives in health care, including the National Quality Strategy (NQS),<sup>41</sup> and the system and delivery reforms outlined in the ACA.<sup>42</sup> The NQS established three aims for the U.S. health care system: better care, healthy people and communities, and affordable care. It also identified six priorities for QI, which are reflected in the eight series topics:



- Making care safer by reducing harm caused in the delivery of care (HAI)
- Ensuring that each person and family is engaged as a partner in care (Public Reporting, Disparities, Palliative Care, HAI, Medication Adherence)
- Promoting effective communication and coordination of care (Disability Outcomes, Disparities, Palliative Care, PCMH)
- Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease (Disparities, PCMH, Medication Adherence)
- Working with communities to promote wide use of best practices to enable healthy living (Disability Outcomes, PCMH)
- Making high-quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models (Bundled Payment, Medication Adherence)

The ACA includes many provisions to spur innovation, improve the delivery of health care, and promote the generation and use of evidence in decisionmaking and programs. It also emphasizes health care quality, system efficiency, and costs. Specific provisions related to the Closing the Quality Gap topics include support of the medical home model, bundled payment demonstration projects, data collection on health disparities, development of quality measures, improvement of public reporting of quality and performance, grants to implement medication management services, reducing Federal payment for certain hospital-acquired infections, and continued support of the Aging and Disability Resource Center initiatives. With the ACA emphasis on health care quality and explicit support of evidence-based practices and programs, it is hoped that evidence synthesis of these topics will provide additional information to decisionmakers and other stakeholders as they move forward with these initiatives.

Finally, the focus of some topics, such as Disparities and Disability Outcomes, are specific to priority populations that reflect AHRQ's legislative mandate to improve health care in Medicare, Medicaid, and the Children's Health Insurance Program, as well as ongoing AHRQ activities such as producing the National Healthcare Disparities Report and National Healthcare Quality Report. For other topics, such as HAI and PCMH, the timing of this series allowed teams to build on or complement ongoing work.

## Series Key Questions and Framework

Each topic for the series is broad and requires choices among numerous scope options to balance a wide range of considerations and ultimately yield a report that provides stakeholders with information that is useful, relevant, and actionable for improving quality of care. To help guide this complex scoping task, the topic teams relied on an overarching framework and set of Key Questions common to all topics within the series.

Each topic team considered all scope options in light of specific prioritization criteria that were described by the earlier IOM National Priorities Committee, with the goal of ensuring that the original series reported actionable information that could be used in the near term to achieve improvements.<sup>5</sup> For the current series, these criteria were extended based on additional considerations relevant to the current health care delivery system (e.g., focus on value in health care). The final set of criteria used for the current series were:

- Impact: What opportunities exist for a sizable improvement in patients' health and well-being (the quality gap)? What are the economic implications?

- **Improvability:** What strategies might be expected to reduce quality gaps and improve the value of care delivered?
- **Inclusivity:** What is the relevance of the topic to patients, conditions, or settings that are underrepresented in research?

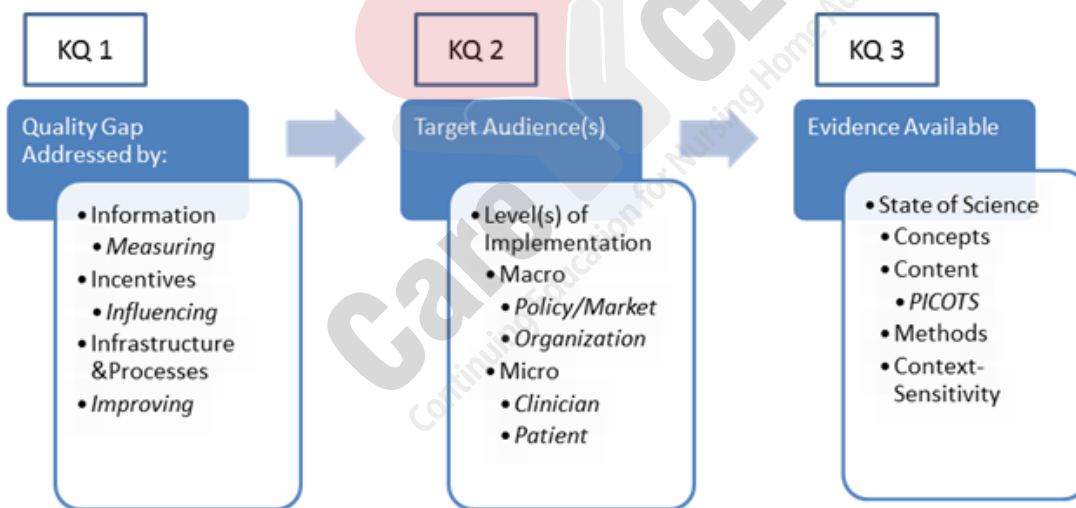
With these criteria in mind, the topic teams used a set of series Key Questions (KQs) to guide their decisions about topic scope, Technical Expert Panel composition, analysis, and reporting (Figure 1).

**KQ1 for the Series:** What are the quality gaps targeted by this review, and how might each gap be approached to lead to improvements?

**KQ2 for the Series:** Who are the likely stakeholders who could act upon each gap, and what evidence will they need? What are the likely levels for implementation of results from the topic report? Consider macro-level audiences (e.g., public policymaking, organizational policymaking) and micro-level audiences (e.g., clinician, patient), and their potential leverage in using the evidence.

**KQ3 for the Series:** From an initial exploration of the potential literature, what is the state of the science for the topic area and gap? What populations, interventions, comparators, outcomes, timing, and setting (PICOTS) are relevant to the topic? How has the topic been studied in terms of concepts (e.g., logic models, relevant theories), methods (e.g., primary data collection study designs available), and context-sensitivity?

**Figure 1. Analytic sequence of Closing the Quality Gap series Key Questions for topic scope development**



KQ = Key Question; PICOTS = populations, interventions, comparators, outcomes, timing, and setting

The first of these KQs examines how each quality gap might be addressed through improvement activities. As shown in the first box of Figure 1, there are three core approaches (“3 I’s”) to achieving improvements. These stem from a quotation from Victor Fuchs, a renowned health care systems researcher, who said that real reform “requires changes in the organization and delivery of care that provide physicians with the *information, infrastructure, and incentives* they need to improve quality and control costs” (italics provided by methods report authors).<sup>43</sup> In today’s complex health system, these leverage points for improvement apply beyond the

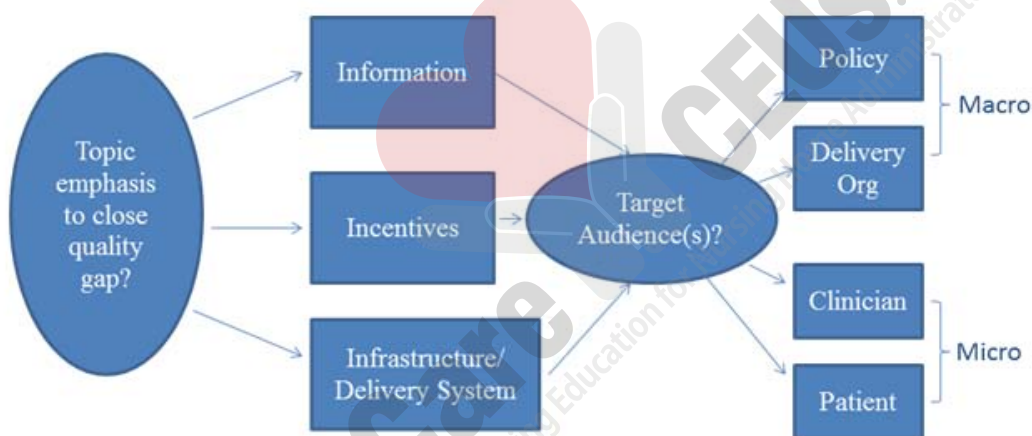
physician to include other clinicians, systems managers, and patients themselves. As a result, these three general approaches are hypothesized to address quality gaps (KQ1) by:

- Measuring quality: gathering *information* or data on quality.
- Influencing quality: creating *incentives* for better quality.
- Improving quality: implementing changes to *infrastructure*, processes, and other elements of the delivery system. (Often interventions in this category are aimed at changing clinician or organizational behavior at a local level.)

For each topic, these approaches may be matched to the applicable target audience(s) at the expected level(s) of implementation (macro or micro), shown in Figure 1 (KQ2). Further, the review of literature about each topic will build from the state of the science (KQ3) available on specific strategies to implement the general approach.

In addition to these KQs developed to help guide decisions about topic scope, we developed an overarching organizational framework for the series to help specify potentially relevant areas of study for each of the topics (Figure 2). This framework depicts the approach used for all topics to summarize important aspects of the evidence. It also conveys the relationships among the topics, helping to identify cross-cutting lessons across topics for QI science. It further helps ensure use of a common lexicon throughout the series.

**Figure 2. Closing the Quality Gap series analytic framework to summarize applicable areas for each topic**



For each series topic, the topic team also considered potential audiences, levers for action, and the state of the science. The topic teams balanced considerations related to stakeholder input about the most relevant interventions, outcomes, and comparisons; ongoing work; feasibility; generalizability; and impact. For example, when considering potential questions and analyses, the team conducting the Medication Adherence review considered including analysis of factors that could potentially affect implementation, such as time limitations, staffing patterns, and expertise in behavior change; intervention characteristics, such as complexity, that might promote or hinder rapid dissemination; the impact of provider type on outcomes; analysis by type of intervention rather than by condition; cost-effectiveness analysis; and a number of subanalyses related to population characteristics, intervention characteristics, and methods of outcome ascertainment. In the end, the review did not include all of these analyses, but rather focused on a broad approach of analysis of interventions across conditions and included observational studies to provide more guidance for strategies to improve health care quality.

The teams also considered the “sweet spot” for their topic, where an evidence review had a reasonable expectation of netting useful information for specified stakeholders who are empowered to act on that information to close the identified quality gap. Stakeholders were specified as end-users of the reports and people who would be impacted by the report or topic. These included patients/consumers, health care providers, health care delivery organizations, policymakers, and researchers. Each topic team engaged a group of stakeholders to provide input during development of topic KQs and the review protocol.



## Cross-Topic Summary

To summarize findings across topics, we filtered the evidence from the topics in three steps and identified overarching cross-topic lessons. First, we assembled a brief structured abstraction of each series report (Appendix A, Topic Findings by Report) to answer the following questions:

- How was the central topic defined for this review?
- What is the quality gap addressed by this topic?
- Who is interested in the topic?
- What evidence are stakeholders seeking?
- What is the scope of the review?
- What were the key findings by Key Question?

Second, for each of the topics, we organized the evidence according to audiences reflected in the series framework: patients/consumers and their caregivers, clinicians and health care professionals, quality leaders from health delivery organizations, and policymakers (Appendix B, Focus on Action: Key Messages for Improving Quality). Third, we further categorized findings from each topic in terms of research gaps, messages for researchers, and messages for research funders, another key policymaker audience (Appendix C, Advancing the Science: Key Messages for Informing Further Research).

These exercises in digesting information from the series reports provide the first cross-topic lesson: every topic has relevance to many different potential players in health care, with potential followup actions possible for those looking to improve quality as well as those wishing to advance the state of the science. All audiences can actively engage in efforts to improve health care quality. While this finding may seem obvious given the high profile of the topics chosen, the likelihood of action is heightened through recognition of how the pieces of evidence link to specific audiences. The series framework demands this type of lens.

Similarly, the series framework posited that the topics could be linked to three quality levers (information, incentives, and infrastructure). In synthesizing lessons learned across topics, we asked: How do the topics relate to each lever? Why is it useful to categorize topics according to the lever for potential action? Often quality improvement (QI) work targets specific interventions, populations, or outcomes, without considering a broader context of actions and responses of people and organizations. By looking at a health care topic from a higher level of analysis, the second cross-cutting lesson emerges: that quality at the scale of a health care system requires action from each lever. We explore this idea in more depth by organizing the topics into the main quality levers to which each relates, while also pointing out some of the spillover between categories.

### Topic Coverage by Quality Lever

The framework for the Closing the Quality Gap series rests on three levers for affecting quality of health care: information, incentives, and infrastructure.<sup>43</sup> The topics in the series each relate to a primary lever (Table 1), with the other two levers often playing a supporting role. For example, the patient-centered medical home (PCMH) is classified as an infrastructure lever because it is a model of primary care delivery, one hypothesized to improve quality through its key components supported through appropriate infrastructure of systems, teams, principles, and processes. However, PCMH does not develop in a vacuum. Commercial payers are creating incentives for this form of care delivery (incentive quality lever). To provide some assurance to payers—and patients—that an organization is delivering care in accordance with the principles

of PCMH, accrediting organizations seek ways to evaluate the “insides” of PCMHs through quality measures (information lever).

**Table 1. Closing the Quality Gap series topics and quality levers**

<b>Information: Measuring Quality</b>	<b>Incentives: Influencing Quality</b>	<b>Infrastructure: Improving Quality</b>
Disability Outcomes	Bundled Payment Public Reporting	Disparities PCMH Medication Adherence HAI Palliative Care

HAI = healthcare-associated infection; PCMH = patient-centered medical home

## Information

The report on Disability Outcomes focuses exclusively on information development, although all of the reports in the series supply information that may be used to improve quality. This review sought to identify measures available and to measure gaps for a specific group of people—those with disabilities—for the purpose of improving the quality of their health care and their experiences with the health care system. Measures shed light on areas where more improvement work is needed. Without measures that reflect the interests of this population, it is less likely that their needs will be met through the care they receive. Furthermore, without appropriate measures, it will be impossible to monitor how the health care system is performing with respect to outcomes that are meaningful and important to people who have disabilities. Evaluating care through outcomes well matched to the population of interest is critical to QI efforts, as ultimately those efforts strive to make improvements in ways that directly and meaningfully benefit patients.

## Incentives

The Bundled Payment and Public Reporting topics focus on incentives to provide high-quality care (care that is safe, effective, patient centered, timely, efficient, and equitable<sup>6</sup>) and make improvements leading to better care, healthy people and communities, and affordable care.<sup>41</sup>

The report on Bundled Payment seeks to examine the influence on organizations of changing the approach to paying for care, and how organizational response to such new incentives either enhances or deters health care quality, including efficiency.

The Public Reporting topic may, at first, seem to fall within the rubric of the information lever. Indeed, the substance of public reporting—quality measures—is information that demonstrates performance of the health care system. However, the focus of this topic is how public reporting of such information affects behaviors of people and organizations in ways that potentially improve the quality of care received by patients. The topic review seeks to answer the questions: How are care seeking and purchasing behaviors affected by reports of health care quality? How is the behavior of a health care delivery organization influenced by the presence of public reports of its quality? Do the behavior changes of individuals seeking, purchasing, or managing care translate to observable improvements in care and outcomes? At the core of these inquiries is the question of whether public reporting incentivizes improvements in the health care system in a way that benefits patients. Information is the centerpiece for the incentive, but the ultimate aim of the evidence report on Public Reporting is to understand how these approaches



affect quality-enhancing behaviors, as well as examining instances of no effect or unintended adverse effects.

## **Infrastructure and Delivery System**

The remaining five reports in the series examine interventions that modify the infrastructures undergirding health care provision, often targeting behaviors. The Disparities, Healthcare-Associated Infections (HAI), and Medication Adherence reports address how organizations can improve these aspects of care and the intervention characteristics associated with successful improvements. The Palliative Care report focuses on interventions to improve the care of one particular population—patients with serious or advanced illness who have few prospects for cure. The final topic focuses on PCMH, an intervention that aims to improve the quality of care through changes in health delivery infrastructure.

## **Patterns Across Reports**

Regardless of quality lever categorization, a third cross-cutting lesson is that interventions and contexts were always complex. To reduce the complexity and develop guidance for future systematic reviews (third chapter) and next steps for the QI field (fourth chapter), it is instructive to look at patterns with respect to five relatively common aspects of the evidence base reviewed for the series: intervention strategies, characteristics of those interventions, the impact of contextual factors on effectiveness of QI efforts, potential harms from QI activities, and QI impacts on health disparities and vulnerable populations.

## **Intervention Strategies**

Seven of the eight series reports examine the effectiveness of QI interventions: three reports focus on a particular type of intervention (Bundled Payment, Public Reporting, and PCMH), while four assess evidence about a wide range of interventions applied to a particular setting or topic area (Disparities, Palliative Care, HAI, and Medication Adherence). Table 2 summarizes the range of interventions examined in these seven reports, using the QI intervention strategy taxonomy developed for the original Closing the Quality Gap series (Appendix D).<sup>8</sup> The Disability Outcomes report focuses on identifying outcomes measures and is not included in the table. This report shares a feature with several of the others by including attention to care coordination as an organizational strategy aimed at addressing quality problems across settings and providers.

**Table 2. Types of quality improvement strategies studied and evidence of benefit for Closing the Quality Gap series topics**

Intervention Type <sup>a</sup>	Bundled Payment	PCMH	Disparities	Medication Adherence	Public Reporting	HAI	Palliative Care
Patient education			■ <sup>b</sup>	■		□	■
Promotion of self-management			□	■		□	■
Patient reminder systems				■		□	
Audit and feedback					■ <sup>c</sup>	■	□
Provider education			□			■	□
Provider reminder systems						■	□
Facilitated relay of clinical data to providers				□ <sup>d</sup>		□	□
Organizational change		■ <sup>e</sup>	□ <sup>f</sup>	■ <sup>g</sup>		■	■
Financial incentives, regulation and policy	■ <sup>h</sup>			■ <sup>i</sup>		□	

HAI = healthcare-associated infections; PCMH = patient-centered medical home

<sup>a</sup>Intervention types based on taxonomy from the original Closing the Quality Gap series (Appendix D).<sup>8</sup>

<sup>b</sup>Language-concordant education.

<sup>c</sup>Public reporting.

<sup>d</sup>Pharmacist or physician access to patient adherence data.

<sup>e</sup>PCMH.

<sup>f</sup>Case management, collaborative care.

<sup>g</sup>Case management.

<sup>h</sup>Bundled payment.

<sup>i</sup>Payment policies, copayment reduction.

Note:

□ Indicates that a particular strategy has been examined for the topic. If applicable, footnotes contain further details of the strategy.

■ Indicates that evidence was found in the topic report for benefit of the strategy.

The Disability Outcomes report did not evaluate the effectiveness of quality improvement interventions and therefore is not included in this table.

The four reviews that focused on interventions in particular settings or topic areas (Disparities, Palliative Care, HAI, and Medication Adherence) included multifaceted interventions, typically with two to five intervention components. The most common types of QI strategies studied were patient education, promotion of self-management, organizational change, provider education, and provider reminders. In most studies the comparator was usual care or no intervention. Due to the number and diversity of interventions, it was difficult to identify the effect of one component in relation to others. As the authors of the HAI report noted, this situation reflects common practice.

Interventions could be targeted at patients, providers, health systems, and/or health policies. In many studies interventions had multiple targets, although most did not target the full spectrum of actors that could potentially impact health care quality. Except in the HAI review, many interventions targeted patients (with or without additional targets). Single-target interventions were typically directed at patients via education, self-management, and reminders. Similar types of interventions, such as education and reminders, were reported in the HAI review, although they were targeted at providers rather than patients.

These four reviews generally found promising results for interventions that included an educational component. Evidence from the Disparities and Medication Adherence reports indicates that tailoring or enhancement may confer benefit, in particular language concordance and visual aids. For the three reports that include interventions targeted to patients or caregivers (Disparities, Palliative Care, and Medication Adherence), self-management and patient education interventions conferred benefits. Organizational change (such as collaborative care, case management, and care coordination) also demonstrated benefit for improving some clinical outcomes or care quality. Interventions that focused solely on the provider as a target tended to demonstrate less benefit, except for HAI.

Inconsistent results were seen for some strategies across the series. In the HAI review, the addition of audit and feedback to baseline strategies (organizational change and provider education) had consistent benefit for lowering infection rates. However, similar results were not found for use of this intervention in the Palliative Care and Disparities reviews, although audit and feedback were less frequently studied in those areas and not necessarily used in conjunction with the same baseline strategies. Public reporting, a type of audit and feedback at a more global and visible level, was associated with a reduction in mortality rates and improvement in quality and process indicators, but the evidence was generally insufficient to draw conclusions about the type of report characteristics that impacted outcomes. While no firm conclusions could be made, the Public Reporting report notes that information that is relevant, readable, and clear is useful for decisionmakers, and that the mode of delivery may affect the use of public reports. However, the studies included in their review either did not or were not able to further analyze characteristics of public reporting; issues such as timing, inclusion of relevant or specific information, and mode of delivery could impact the usefulness and effectiveness of this strategy. Other issues that could contribute to apparent inconsistencies both within an evidence report and across the series pertain to the diversity of study designs included, differences in interventions within a QI taxonomy category and ways they were combined, and the potential impact of contextual factors.

Two reviews in the series, Medication Adherence and HAI, examined the outcome of adherence. Both included interventions focused on a particular target—the patient in the case of Medication Adherence and the health care provider in the case of HAI. Across clinical

conditions, both reviews found that education, reminders, and organizational changes were associated with improved adherence.

## **Intervention Characteristics**

Intervention characteristics were examined in five reviews (Table 3), but for four reviews there was insufficient evidence available to draw conclusions about characteristics associated with effectiveness, and one review (Palliative Care) identified interventions according to targets (pain, communication, transitions) or model of care (integrative or consultative). (Assessments on these dimensions are highlighted in Appendix B.) The Bundled Payment review found no studies that analyzed system effectiveness by intervention design features. Analysis by the topic team found that quality metrics and pay-for-performance incentives were rarely incorporated into bundled payment programs, so the team could not examine the relationship of these features to outcomes. Like Bundled Payment, the Public Reporting review found little quantitative evidence about whether and how intervention features—in this case, characteristics of reports—affected outcomes. However, evidence from qualitative studies suggested that relevance to patients, readability, and clarity of presentation were important to patients' use of publicly reported quality information. The PCMH review examined the aspects of the PCMH model that were implemented in each intervention but did not attempt to determine which combinations of these components were most effective. Although a majority of studies (21 of 27) included all seven major PCMH components within the intervention, the strategies employed to implement those components varied widely (51 different strategies across 27 studies). Like the other three topics, the Medication Adherence review found little evidence that addressed differential effectiveness of intervention features. Across four randomized controlled trials that addressed this research question, there was insufficient evidence about the effects of intervention agent, mode, or intensity on medication adherence. The Medication Adherence review further assessed frequency of specific patient-level intervention components from an existing taxonomy (e.g., knowledge-based activities, awareness-based pursuits, self-efficacy enhancement, and contingent rewards) and novel additional components present in some of the interventions (e.g., shared decisionmaking, gain sharing).

**Table 3. Additional assessment areas explicitly targeted in Closing the Quality Gap topic reports**

Topic	Intervention Features	Context	Potential Harms	Disparities/Vulnerable Populations
Bundled Payment	■	■	■	
PCMH	■		■	
Disparities			■	■
Medication Adherence	■		■	■
Public Reporting	■	■	■	■
HAI		■	■	
Disability Outcomes	N/A	N/A	N/A	■
Palliative Care	■ <sup>a</sup>			

HAI = healthcare-associated infections; N/A = not applicable; PCMH = patient-centered medical home

<sup>a</sup>Features studied were intervention target (e.g., pain, communication, transitions) and palliative care model (integrative vs. consultative).

Note:

■ = Assessment area for this topic report.

## Contextual Factors

Three reviews examined the impact of contextual factors on QI interventions (Table 3). The Public Reporting review found that public reporting more readily led to quality improvements in competitive markets and among low-performing organizations and providers (high strength of evidence). The Bundled Payment review found that few studies reported on contextual factors, but some evidence of low strength suggested that the effect of bundled payments in reducing health care utilization was magnified for for-profit providers and for hospitals under greater financial pressure. The most commonly examined contextual factor was patient disease severity, but results were inconsistent about its impact on the effectiveness of bundled payment programs. The authors of the HAI report analyzed the types of contextual factors reported among the 72 studies included in their review but did not attempt to synthesize evidence about how those factors impacted HAI rates or provider adherence to best practices. Overall, the types of contextual factors examined across these topics varied considerably, ranging from economic considerations (for-profit status, financial pressure, market competitiveness) to patient characteristics (disease severity, age, insurance coverage, health needs) and organizational characteristics (leadership, change, resource availability).

## Potential Harms

Six reviews sought information about potential harms associated with QI interventions (Table 3). In general, little evidence was available about potential harms related to QI interventions for these topics. The Bundled Payment and Medication Adherence reviews found few studies that assessed potential harms, limiting the ability to draw conclusions. There was consistent evidence that single-setting bundled payment programs resulted in care shifting to

other settings. However, the review authors noted that most current bundled payment programs are now multi-setting, which is expected to reduce incentives for care shifting. The Disparities and HAI reviews found no studies that addressed potential harms, while the PCMH review found only two uncontrolled studies that did so. Two studies of Medicare programs that met PCMH inclusion criteria found that when program costs were considered, the overall cost of care was greater for the PCMH intervention. Although the potential for unintended negative consequences of public reporting was widely discussed, the review authors found only limited evidence examining whether those harms actually occurred. Evidence was mixed, but overall the authors concluded that evidence of no harm outweighed evidence of harm. The most widely examined potential harms were related to provider behaviors that could limit patient access to care (e.g., cherry-picking low-risk patients or avoiding high-risk patients), but the evidence was of low quality and yielded mixed results. Results from all six reviews suggest that further research is needed into potential harms resulting from QI activities.

## **Health Disparities and Vulnerable Populations**

In seeking to improve health care quality, interventions have the potential to also eliminate disparities in care (specifically targeting the equity goal of the Institute of Medicine definition of quality).<sup>6</sup> For example, efforts to improve medication adherence may improve outcomes in some populations, such as minorities and patients with low health literacy. Public reporting may hold promise for reducing disparities by improving the availability of relevant information about facilities and providers that are available to vulnerable populations. While one review focused exclusively on the potential for reducing health care disparities through QI interventions, several other series topic reviews also touched on health disparities by examining the impact of interventions in specific patient groups or vulnerable populations (Table 3). Although the available literature was limited, the Disparities review found some promise for improving health outcomes using collaborative care and targeted patient education interventions, particularly among racial minorities. Similarly, medication adherence improved among black patients with diabetes and depression with use of an integrated care intervention, although these results were from a single study. No evidence is available in the Medication Adherence report about the impact of interventions on the uninsured, other minorities, and low-literacy populations. Results were not consistent on the impact of public reporting on vulnerable populations or health care disparities. Although most studies concluded that public reporting did not contribute to reduced access to care for patients or adverse selection of patients by providers (e.g., cherry-picking, cream-skimming), one study found that public reporting appeared to increase the disparity between white and black or Hispanic patients in the receipt of coronary artery bypass graft surgery. In the future, other initiatives such as PCMH could provide additional evidence about benefit in addressing disparities, and the development of relevant outcomes measures for assessing quality of care in disabled populations could facilitate identification and monitoring of disparities.<sup>44</sup> Evidence exists about disparities in the delivery of palliative care; further research is needed into how such disparities may be reduced.



## Implications for Future Evidence Reviews

The Closing the Quality Gap series topics were reviewed by teams from eight Evidence-based Practice Centers (EPCs), each bringing to bear extensive experience with systematic reviews and comparative effectiveness. Although conducting their topic reviews separately, the EPCs were guided by a common methodology<sup>45</sup> and the overarching framework (Figure 2) developed for this series to refine each topic's scope. They were further guided by the series overview investigators in addressing common challenges and adapting methods. The experience of all eight topic teams—combined with the “view from above” afforded the series overview investigators—provides lessons for how to better adapt traditional systematic review methods to complex topics and interventions in future evidence reviews.

All of the topic teams had significant challenges applying aspects of the EPC program Methods Guide to their topics.<sup>45</sup> The traditional method guidance works well for clinical treatments but has not been fully developed to support reviews of topics related to organization and systems interventions. In addition, the experience of leading this series points to the potential need for separating this diverse set of topics into subgroups that might each require different guidance on effective and efficient systematic review methods. The series analytic framework (Figure 2) may be a starting point for organizing subgroups with needs for different adaptations to the Methods Guide, but it does not address the “how” to do reviews for each of these groups. That work remains to be done, although we have insight about what methods areas diverge most from the traditional guidance. The subsequent six lessons target the most pressing methods areas for reviews of complex interventions aimed at improving health care quality.

### Sensible Scoping: Key Questions, Frameworks, and Logic Models for Complex Topics

All of the topic teams experienced significant challenges in molding the scope of their topics (“scoping”). The upfront efforts to refine Key Questions required numerous iterations. The series analytic framework itself (Figure 2) was less useful in this effort than was anticipated, although it did help topic teams stay focused on the potential audiences for their reports. As previously noted, the quality levers (i.e., information, incentives, infrastructure) were most useful for categorizing topics for later cross-topic analysis and summary (as in this methods report). In the future, designating a formal topic refinement phase prior to the systematic review phase may be a crucial step for such complex topics in order to shape the topic with input from a panel of experts/stakeholders and the public.<sup>46</sup> It also would provide time to explore the feasibility of the proposed topic scope in light of the allotted timeframe, available resources, and stakeholder needs.

While the series analytic framework's quality lever categorization may not have helped the topic teams with their scoping efforts, we observed common challenges and adjustments to the traditional methods for topic scoping for the infrastructure and incentive lever categories. This observation suggests that some common adaptations of the traditional EPC review methods may be possible for future topics that fall within these categories. In particular, the teams for the Disparities, Palliative Care, Patient-Centered Medical Home (PCMH), Healthcare-Associated Infections (HAI), and Medication Adherence topics (infrastructure category) had the benefit of adopting methods for defining health care quality interventions that were developed as part of the original Closing the Quality Gap Series, such as use of the quality improvement (QI) strategies

taxonomy for describing interventions targeted at patient, provider, or organizational behavior change (Appendixes A and D).<sup>8</sup>

Traditionally, the EPCs have used the PICOTS categories, which identify population, intervention, comparator, outcomes, timeframe, and setting to guide scoping of systematic review topics.<sup>45</sup> These categories assure appropriately comprehensive formulation of inclusion and exclusion criteria for the review. Developing an analytic framework further supports specification of each element of PICOTS. EPCs create the analytic framework to show how an intervention is hypothesized to influence a population's outcomes. However, the topic teams for this series found that the PICOTS categories did not completely cover their scoping needs. Indeed, many of the teams went beyond an analytic framework specifying PICOTS for their topics and developed a logic model hypothesizing mechanisms through which interventions and context interact to impact outcomes. Both of the incentive quality lever topics developed logic models showing the sequence of influences of information or payment structures, first on care delivery organizations, then on individuals acting within those organizations, and ultimately in potential effects on patient behavior and outcomes. Both of their logic models also included design features and characteristics of the payment bundle or public report as a distinct set of variables to collect. The Bundled Payment logic model was adapted from a previous EPC review on quality-based purchasing.<sup>47</sup> Future methods guidance could provide a catalog of logic models used in systematic reviews for these types of incentive interventions and determine common elements to include for future reviews.

Teams for several of the infrastructure topics also developed logic models to help guide their reviews. The Disparities team developed a simple model hypothesizing how QI interventions may change processes or outcomes for selected conditions or populations, thereby reducing disparities with respect to those outcomes. The PCMH team developed a model hypothesizing mechanisms by which comprehensive PCMH interventions impact outcomes. The HAI team adapted a logic model from Shekelle and coauthors to hypothesize how organization and health system factors, patients, settings, clinicians, system leaders, and characteristics of QI strategies interact to impact first care processes and then outcomes, including economic outcomes.<sup>48</sup> The Medication Adherence team developed a model of interactions among patients, interventions, modifying effects of intervention characteristics, medication adherence, and ultimately outcomes. This model also included adverse events in the causal chain, as did the Public Reporting, Disparities, and PCMH models.

Logic models describe the ways in which an intervention is hypothesized to achieve specific changes through a causal chain of actions and effects.<sup>49</sup> These models enrich the typical EPC analytic frameworks by incorporating factors beyond the clinical logic (e.g., adding intervention component logic, potential interactions with context surrounding the intervention, and broader sets of outcomes of QI efforts that are likely to be of interest to multiple stakeholders). Incorporating a logic model into the scoping exercise acknowledges its fundamental importance in identifying and assessing the potentially complex evidence base for these types of topics. It also facilitates generalization of evidence from one intervention, setting, or context to another by helping elucidate the mechanisms through which QI activities achieve change (or fail to do so). This, in turn, can help QI practitioners select interventions that are likely to be effective in their own particular circumstances.<sup>49,50</sup> For example, the logic model developed for the Public Reporting review postulated that improvements in health care quality might be achieved both through changes in patients' behavior (e.g., through choice of providers) and through changes in health care delivery structures and processes (e.g., engaging in QI activities, changing policies or

guidelines). Evidence from the review supported the hypothesis that providers and systems administrators make changes in response to public reporting, but the review found little evidence that patients changed their behavior in response to publicly reported information. Evidence from qualitative studies provided further insight, suggesting that the lack of behavior change by patients may be explained by frequent mismatches between report content, format, and timing and patients' informational needs at the time they make various health care decisions. By identifying two distinct mechanisms through which public reporting is hypothesized to lead to quality improvements, the logic model, combined with this evidence, points to two avenues for achieving quality gains through public reporting: by targeting reporting initiatives to providers and administrators, and by carefully matching report content, format, and timing to patients' informational needs. The evidence also suggests ways in which the logic model may be refined (e.g., specifying patient decision points), furthering a cycle of theory, testing, and refinement.

Thus, in the case of these complex topics directed at health care quality enhancement, we recommend extending the PICOTS categories to add an "L" for "logic" model and prioritizing this category right after consideration of the population whose health is of interest. We further recommend adding a "C" for context,<sup>48,51</sup> given the potentially important impact of contextual factors on the effectiveness of systems-level interventions. The acronym for health care quality reviews would then become "PLICCOTS," although a simpler naming convention would be desirable as a mnemonic. The overarching question is: For a defined *population*, what is the *logic* argument that a complex *intervention* works better than its *comparator* in a given *context* to produce *outcomes* (of interest to QI) within a *time* period and *setting*?

## Challenges in Defining Complex Health Care Interventions and Concepts

Differences in the definitions and terminology used for key concepts within the universe of health care QI research pose an additional challenge to systematic reviewers. For this series, topic teams typically developed statements to define their concepts and then searched the literature to find evidence relevant to the underlying meaning of those statements, even when the specific terminology used varied. For example, the PCMH review authors searched for and included studies that were judged to meet the intervention definition but did not necessarily use the term "medical home." The merit of this approach is reflected in the fact that this "search by meaning" strategy more than doubled the relevant literature identified, compared with a "search by term" strategy. Future systematic reviewers may expand the yield of literature searches through similar "search by meaning" methods.

A related challenge lies in the different ways in which a single term can be used by different groups. Concepts and definitions of QI itself vary. The Closing the Quality Gap series took a broad view of QI interventions as those that could be described as aimed at improving quality, with quality defined according to the Institute of Medicine's very inclusive definition of care that is effective, efficient, patient centered, timely, safe, and equitable.<sup>6</sup> However, some of the peer reviewers of the series reports conceptualized QI more narrowly, focusing on distinctions between activities that do and do not typically require research regulatory oversight (i.e., review by an Institutional Review Board). The U.S. Department of Health and Human Services has provided guidance and considers "quality improvement" as work using tested interventions to improve care or using data for clinical or administrative purposes, as opposed to "research" designed to develop or contribute to generalizable knowledge.<sup>52,53</sup> Far from being abstract, this type of semantic ambiguity impacted the series reports. For example, in response to peer review

discomfort with the QI terminology, the authors of the Palliative Care review revised the way they referred to their topic as “health care and palliative care” interventions to improve quality and patient outcomes.

Similarly, the HAI team specified terminology to distinguish preventive interventions from QI strategies in response to expert and stakeholder confusion about the continuum of conceptual leverage points for improving quality and assessing evidence. The team took the preventive intervention (the infection control practice demonstrated to reduce the incidence of HAI) as a given and pointed to other sources for that evidence. Their review assessed QI strategies targeted toward effective adoption of these preventive interventions. Their QI strategy definition drew from the earlier Closing the Quality Gap series.

Given ambiguity in the use of terminology within the QI field, future systematic reviews will be strengthened by addressing that ambiguity in research publications by clearly defining core concepts, explicitly calling out any definitional ambiguity within the body of literature reviewed, and placing reviews in the context of alternative conceptualizations.

## **Assessing Individual Study Quality**

The paucity of existing tools to evaluate such a diverse set of heterogeneous studies created a challenge for the series topic teams in trying to assess the quality of individual studies included within their reviews. In addition, when tools were available, uneven reporting of important aspects of the primary studies limited the investigators’ ability to accurately assess study quality.

For example, the HAI team spent significant time developing strategies to assess statistical analyses conducted in the primary studies included within their review. The Public Reporting team also noted that the usual EPC Methods Guide procedures for assessing study quality did not apply to the designs of all the primary studies included within their review, necessitating development of additional criteria.<sup>45</sup> They then needed to evaluate how consistently the adapted criteria were applied by data abstracters before proceeding with the full review. The Palliative Care team found that many studies had small sample sizes, reported only on specific aspects of outcomes, or reported differential findings across multiple outcomes. Even if tools were available for thorough quality assessment of complex health services interventions (and thus far, they are not), most series topic teams found that studies often lacked detail about methods that would be needed for a complete assessment of quality.

Systematic reviews identify important gaps in the available literature. Future systematic reviews can improve research by continuing to report on weaknesses in the underlying evidence base contributing to evidence gaps, and ways to address these weaknesses to strengthen the evidence base. Improving tools for assessment of study quality can provide an accurate, systematic, and transparent way of assessing the quality of the evidence base. Until these quality assessment approaches are available for QI topics, systematic reviewers should continue to thoughtfully adapt existing tools, and report such adaptations and the rationale in a transparent manner in reports.

## **Assessing Strength of the Evidence**

The series topic teams also found that although the EPC Methods Guide offered a starting point for assessing strength of evidence across studies, it required adaptation for the complex body of literature on QI of health services.<sup>45</sup> In particular, the Bundled Payment team found little guidance available for gauging the strength of evidence related to payment interventions. Another challenge that cuts across series topics was highlighted by the HAI team, which found

evidence of publication bias wherein only positive results appeared to be published. The literature in this field also appears to be susceptible to reporting bias, making it difficult to determine whether published studies are presenting all of the interventions and outcomes that were explored. The topic teams at each EPC used general principles to make strength-of-evidence assessments, but further research and development are needed to create tools that guide assessment of both quality of individual studies, as noted above, and overall strength of a body of evidence when synthesizing literature pertaining to complex QI interventions. Ultimately, an adaptation is needed of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group system,<sup>54</sup> similar to that proposed in a methods report on patient safety practices,<sup>48</sup> that would answer the question: Does this evidence help me decide whether I can implement this QI intervention in my organization (or other sphere of influence) and get a similar result?

## Meaningful Synthesis and Audiences

Whether a patient or a policymaker, a physician or a hospital manager, each individual with a stake in health care quality needs systematic reviews to present accurate and actionable evidence. Providing meaningful synthesis for key audiences has been a priority for both the individual reports in the series and for this report. While these are simple marching orders to the systematic reviewer, meeting this goal with the available scientific base is tough to do. The topic teams for this series used some innovative approaches to meet this challenge, which could be considered for future systematic reviews on QI topics.

For example, when quantitative studies were largely lacking, the Public Reporting team used qualitative research to address the question of how report characteristics influence the effectiveness of public reporting initiatives. Although not assessed for strength or quality, this qualitative evidence provided readers with a starting place to understand what report characteristics might be important to consider in designing or evaluating a public reporting initiative. Future reviews that include and synthesize qualitative research may improve the applicability of findings and shed light on the impact of various contextual factors.

The rapid growth in evaluations of the PCMH model presented a challenge to the team reviewing that topic, one they met by incorporating a “horizon scan” of upcoming research into the scope of their review. Audiences could then see where evidence is forthcoming to fill gaps identified in the review and could use this information to inform future research and evaluations.

In another example, the HAI and Medication Adherence teams evaluated the effectiveness of interventions both with respect to care processes (e.g., adherence to HAI-prevention best practices, improved medication adherence) and to patient and system outcomes (e.g., infection rates, symptoms, biomarkers, health care utilization), addressing the presumed causal chain between key care processes and ultimate outcomes. Further elucidating the causal chain, identifying enabling factors, and assessing the evidence for these relationships in systematic reviews will better inform the choice of interventions and their application.

To help organize diverse and heterogeneous bodies of literature, the topic teams grouped studies into clusters likely to be meaningful to their audiences, such as evaluating public reporting initiatives by setting (e.g., hospital, long-term care), evaluating medication adherence interventions by medical condition, and structuring findings by targeted outcome (e.g., distress for palliative care). Future reviews could consider other ways of grouping studies, such as the theoretical underpinnings of interventions based on models and/or frameworks relevant to key



stakeholders. These approaches to synthesis and reporting help those who may implement the evidence understand its applicability to their context.

## **Methods for Synthesis**

In addition to the challenges in defining complex interventions, the topic teams faced challenges in methods of synthesis. They encountered complexity in the systematic reviews with respect to the multifaceted nature of interventions, diversity of study designs, variation in the inclusion of contextual factors, and differing models of implementation. All these factors contribute to heterogeneity in results, limiting the ability of topic teams to quantitatively synthesize evidence. The teams took different approaches to managing this complexity and synthesizing the evidence in logical ways.

Based on this experience, the topic teams identified areas for methods development to improve future reviews and their ability to answer questions relevant to decisionmakers. They indicated the need for methods adapted to the QI field; such areas could include accounting for extreme heterogeneity in intervention designs, features, context, and implementation strategies, and inclusion of qualitative research or mixed-methods studies.





## Quality Improvement: Next Steps in an Evolving Field

The Closing the Quality Gap series offers insight about challenges—and potential solutions—in performing systematic reviews of complex quality improvement (QI) interventions by including diverse topics that address each of the three main levers for improving quality (information, incentives, and infrastructure). In addition, this series provides a window into the “state of the science” for the field of QI research. In this chapter, we discuss five current challenges facing the QI research community that are apparent from review of the eight series topic reports and propose steps that may help advance this rapidly evolving field. Some of these insights echo those aimed at future systematic reviews, but apply especially to primary research studies and the practical needs of those working to improve quality.

### Advancing the Field Through Evidence Synthesis

Many topics included in this series are at early stages of scientific exploration, and theories about the mechanisms through which QI initiatives lead to improvements are still evolving. For example, the patient-centered medical home (PCMH) review focused on one particular model for care delivery—the patient-centered medical home—and found that many investigations exploring the effectiveness of the model overall and its various component parts are just getting underway. Those studies that have already been published vary greatly in their implementation of PCMH components, underscoring the still-evolving nature of the PCMH model. The topic team estimated that the amount of evidence relating to the effectiveness of PCMH as a delivery model will more than double in the next few years. Both the Disability Outcomes and Disparities teams also found an evidence base that is early in its development. The Palliative Care team found that theoretical underpinnings for improvement strategies targeted at patients with advanced and serious illness were frequently lacking and suggested that future improvement efforts incorporate theory from the QI field. Authors of the Bundled Payment report found that implementations of this payment model are shifting from predominantly single-setting designs to more complex multiple-setting initiatives, but that the literature base on bundled payment has not yet caught up to this shift.

Although reviewing the literature related to topics in an early stage of theoretical and evidentiary development can yield only preliminary evidence, it will help to improve the quality of future evidence by identifying knowledge gaps, providing an organizing framework for subsequent reviews, and suggesting best practices for future evaluations. Ultimately, the aim is to guide further primary research and enable future evidence synthesis that will be able to address, not just whether particular improvement models are or are not effective, but *why* and under what circumstances they are effective. Addressing those questions will require further development of theoretical models that concern mechanisms for achieving systems change.

Other reports in this series, in particular Public Reporting, healthcare-acquired infections (HAI), and Medication Adherence, addressed “hot topics” with a more established body of literature but for which many combinations and permutations of improvement approaches have been tried, such that there are often only one or two studies of the same approach. For such topics, systematic reviews contribute to hypothesis generation about components to test together or singly as the theory and implementable solutions evolve through further well-directed research. Including some information from qualitative research within reviews, as the Public Reporting reviewers did, can also contribute to hypothesis generation and development of change theory. For example, information from patient interviews and focus groups identified

shortcomings in many current public reporting initiatives that limited their usefulness to consumers. This qualitative evidence suggested aspects of public reports that should be evaluated in future investigations, and also hinted at how and why consumers might use publicly reported information for making particular health care decisions. In this way, the review suggested avenues for further exploration of the role of consumer behavior in improvement efforts, in addition to the primary objective of synthesizing evidence about the effectiveness of various public reporting initiatives.

## The Challenge of Measurement

All eight reviews in this series were limited in their ability to synthesize the available evidence and draw conclusions across studies, in part by the extreme heterogeneity in outcomes measured. Studies varied widely, not just in the choice of specific outcomes reported but also in how those outcomes were measured. For example, medication adherence was, by definition, an outcome in all studies included in that topic review, but synthesis was hampered by the great variability in how medication adherence was defined across studies. The Palliative Care review found a wide variety of outcomes reported across studies, including pain, symptoms, distress, patient and family satisfaction, quality of life, and health care utilization. A number of these outcomes are patient centered and therefore aligned well with quality concepts. However, this heterogeneity, along with broad differences in interventions and study designs, limited the review authors' ability to draw conclusions across studies and to quantitatively assess the strength of evidence. They also noted that many studies reported multiple outcomes but rarely designated a single primary outcome as the focus of the study, diluting assessments of intervention effectiveness.

Across all topics, we see the need for more coordinated efforts at measure development. While much of the current research includes commonly measured outcomes such as patient satisfaction, health care utilization, and quality of life, variability across studies in how these concepts are defined, as well as which of these common outcomes are reported in particular studies, continues to limit comparative synthesis. More consistent use of particular outcomes—those most pertinent to a particular topic—would better facilitate comparative synthesis across studies. The experience of this series suggests that QI research would greatly benefit from efforts to develop a core set of clearly defined and fully specified outcomes measures. Some such efforts are underway, such as development of a core set of children's health care quality measures for use by Medicaid and the Children's Health Insurance Program,<sup>55</sup> development of a set of measures for use in Medicaid-eligible adults,<sup>56</sup> and prioritization of outcomes in comparative effectiveness research on services and care coordination for people with disabilities.<sup>57</sup> These proposed sets include a mix of process and outcomes measures; outcomes typically relate to health care utilization (emergency department visits, hospitalizations, and readmissions) but also include some measures of patient experience. Efforts to harmonize measurement for other commonly used outcomes, such as quality of life, would further benefit the field. Consensus-based measures of economic outcomes are also particularly needed. Less commonly reported in QI research, but also important, are measures applicable to the equity dimension of quality and therefore applicable to disparity reduction. The reports in the series may offer a starting point for consensus development, or at a minimum, provide a one-stop shop to see which previous measures have been used more frequently in primary studies of these topics.

In addition to outcomes that apply across a broad range of patient populations, care processes, and systems, particular areas with a large number of research studies, such as PCMH

and medication adherence, would further benefit from a topic-specific core measure set. Recently, the Agency for Healthcare Research and Quality led efforts to develop a core set of process measures for care coordination, another complex context-dependent topic related to QI via infrastructure.<sup>58</sup> The resulting measure set is limited by weaknesses in the underlying measures. Only existing measures were considered; no new measure development was undertaken. However, this preliminary effort demonstrates how even a provisional measure set can provide a starting place for more consistent measurement while efforts to develop new measures or refine existing ones are underway. The care coordination measurement effort began with a systematic review and environmental scan of available measures similar to the Disability Outcomes review included in this series. The Disability Outcomes review and other series reports (e.g., Palliative Care, Medication Adherence, PCMH) even included aspects of care coordination in their scope. Similar efforts to review and evaluate outcomes measures for wide application in QI research could benefit the field.

While including at least one of a core set of outcomes would greatly facilitate comparative synthesis across studies, use of standardized measures from a core measure set must be balanced with the need to tailor outcomes measures to the research questions and goals of particular QI efforts or research studies. Across series topics, results were often mixed for different outcomes evaluated. This was particularly true for the Bundled Payment review, which found that both the magnitude and direction of effects varied within and across studies that used different quality measures. Likewise, the Palliative Care review found that many interventions improved some, but not all, outcomes measured, and the Medication Adherence review found that only a subset of the interventions that improved adherence also improved other outcomes.

These results underscore the importance of selecting outcomes measures that closely match intervention goals for researchers. Choice of outcomes should also include consideration of the many different stakeholders involved in care, while staying centered on the needs and values of the population under study. The authors of the Disability Outcomes review especially emphasized this point, noting that the professional perspective of study leaders (e.g., medicine, rehabilitation, social support) tended to influence the choice of outcomes in disability research, with important implications for whether a particular intervention was shown to be effective. They cautioned that choice of outcomes can contribute to health care disparities if the outcomes are not aligned with the values and needs of the population under study. If developed, a core set of outcomes measures for use in QI research should include input from a wide range of stakeholders, cover a broad scope of potential outcomes of interest, and serve as a set of standardized options from which researchers can select individual measures as needed.

## **Improving Study Quality**

Across all eight series topics, study quality was modest at best. Only a handful of individual studies were rated as high quality (with minimal risk of bias), and among all eight reports, only two conclusions, both related to contextual factors impacting effectiveness of public reporting, were based on high strength of evidence. The HAI review found that the quality of studies had increased between the previous review in 2007 and the update for this series, but overall quality still had ample room for improvement. All of the reports that evaluated interventions (excluding Disability Outcomes) noted a need for more rigorous study designs within their topic areas (Table 4), including greater use of randomized controlled trials (HAI) or quasi-experimental or natural experiment designs (Bundled Payment, PCMH, HAI); use of appropriate comparison groups (Bundled Payment, Disparities); incorporating multiple preintervention and

postintervention measurements into before-after studies; and, when possible, conducting interrupted time series analyses (Bundled Payment, HAI); using longer followup periods (Bundled Payment, HAI, PCMH, Medication Adherence); increasing sample sizes and participant retention (Palliative Care); controlling for confounding factors (Bundled Payment, Public Reporting, HAI); and adjusting for clustering of patients within providers, clinics, hospitals, or other health care delivery organization units (PCMH) (Table 4). Other recommendations to advance the state of the science are discussed below under Consistent and Complete Reporting.

**Table 4. Recommendations for improving the quality of evidence across Closing the Quality Gap series topics**

Topic	Use More Rigorous Study Designs	Investigate Harms	Report/Examine Context	Report/Examine Intervention Features	Study Additional Subgroups
Bundled Payment	■	■	■	■	■
PCMH	■	■		■	■
Disparities	■	■			■
Medication Adherence	■	■		■	■
Public Reporting	■		■	■	
HAI	■		■		
Disability Outcomes	N/A	N/A	N/A	N/A	N/A
Palliative Care	■		■	■	■

HAI = healthcare-associated infections; N/A = not applicable; PCMH = patient-centered medical home

Note:

■ = Recommended in this topic report.

Overall, the low to moderate strength of evidence found across the eight series reports speaks to the immaturity of the QI and implementation science fields, where standards for robust study design continue to evolve. The authors of the HAI report noted that, although randomized controlled trials are considered the gold standard for demonstrating efficacy of medical treatments, they may be less applicable to QI research, where complex context-dependent interventions are typically applied at a system level rather than at the level of the individual patient or provider. Similarly, the authors of the Public Reporting review suggested that further methodologic research is needed to adapt the tools of comparative effectiveness research from the clinical research domain, where they were developed, to the QI and health services research domains. The experiences of all eight topic teams for this series support both these recommendations and echo many others in the somewhat overlapping patient safety, QI, and implementation fields. An additional weakness ripe for further methodologic development is achieving sufficient statistical power with relatively few intervention units (e.g., hospitals, clinics, health systems) for organization-level interventions.

While calling for continued improvement in study quality, we also acknowledge that a tension exists between calls for more research, better study designs, and more detailed reporting of primary studies and recognizing the inherent challenges of developing robust, thorough, and abiding insight about complex interventions.

## **Consistent and Complete Reporting**

A common challenge across the evidence reports was uneven reporting of important aspects of the primary studies, such as descriptions of how the study was conducted, interventions, and comparators. This presented challenges in assessing study quality and categorizing interventions. Journal space is often limited, and authors make different choices about what to report. Applicable reporting guidelines, such as Standards for Quality Improvement Reporting Excellence (SQUIRE),<sup>59</sup> are followed by an increasing number of journals. Such incentives for more standardized reporting often provide an important foundation for the development of quality assessment tools.

Other recommendations to advance the state of the science for the series topics included systematically reporting potential harms from QI interventions; studying additional patient subgroups, in particular vulnerable populations at risk for health disparities; and more thoroughly reporting and examining the impact of context and intervention features on effectiveness (discussed below). In addition, reporting the theoretical basis or use of models in the development and description of interventions may assist with synthesis. Reporting such information will improve our understanding of the effectiveness and applicability of interventions under various circumstances.

## **Health Care as a Means to Health**

Ultimately, efforts to improve the quality of health care aim to improve health; the importance of generating evidence about patient-centered outcomes cannot be overstated. While all topic reports in the Closing the Quality Gap series included patient-centered outcomes, many identified gaps in the evidence. When reported, clinical outcomes were generally short term, limiting reviewers' ability to comment on sustainability and long-term improvements in health. More often, intermediate outcomes and process outcomes were reported. The topic reports noted instances in which the lack of evidence about the association between intermediate and clinical outcomes limited conclusions.

Influences on health go beyond health care. While the focus of this series is on health care quality, many reports in the series noted the importance of examining contextual factors in future research. Viewing health care within a broader context may inform future efforts in developing and implementing interventions. Generating evidence to improve our understanding of the relationships among intermediate outcomes, clinical outcomes, and other health influences, such as social context and environment, will improve our understanding of how to better intervene to improve health.

## **Understanding Context**

The evidence base is growing about the importance of context for quality and patient safety topics,<sup>48-51</sup> yet all three series reports that examined the role of context (Table 3)—Bundled Payment, Public Reporting, HAI—found that information on contextual factors was often lacking, incompletely described, or noted only anecdotally. Often implementers want details



about the QI environment in which studies are done (e.g., presence of six sigma or lean techniques at a hospital where a provider education strategy is tested), but this information may not be reported in the primary study. Few studies explicitly investigated interactions between context and interventions during QI implementation. The authors of four topic reports recommended that contextual factors be more frequently and robustly measured and reported (Table 4). This recommendation can be applied beyond these particular topics to other areas of QI research.<sup>50</sup> Measuring context, combined with reporting greater detail about interventions (discussed below), would help to pry open the black box of QI implementation, yielding knowledge about which components of interventions are effective under what contexts and in modifying which outcomes. Studies designed specifically to investigate how interactions among intervention features and context affect care delivery processes and outcomes would provide information to help guide selection and design of interventions appropriate to particular settings, patient populations, and organizations. Additionally, the interaction underscores the importance of logic models to interpret and link the findings from primary studies to more systematically build the evidence base for a topic. Such studies will be dependent on reliable and valid measures of contextual factors.

Although this series did not directly address measurement of QI implementation context, the sparse evidence relating to context found in the series reviews and other sources suggests that much measure development will be needed before a core set of context measures can be identified.<sup>48-51</sup> At this early stage of exploration, little is known about which contextual factors are important to measure and how to do so. Thus, filling this knowledge gap will require iterative measure development, measurement, research, and measure refinement. Each of these steps will contribute valuable knowledge to the field of QI research.

## **Adopting a Common QI Intervention Lexicon**

Teams for five series topics sought to examine QI intervention features that influence effectiveness (Table 3). All five reported that descriptions of interventions were often incomplete and lacked a common language for describing intervention features, and recommended more complete descriptions of interventions (Table 4), including key features, in order to strengthen the evidence base for their topic. All of these reports commented on the difficulty in synthesizing evidence across studies given the variability in how interventions are described. The topic teams themselves varied in how they defined intervention features. Three of the five reports that examined intervention features used categories narrowly focused to their topic, such as components of care bundles (Bundled Payment); report acceptability or accessibility (Public Reporting); and incorporation of team-based care, coordinated care, or a sustained partnership (PCMH). In contrast, the Medication Adherence and Palliative Care reviews used a much more broadly applicable framework, with Medication Adherence describing interventions with respect to their target, agent, mode, intensity, duration, and components, and Palliative Care creating a de novo framework for sorting interventions. Medication Adherence investigators further described the components using a previously developed taxonomy of 16 strategies, such as use of knowledge, attitudes, facilitation, organizational learning, and clinical champions.<sup>60</sup> For the purposes of this series methods report and companion summary report, we have used a taxonomy of intervention types developed for the original Closing the Quality Gap series (Appendix D).<sup>8</sup> Using this taxonomy enabled us to synthesize evidence about the effectiveness of interventions across topics, as is done in Table 2. However, although it is useful for this series and similar to approaches used for Cochrane Effective Practices and Organization of Care (EPOC) reviews,<sup>61</sup>



this taxonomy is fairly generic and leaves out details required for more nuanced analysis and insight.

This diversity in how interventions were categorized within the series partially reflects differences in the topics' scope and Key Questions but also points to the need for an underlying framework to describe QI interventions, one that would yield a common lexicon for describing interventions within the research literature. While a framework and terminology must be flexible enough to cover the diverse universe of QI strategies, consistent use of a common set of terms would help facilitate synthesis of results across studies. A common framework and lexicon for describing contexts would also help advance the field. The taxonomy of intervention types used in this methods report (and developed for the original Closing the Quality Gap series), together with additional elements from topic reviews, may provide a useful starting place for developing a consensus-based framework and lexicon.



## Conclusion

The Closing the Quality Gap series evaluates the state of quality improvement (QI) science for eight high-priority health care topics, while also providing a window into the evolution of QI research overall. Individually, each of the eight reports synthesizes the most up-to-date evidence about its topic—Bundled Payment, the Patient-Centered Medical Home (PCMH), Disparities, Medication Adherence, Public Reporting, Healthcare-Associated Infections (HAI), Disability Outcomes, and Palliative Care—providing a key resource for stakeholders with an interest in QI in these areas. Taken together, the reports in the series provide a broad view of QI science, revealing trends, advances, gaps, and challenges that are common across topics. While highlighting key results of each topic review, this methods report focuses primarily on this broad view, summarizing take-home messages for key stakeholders, identifying common challenges and solutions across topics, and discussing implications for future evidence synthesis and QI research in light of lessons learned from all eight topic teams.

Looking across the eight series topic reports, we see that many different outcomes have been used to assess effectiveness in QI research, posing a major challenge to reviewers trying to synthesize evidence across studies. In many cases, whether or not an intervention was found to be effective depended on the outcome examined; many interventions demonstrated improvements for one outcome but not others, both within and across studies. Although several topic teams sought to examine the impact of particular intervention features and contextual characteristics on effectiveness, incomplete and inconsistent reporting of these characteristics generally precluded addressing this question. Potential harms from QI interventions were also rarely investigated, as were economic outcomes such as costs, savings, or return-on-investment.

Together, the experience of the eight topic teams points to the difficulty in applying traditional systematic review methods to literature on complex QI interventions, where many different permutations of intervention features and improvement techniques have been tried across a wide range of populations, settings, organizations, and contexts. Heterogeneity in how interventions were described and the choice of outcomes measures further hampered synthesis across studies. Each of the topic teams also identified weaknesses in the quality of the available literature, recognizing that randomized controlled trials are not always feasible or appropriate for evaluating multifaceted QI interventions.

Lessons learned from the series suggest several recommendations to advance the field of QI research. Specifically, these are to develop a core set of outcomes measures for QI research, develop a framework for QI interventions that includes a lexicon for describing interventions and contextual factors, develop measures of context that can be applied broadly, and adapt or develop new methods of studying effectiveness and performing comparative synthesis that are better suited to the complex, context-dependent, systems-level interventions typical of QI research.

Together, the series topics reveal a comprehensive cross-cutting view of QI and a refreshing chance to continue deriving more lessons beyond those distilled in this report and other syntheses.<sup>62-64</sup> By conducting these reviews in parallel, we were able to coordinate approaches across topics using an overall improvement framework aimed at gaps in quality and the potential quality levers for shrinking these gaps (i.e., through information, incentives, and infrastructure/delivery system change). By examining commonalities across the individual series topic reviews, this report provides insight into how to advance the state of the science in QI and systematic review of complex interventions, while also making information accessible now that is actionable by key stakeholders working to improve the quality of care in the United States.

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# Appendix A. Topic Findings by Report

In this appendix, we provide a summary of the scope, methods, and findings from each of the eight reports in the Closing the Quality Gap: Revisiting the State of the Science Series. For each topic, we provide the working definition used to guide the review and summarize information about knowledge gaps addressed through each review, stakeholders that may be interested in the topic, Key Questions used to guide the reviews, and principal findings.

## 1. Effects of Bundled Payment Systems on Health Care Spending and Quality of Care

### What Is Bundled Payment?

The review authors defined “bundled payment” as a payment method in which payments to health care providers are related to the predetermined expected costs of a grouping, or “bundle,” of related health care services. This includes several different methods for aggregating services into a single unit of care for which a payment will be made. The review authors distinguished the following general aggregation methods and acknowledged that specific payment models may include some or all of these approaches:

- Aggregation of services *longitudinally in time* for an episode of care. The episode is defined to encompass services related to a health care treatment or condition taking place within a defined time window. For example, a single payment could include a surgical procedure and followup care.
- Aggregation of services *across providers* that may be practicing in different care settings. For example, a single payment could be made for inpatient hospital facility services and physician professional services during an inpatient stay.
- *Warranties*, payment arrangements by which payment for complications is aggregated into the unit of payment. Providers assume financial risk for the cost of care defects above a predetermined amount.

### What Is the Quality Gap Addressed by This Topic?

Although alternatives have been proposed and piloted, fee-for-service remains the predominant method of paying for health care in the United States. As health care costs have continued to rise dramatically, even while major quality gaps remain, interest has grown in alternative payment methods, including bundled payment programs, that aim to reduce health care spending while maintaining or improving quality of care. However, many questions remain about how bundled payment affects costs and quality of care, and whether it has unintended negative consequences. It is also unclear how contextual factors such as health delivery organization structure, for-profit status, or leadership impact the outcome of bundled payment programs.

### Who Is Interested in the Topic?

Given the widespread agreement that the current trend in growth of health care costs within the United States is unsustainable, this review provides valuable information to a broad group of audiences interested in bundled payments as one potential mechanism to reduce costs while also potentially improving quality. Those with an interest include policymakers, who need to understand the potential benefits and unintended consequences of bundled payment if

considering it as alternative to fee-for-service payment. Payers, including the Centers for Medicare & Medicaid Services (CMS), will be interested in understanding the effect of bundled payments on health care spending, as well as its quality. In August 2011, CMS announced a large national bundled payment initiative. Providers and health care delivery organizations will be interested in understanding how their reimbursement might be affected by bundled payment programs and how such programs may drive changes in the way they deliver care. Patients and their representatives may also be interested, given the potential for changes (positive or negative) in the quality of care received through different payment models.

### **What Evidence Are Stakeholders Seeking?**

The Bundled Payment reviewers for the series sought to answer the following Key Questions:

- **Bundled Payment Key Question 1:** What does the evidence show on the effects of bundled payment versus usual (predominantly fee-for-service) payment on health care quality and spending measures?
- **Bundled Payment Key Question 2:** Does the evidence show differences in the effects of bundled payment systems by key design features?
- **Bundled Payment Key Question 3:** Does the evidence show differences in the effects of bundled payment systems by key contextual factors?

### **What Is the Scope of the Review?**

**Focus:** Hospitals, skilled nursing facilities, home health providers.

**Outcomes analyzed:** Change in health care spending per episode, utilization rates for specific services, provider cost/resource use to deliver episodes, quality of care, average risk/disease severity of patients treated.

**Literature reviewed:** The Bundled Payment reviewers searched for evidence published between January 1985 and January 2012 using the PubMed<sup>®</sup> and Cochrane Library databases. The final review included 58 studies.

**Analyses performed:** The Bundled Payment reviewers summarized the evidence for the effects of bundled payment in comparison with usual payment methods. They did not conduct quantitative synthesis of results because they found relatively low similarity between studies along key dimensions such as study outcomes. They synthesized the results by bundled payment program, and then summarized these findings by Key Question.

### **What Were the Key Findings?**

Table A-1 summarizes the main results by Key Questions for this topic.

**Table A-1. Bundled Payment key findings**

<p><b>Key Question 1: What does the evidence show on the effects of bundled payment versus usual (predominantly fee-for-service) payment on health care quality and spending measures?</b></p>
<p>Although of low strength due to heterogeneity and weaknesses in study design, the available evidence showed consistently that bundled payment programs resulted in small (<math>\leq 10\%</math>) decreases in health care spending compared with cost-based or fee-for-service models. One review of the Medicare Heart Bypass Demonstration program found a 10% reduction in spending across 7 sites; 86% of savings resulted from lower negotiated reimbursement rates, 5% from lower postdischarge spending, and 9% from shifting care to lower cost hospitals. Across all reviewed studies, bundled payment was associated with between 5% and 15% lower utilization of services, in particular shorter hospital length of stay. The evidence for the impact of bundled payment programs on quality measures was less consistent. Changes in quality were generally small and inconsistent in direction and magnitude. This inconsistency was observed both within studies (different effects for different quality measures within a single study) and across studies (different effects for similar measures across different studies).</p> <p>Other than the impact on quality measures, studies rarely assessed unintended negative consequences of bundled payment programs, such as underutilization of effective services, avoiding high-risk patients, increasing the number of bundles reimbursed, changing coding practices to maximize reimbursement for bundles, or moving services in time or location to qualify for separate reimbursement. However, there was consistent evidence from multiple single-setting bundled payment programs that care shifted to other settings (i.e., from inpatient to outpatient care). Some evidence demonstrated increases in patient risk following implementation of bundled payment programs, but it is unknown whether this was due to changes in coding practices (i.e., shifting to higher risk codes) or to actual changes in the level of risk among the patient population. Several programs that blended bundled payments with fee-for-service reimbursement reported greater use of services that generate higher reimbursement after blending, such as providing additional rehabilitation time under the Medicare Skilled Nursing Facility Prospective Payment System (PPS) or providing more therapy visits per episode of care in the Medicare Home Health PPS.</p>
<p><b>Key Question 2: Does the evidence show differences in the effects of bundled payment systems by key design features?</b></p>
<p>The framework used to guide this review specified key bundled payment program design features of interest, including bundle components, payment methodology, level of payment, method for determining payment, risk-sharing properties, risk-adjustment methods, use of quality measurement, and distribution of payments among participating providers. No studies directly evaluated the effects of these design features on outcomes such as spending or quality measures. Heterogeneity in bundled payment interventions precluded the review authors from undertaking comparisons across studies to estimate such effects. Thus, the authors were unable to draw conclusions about the effects of bundled payment program design features on outcomes. Most programs reviewed focused on bundling for single-institution providers rather than bundling payments across settings. Bundle definitions were generally based on diagnoses. Few bundled payment programs integrated quality measurement or pay-for-performance into the payment mechanism.</p>
<p><b>Key Question 3: Does the evidence show differences in the effects of bundled payment systems by key contextual factors?</b></p>
<p>The framework used to guide this review specified key contextual factors that were hypothesized to impact the effectiveness of bundled payment programs, including the financial environment; incentives, charters, or missions of participating organizations; market characteristics; capabilities and goals of the participating organizations; the degree of integration among participating organizations; staff factors; and patient factors. However, few of these factors were evaluated by any of the identified studies. The reviewers found low strength of evidence that health care utilization declined to a greater extent when payment bundling was used to reimburse for-profit providers compared with not-for-profit providers. Likewise, the Medicare inpatient PPS program reported greater declines in utilization for hospitals that were under greater financial pressure (low strength of evidence). Although the influence of patient disease severity was examined by several studies, results were inconsistent (low strength of evidence).</p>

## 2. The Patient-Centered Medical Home

### What Is a Patient-Centered Medical Home?

The review authors created an operational definition of a patient-centered medical home (PCMH) intervention based on the Agency for Healthcare Research and Quality definition of PCMH.<sup>25</sup> To be considered, a PCMH intervention required:

1. Team-based care
2. At least two of four elements focused on how to improve the entire organization of care (enhanced access, coordinated care, comprehensiveness, systems-based approach to improving quality and safety)
3. A sustained partnership
4. An intervention that involves structural changes to the traditional practice

Studies that did not use the term “medical home” but met this definition were categorized as “functional PCMH” interventions.

### What Is the Quality Gap Addressed by This Topic?

The PCMH model aims to improve both care and patient experience across the full care continuum, from prevention through treatment of chronic and acute illness. It also holds promise for improving providers’ experience and potentially reducing costs through greater efficiency. Widely endorsed by professional societies, payers (e.g., Medicare), and large health systems, PCMH-based interventions have been implemented in many different health care organizations. Studies of these interventions have shown that individual elements of the PCMH model are associated with improvements for some specific conditions and outcomes, but much remains unknown about whether implementation of a comprehensive PCMH improves care overall for the full population of patients served by a health care organization.

### Who Is Interested in the Topic?

The comprehensive nature of the PCMH model means that it has implications for a wide range of stakeholders, including health maintenance organizations, networks of Medicaid providers, community health centers, private integrated delivery systems, private practices, the U.S. Department of Veterans Affairs health care system, and parts of the Department of Defense military health care system. As its name implies, the PCMH model is centered on supporting the needs of patients. Thus, organizations representing patients, such as advocacy groups, large employers and other purchasers, and individual patients themselves may also be interested in this topic.

### What Evidence Are Stakeholders Seeking?

The PCMH reviewers for the series sought to answer the following Key Questions:

- **PCMH Key Question 1:** In published primary-care-based evaluations of comprehensive PCMH interventions, what are the effects of PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
  - **1a:** Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
  - **1b:** Is implementation of comprehensive PCMH associated with unintended consequences (e.g., decrease in levels of indicated care for nonpriority conditions) or other harms?

- **PCMH Key Question 2:** In published primary-care–based evaluations of comprehensive PCMH interventions, what individual PCMH components have been implemented?
- **PCMH Key Question 3:** In published primary-care–based evaluations of comprehensive PCMH interventions, what financial models and implementation strategies have been used to support uptake?
- **PCMH Key Question 4:** What primary-care–based studies evaluating the effects of comprehensive PCMH interventions on patient and staff experiences, process of care, clinical outcomes, or economic outcomes are currently underway? In these ongoing studies, what are the study designs, PCMH components, comparators, settings, financial models, and outcomes to be evaluated?

### **What Is the Scope of the Review?**

**Population:** Adults seeking care in general primary care and children with special health care needs.

**Outcomes analyzed:** Patient experiences, staff experiences, process of care, clinical outcomes, and economic outcomes.

**Literature reviewed:** For Key Questions 1 through 3, the PCMH reviewers searched PubMed (through December 6, 2011), CINAHL<sup>®</sup>, and the CDSR (through March 30, 2011). For Key Question 4, they used the term “medical home” to search for ongoing or recently completed studies in the following databases: ClinicalTrials.gov, Commonwealth Fund, Robert Wood Johnson Foundation, and databases of federally funded studies—Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Health Services Research Projects in Progress, National Institutes of Health (NIH) Reporter (NIH Research Portfolio Online), Health Resources and Services Administration, Veterans Affairs, and Department of Defense. All databases were searched using the enGrant Scientific<sup>®</sup> interface. The final review included 51 articles representing 27 unique peer-reviewed studies.

### **Analyses performed:**

- For Question 1 (effects of PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes), the PCMH reviewers identified the subset of studies using randomized controlled trial designs and employed a random-effects model to compute summary estimates of effect for two outcomes: hospitalizations and emergency department visits. They calculated summary estimates using Comprehensive Meta-Analysis software (Version 2; Biostat, Englewood, NJ) and reported summary risk ratios.
- For other outcomes, variation in the study populations, designs, and outcomes precluded quantitative analysis. Instead, to aid interpretation of the qualitative synthesis, the review authors computed effect sizes, represented as the standardized mean difference. This measure is useful when studies assess the same outcome using different measures or scales.<sup>26</sup> The review authors presented beneficial effects as positive effect sizes.

### **What Were the Key Findings?**

Table A-2 summarizes the main results by Key Questions for this topic.



**Table A-2. Patient-Centered Medical Home (PCMH) key findings**

<b>Key Question 1: What are effects of PCMH on outcomes (patient and staff experiences, process of care, clinical outcomes, economic outcomes)?</b>
PCMH interventions had a small positive impact on patient experiences and small to moderate positive effects on the delivery of preventive care services (17 comparative studies, moderate strength of evidence). There was also a small to moderate impact on staff experiences (low strength of evidence). Among older adults, there was evidence that PCMH interventions reduced emergency department visits (risk ratio [RR], 0.81; 95% confidence interval [CI], 0.67 to 0.98) but not hospital admissions (RR, 0.96; 95% CI, 0.84 to 1.10) (low strength of evidence). However, there was no evidence for overall cost savings. Little evidence was available addressing unintended consequences of PCMH implementation.
<b>Key Question 2: What individual PCMH components have been implemented?</b>
Of 27 studies of PCMH interventions, 21 included all 7 major components of the PCMH model. Overall, studies used 51 different strategies to implement these core components. The most commonly addressed PCMH components were management of chronic illness, preventive care needs, and acute care needs; use of multidisciplinary teams; and coordination of care transitions. More than 75% of studies noted that new staff had been added during the intervention. Nearly all interventions included strategies to improve patient access, but studies varied widely in the choice of those strategies. The most widely used methods to improve health care quality and safety included identifying high-risk patients, using evidence-based clinical guidelines, monitoring performance, and using electronic health records. The number of studies reporting use of specific PCMH components can be found in <b>Table 4</b> of the full report. <sup>27</sup> <b>Tables 16 and 18</b> show further detail on subcomponents of the PCMH model.
<b>Key Question 3: What financial models and implementation strategies have been used to support uptake of PCMH?</b>
Fewer than half (11 of 27) of included studies described aspects of their financial model. The payment models used to support PCMH implementation varied widely, including receipt of external study funding, capitation payments, enhanced fee-for-service, and a hybrid approach. Formal learning collaboratives and collaborative program planning forums were the most widely used organizational learning strategies (n = 19). More than half of studies used audit and feedback, usually with a quality improvement methodology, to implement PCMH. <b>Table 20</b> of the full report summarizes financial, organizational learning, and implementation strategy types, and numbers of studies. <sup>27</sup>
<b>Key Question 4: What primary-care-based studies evaluating the effects of comprehensive PCMH interventions on outcomes are currently underway? In these ongoing studies, what are the study designs, PCMH components, comparators, settings, financial models, and outcomes to be evaluated?</b>
The horizon scan identified 31 ongoing PCMH studies, many performed in conjunction with payer organizations. These represented the wide range of payers (public and private), delivery networks, and geographic areas within the U.S. health care system. Most studies are expected to be completed in the next 2 years.

### 3. Quality Improvement Interventions To Address Health Disparities

#### What Are Health Care Disparities?

Health care disparities are the differences or gaps in care experienced by one population compared with another. By definition, a disparity in health care quality or health outcomes is not due to differences in health care needs or preferences of the patient, but to other factors.<sup>14</sup> Differences in health outcomes and their determinants are associated with certain social conditions such as socioeconomic status or education and demographic attributes such as race, ethnicity, sex, or age.

## What Is the Quality Gap Addressed by This Topic?

There is abundant evidence of health care disparities in the United States. A recent report from the Centers for Disease Control and Prevention (CDC) found that the rate of death due to coronary artery disease is substantially higher among black men and women than among white patients and that hypertension is more prevalent in the black population compared with other racial and ethnic groups in the United States. Furthermore, minority populations, in particular Native Americans, use tobacco at higher rates than whites, and rates of preventable hospitalization are higher among lower income patients.<sup>15</sup> The 2011 National Healthcare Disparities Report found that disparities related to race, ethnicity, and socioeconomic status are widespread throughout the U.S. health care system; disparities are not decreasing over time; and lack of health care insurance is an important contributor to these disparities.<sup>16</sup> The report recommended that particular attention be paid to disparities related to care for cancer, heart failure, and pneumonia. However, despite these well-known health disparities, evidence is lacking about how they might be reduced through quality improvement interventions.<sup>16</sup> A 2006 systematic review found few studies that sought to reduce disparities through quality improvement approaches.<sup>17</sup>

## Who Is Interested in the Topic?

This review will primarily be of interest to researchers and research funders interested in health care disparities. It may also be of interest to health delivery organizations and policymakers interested in reducing disparities among patient populations. Advocacy organizations representing specific social groups experiencing disparities may also be interested in ways to reduce those gaps.

## What Evidence Are Stakeholders Seeking?

The Disparities reviewers for the series sought to answer the following Key Questions:

- **Disparities Key Question 1:** What evidence is available about the effectiveness of quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?
- **Disparities Key Question 2:** What evidence is available about the harms related to quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?

## What Is the Scope of the Review?

**Population:** Individuals receiving health care in the United States for a prespecified clinical condition.

**Outcomes analyzed:** Health outcomes (e.g., morbidity and mortality, indirect health outcomes such as blood pressure and hemoglobin A1c), process measures (e.g., proportion of patients treated according to clinical guidelines), changes in disparity, and harms (i.e., any negative impact of the intervention on the individual patients or the health care system).

**Literature reviewed:** The Disparities reviewers searched for evidence between 1983 and 2011 using the following databases: MEDLINE, CINAHL, Web of Science<sup>®</sup> Social Science Index, and PsycINFO<sup>®</sup>. Non-U.S. studies were excluded due to important differences in health care system, disparity indicators, and groups experiencing disparities between the United States and other countries. The final review included 19 articles representing 14 studies of cancer,

cardiovascular disease, depression, and diabetes. They targeted or described disparities associated with differences in race or ethnicity (n = 11 studies), socioeconomic status (n = 3), insurance status (n = 2), language (n = 2), health literacy (n = 1), and sex (n = 1). Eleven of the 14 studies were randomized controlled trials.

**Analyses performed:** The reviewers synthesized evidence by effect on particular disparities and by clinical condition.

### What Were the Key Findings?

Table A-3 summarizes the main results by Key Questions for this topic.

**Table A-3. Disparities key findings**

<b>Key Question 1: What evidence is available about the effectiveness of quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?</b>
<p>Disparities among racial and ethnic groups were the most frequently studied (11 of 14 studies). Only one of these studies demonstrated a reduction in disparity as a result of the quality improvement intervention.<sup>18</sup> This study found that black but not white patients increased their hemoglobin A1c testing following a disease management and patient education program. An additional study of patient and provider education, self-management, and audit and feedback showed a reduced disparity in lipid testing between black and white patients with diabetes enrolled in Medicare, although the study design lacked a control group and therefore could not demonstrate whether this change was due to the intervention or other factors. Several other quality improvement interventions showed an amplified effect in minority populations, even though they did not reduce disparities. These included several patient education programs aimed at reducing blood pressure and a complex collaborative care model targeting providers caring for patients with depression.</p> <p>Both studies that examined language-based disparities focused on language concordance—providing health-related materials and support in patients’ native or preferred language—and both found some evidence of greater intervention effects for non-English-speaking populations compared to English-speaking patients.</p> <p>Overall, the available evidence was not sufficient to draw clear conclusions about whether specific quality improvement strategies were effective at reducing health care disparities. However, some results from individual studies suggested the potential for effectiveness, pointing to strategies—specifically the collaborative care model and targeted patient education with language and health literacy concordance—that warrant further investigation.</p>
<b>Key Question 2: What evidence is available about the harms related to quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?</b>
<p>This review found no information to address this Key Question.</p>

## 4. Comparative Effectiveness of Medication Adherence Interventions

### What Is Medication Adherence?

Medication adherence is the extent to which patients take medication as prescribed by their health care providers.<sup>35</sup> It is the patient’s conformance with the provider’s recommendation with respect to timing, dosage, and frequency of medication-taking during a prescribed length of time.<sup>36,37</sup> Medication persistence, the act of continuing the treatment for the prescribed duration, is also important.<sup>37,38</sup>

## What Is the Quality Gap Addressed by This Topic?

Although pharmacotherapy is available to treat an astounding array of health conditions, even efficacious medications cannot be effective if not taken according to the timing, dosage, frequency, and duration prescribed by health care providers. Yet research suggests that between 20 and 30 percent of prescriptions are never filled and that half of medications prescribed to treat chronic disease are not taken appropriately.<sup>35,39-41</sup> Direct costs of nonadherence are estimated to range between \$100 and \$289 billion in the United States,<sup>35,37,40-42</sup> and strong evidence suggests that benefits attributable to improved self-management of chronic diseases could result in a cost-to-savings ratio of approximately 1:10.<sup>43</sup> This review aimed to address both the efficacy and effectiveness of interventions designed to improve medication adherence for adults with chronic conditions. It updated a previous systematic review completed in 2008,<sup>39</sup> further expanding the scope of that review to include interventions at the health system and policy levels. In addition, this review addressed evidence gaps by targeting studies of vulnerable populations (Key Question 4) and unintended consequences of medication adherence interventions (Key Question 5), and by including studies that reported medication adherence as an outcome, even if additional outcomes (e.g., mortality, morbidity) were not also reported.

## Who Is Interested in the Topic?

Given the potential cost-savings associated with effective pharmacotherapy, this review will be of interest to health plans and other payers such as large employers and Federal and State governments that pay for care through Medicare, Medicaid, the Veterans Health Administration, Indian Health Service, and Federal employee health care plans, among other programs. Key Question 2, which focuses on policy interventions to improve medication adherence, will be of particular interest to payers and policymakers, as will Key Questions 4 and 5, which focus on vulnerable populations and unintended consequences of medication adherence interventions. In the results of Key Question 1, health care providers and health delivery organization administrators that directly prescribe and provide medications will find information about methods to increase adherence among their patients through quality improvement interventions. This audience may also be interested in Key Question 3, which focuses on information about the effectiveness of various intervention characteristics, and Key Question 5. As the targets of efforts to improve medication adherence—and ultimately treatment for chronic disease—patients and their representatives may also have an interest in the results of this review. In addition, pharmacies and pharmaceutical companies that develop, license, produce, and sell prescription and over-the-counter medications will likely be interested in the effectiveness of medication adherence interventions.

## What Evidence Are Stakeholders Seeking?

The Medication Adherence reviewers for the series sought to answer the following Key Questions:

- **Medication Adherence Key Question 1:**
  - **1a:** Among patients with chronic diseases with self-administered medication prescribed by a provider, what is the comparative effectiveness of interventions aimed at patients, providers, systems, and combinations of audiences in improving medication adherence?
  - **1b:** Is improved medication adherence associated with improvement in patient outcomes?

- **Medication Adherence Key Question 2:**
  - **2a:** Among patients with chronic diseases with self-administered medication prescribed by a provider, what is the comparative effectiveness of policy interventions in improving medication adherence?
  - **2b:** Is improved medication adherence associated with improvement in patient outcomes?
- **Medication Adherence Key Question 3:**
  - **3a:** How do medication-adherence intervention characteristics (e.g., mode of delivery, intervention target, intensity) vary?
  - **3b:** To what extent do the effects of adherence interventions vary based on their characteristics?
- **Medication Adherence Key Question 4:** To what extent do the effects of adherence interventions vary based on differences in vulnerable populations?
- **Medication Adherence Key Question 5:** What unintended consequences are associated with interventions to improve medication adherence?

### **What Is the Scope of the Review?**

**Population:** Adults prescribed self-administered medication for secondary or tertiary prevention of chronic diseases in the United States, excluding patients with severe mental illness and substance abuse.

**Outcomes analyzed:** Biomarkers of clinical outcomes, clinical outcomes (e.g., mortality, morbidity), quality of life, patient satisfaction, health care utilization, quality of care, medication adherence, and adverse events.

**Literature reviewed:** The Medication Adherence reviewers searched evidence from 1994 to December 2011 using the following databases: MEDLINE, Cochrane Library, and the Cochrane Central Trials Registry. The final review included 68 articles that represent 62 studies (64 randomized controlled trials, 4 observational studies).

**Analyses performed:** All the data were qualitatively synthesized, and stratifications or categories were used for subgroup analyses. For Key Questions 1 and 2, the reviewers synthesized the evidence by clinical condition and type of intervention. For Key Questions 3, 4, and 5, they synthesized the evidence from all relevant studies included in Key Question 1 and Key Question 2.

### **What Were the Key Findings?**

Table A-4 summarizes the main results by Key Questions for this topic.



**Table A-4. Medication Adherence key findings**

<b>Key Question 1a: Among patients with chronic diseases with self-administered medication prescribed by a provider, what is the comparative effectiveness of interventions aimed at patients, providers, systems, and combinations of audiences in improving medication adherence?</b>
Evidence from 57 randomized controlled trials (RCTs) suggests that many different types of interventions have the potential to improve medication adherence. Across the 10 clinical condition groups examined, evidence was most extensive and consistent for the effectiveness of education and case management interventions. However, other strategies appeared to be more effective for specific conditions. For example, 6 of 8 studies in patients with asthma, chronic obstructive pulmonary disease, or reactive airway disease showed improvement in medication adherence in the intervention arm; 5 of those 6 used a self-management-focused intervention. In addition to type of intervention, the intensity seemed to impact effectiveness for some conditions. For patients with mild to moderate depression, high-intensity interventions that included face-to-face interactions and longer duration were effective at increasing medication adherence (moderate strength of evidence), while lower intensity, telephone-only interventions were not.
<b>Key Question 1b: Is improved medication adherence associated with improvement in patient outcomes?</b>
Only a subset of interventions that improved medication adherence also improved additional outcomes. These included disease-specific clinical outcomes such as blood pressure, hemoglobin A1c levels, pulmonary functioning, and depression symptoms. Other outcomes such as patient satisfaction, quality of life, or health care utilization were rarely examined; few studies demonstrated improvements in these outcomes, and results were often inconsistent between studies of a particular condition. The strength of evidence relating to outcomes other than medication adherence was generally insufficient.
<b>Key Question 2: Among patients with chronic diseases with self-administered medication prescribed by a provider, what is the comparative effectiveness of policy interventions in improving medication adherence?</b>
Five studies (1 RCT and 4 observational studies) evaluated the effects of policy-level interventions on medication adherence. All focused on the impact of out-of-pocket costs (i.e., copays and drug coverage) on medication adherence, including 1 study on Medicare Part D. Most studies focused on drugs for treating cardiovascular conditions (e.g., angiotensin-converting enzyme inhibitors; angiotensin receptor blockers; beta-blockers; statins; and medications to treat hyperlipidemia, hypertension, and heart failure), although additional medications were included in 2 studies. All 5 studies found better medication adherence in the intervention group for all medications except inhaled corticosteroids (moderate strength of evidence).
<b>Key Question 2b: Is improved medication adherence associated with improvement in patient outcomes?</b>
Only 1 of the 5 policy intervention studies examined outcomes other than medication adherence. This RCT found no difference in death from cardiovascular causes or total spending by the insurer (medication and nonmedication services), but found a 14% decrease in the risk of first vascular event and a 26% decrease in total patient spending in the group with a reduced medication copay. However, the strength of this evidence was judged to be insufficient because it was based on a single study.
<b>Key Question 3a: How do medication-adherence intervention characteristics (e.g., mode of delivery, intervention target, intensity) vary?</b>
Most studies provided information about 6 key intervention characteristics: the target, agent, and mode of the intervention, in addition to its intensity (total time and frequency), duration, and components. However, differences in how this information was presented limited the ability to make comparisons across studies. The most frequent targets of adherence interventions were patients (40%); a combination of patients, providers, and systems (23%); and a combination of patients and systems (19%). Approximately half of adherence interventions were delivered by a pharmacist (19%), physician (11%), or nurse (16%) (agent), and half involved face-to-face contact (mode). Details of intensity (frequency and duration of interaction) were lacking or incomplete from more than half of the studies reviewed. More than three-quarters (77%) of interventions included a knowledge-based component, and nearly half (44%) also included an awareness-based component. Awareness was almost always combined with knowledge components. Few interventions used stress management (3%) or social influence (3%) components, and none used contingent rewards.



**Key Question 3b: To what extent do the effects of adherence interventions vary based on their characteristics?**

Only 4 RCTs directly compared different interventions to assess their effects on medication adherence. All used patient-focused interventions, although 1 also included provider- and system-level components in the intervention. There was low strength of evidence that shared decisionmaking (patient and provider together) improved medication adherence and pulmonary function (among patients with asthma) but not symptoms, quality of life, or health care utilization, compared with clinical decisionmaking (provider only). There was insufficient evidence about the effect of intervention agent (e.g., patient, physician, nurse, research staff), mode (e.g., telephone vs. video reminders), or intensity (e.g., frequency and duration of intervention interactions) on medication adherence.

**Key Question 4: To what extent do the effects of adherence interventions vary based on differences in vulnerable populations?**

In general, interventions had a positive impact on medication adherence for most vulnerable populations examined (low strength of evidence from 15 studies). Specifically, these populations were patients with major depression, severe depression, multiple chronic conditions, or depression with comorbid hypertension, or black patients with coexisting depression and diabetes. Elderly patients with diabetes, hyperlipidemia, congestive heart failure, or hypertension also had improved medication adherence. There was insufficient evidence for improvement following the intervention for patients with coexisting depression and HIV, coexisting hypertension and diabetes, or coexisting depression and diabetes (except for black patients in the latter group, whose adherence improved). Evidence was mixed about the impact of interventions on patients in rural communities (insufficient evidence). These studies were very heterogeneous with respect to population, intervention, and definition of medication adherence.

**Key Question 5: What unintended consequences are associated with interventions to improve medication adherence?**

Only 3 studies were applicable to this question, and they differed greatly with respect to adverse events evaluated, interventions, diseases, and medications included in the studies. Evidence was insufficient to draw conclusions about potential unintended consequences associated with medication adherence interventions. None of the studies reported significantly higher adverse events in the intervention group.

## 5. Public Reporting as a Quality Improvement Strategy

### What Is Public Reporting?

Public reporting is data, publicly available or available to a broad audience free of charge or at a nominal cost, about a health care structure, process, or outcome at any provider level (individual clinician, group, or organizations such as hospitals and nursing facilities) or at the health plan level. While public reporting is generally understood to involve comparative data across providers, the authors of this review adopted a broader approach to include findings in which one provider is compared with a national/regional data report on performance for which there are accepted standards or best practices.

### What Is the Quality Gap Addressed by this Topic?

Public reporting is an important way to motivate delivery of high-quality care. In particular, it provides incentives for engaging in quality improvement activities.<sup>8,9</sup> Public reporting initiatives have expanded greatly in recent years, as has the availability of health data and the ability to aggregate it in meaningful ways.<sup>10</sup> The amount of publicly reported health care quality data is likely to continue to increase substantially in tandem with a growing focus within the U.S. health care system on transparency and patient-centered care. Furthermore, previous systematic

reviews of public reporting have not included studies of quality data within the long-term care (LTC) setting, which is now the focus of major national public reporting initiatives, in particular for nursing homes.<sup>11-13</sup>

### **Who Is Interested in the Topic?**

Public reporting creates incentives for improvements in care and choice of health care providers for a variety of stakeholders, all of whom may find this report of interest. Consumers—patients, families, patient advocates, and health care purchasers such as employers—may use publicly reported quality information when making decisions about where to obtain care. Public reporting may also provide essential information to individual health care providers (e.g., clinicians) or health care delivery organizations (e.g., hospitals, long-term care facilities, health plans) that wish to attract new patients or members, avoid the loss of existing ones, uphold commitments to provide high-quality care, and protect or improve their reputation among peers. Federal and State government agencies, community quality collaboratives, and other health care quality organizations may find that this report informs their use of public reporting as a strategy to improve care at a system level.

### **What Evidence Are Stakeholders Seeking?**

To provide key information to these stakeholders and fill existing evidence gaps about public reporting, the Public Reporting reviewers for the series sought to answer the following Key Questions:

- **Public Reporting Key Question 1:** Does public reporting result in improvements in the quality of health care (including improvements in health care delivery structures, processes, or patient outcomes)?
- **Public Reporting Key Question 2:** What harms result from public reporting?
- **Public Reporting Key Question 3:** Does public reporting lead to change in health care delivery structures or processes (at levels of individual providers, groups, or organizations such as health plans, hospitals, and nursing facilities)?
- **Public Reporting Key Question 4:** Does public reporting lead to change in the behavior of patients, their representatives, or organizations that purchase care?
- **Public Reporting Key Question 5:** What characteristics of public reporting increase its impact on quality of care?
- **Public Reporting Key Question 6:** What contextual factors (population characteristics, decision type, and environmental) increase the impact of public reporting on quality of care?

### **What Is the Scope of the Review?**

**Focus:** Public reporting of hospitals, long-term care facilities, health plans, and individual clinicians.

**Outcomes analyzed:** Health care quality (system structures or processes, or patient outcomes), unintended negative consequences (harms), changes in health care delivery structures or processes, changes in patient or purchaser behavior.

**Literature reviewed:** The Public Reporting reviewers searched for evidence published between January 1980 and December 31, 2011, using the following databases: MEDLINE, EMBASE<sup>®</sup>,

EconLit, PsychINFO<sup>®</sup> Business Source<sup>®</sup> Premier, Cumulative Index of Nursing and Allied Health Literature (CINAHL<sup>®</sup>), Public Affairs Information Services (PAIS), the Cochrane Database of Systematic Reviews (CDSR), the Cochrane Effective Practice and Organization of Care Group (EPOC) Register of Studies, Database of Abstracts of Reviews of Effects (DARE), National Health Service Economic Evaluation Database (NHS EED), Health Economic Evaluations Database (HEED), the Grey Literature Report database (maintained by the New York Academy of Medicine), and AARP Ageline. The final review included 205 articles comprising 198 studies, of which 97 (49 percent) were quantitative and 101 (51 percent) were qualitative.

**Analyses performed:** The heterogeneity of outcomes precluded the review authors from performing a formal quantitative meta-analysis. To synthesize evidence, they separated studies into four groups according to the type of health care entity for which data were publicly reported:

- Hospitals (further divided into cardiac and noncardiac inpatient care)
- Individual clinicians or outpatient group practices
- Health plans
- Long-term care services (predominantly nursing homes)

The review authors chose this grouping because public reporting has a different history in each of these settings, and the content and presentation of public reports differ for each of these settings. They reported results for each Key Question separately for each of these four groups of studies.

### What Were the Key Findings?

Table A-5 summarizes the main results by Key Questions for this topic.

**Table A-5. Public Reporting key findings**

Key Question 1: Does public reporting result in improvements in the quality of health care (including improvements in health care delivery structures, processes, or patient outcomes)?
<p>Most studies of hospital-level public reporting found a decrease in mortality (the most commonly studied outcome) compared with no reporting, although some questions remained about the appropriateness of comparisons in some studies (19 studies, moderate strength of evidence). Analysis of hospitals was divided into those that focused on cardiac care and those that did not. Among cardiac-focused articles, results were mixed, with 8 studies reporting improvements (decreases) in mortality with public reporting, 4 finding no difference, and 1 study reporting increased mortality with public reporting. Ten of 11 studies on public reporting for noncardiac hospital care found slight improvements in quality. Studies of public reporting for health plans or long-term care facilities generally found improvements in quality of care in the reporting group as measured by outcomes such as pain, pressure ulcers, and satisfaction with care. The impact of public reporting on health care quality varied in some studies depending on the health plan or population subgroup. At the health plan level, public reporting of most Healthcare Effectiveness Data and Information Set (HEDIS) and CAHPS domains was associated with improvements in quality measures (5 studies).</p>

### Key Question 2: What harms result from public reporting?

Although harm is frequently cited as a concern, the limited research on unintended negative consequences from public reporting does not generally confirm the potential harm. On balance, evidence that public reporting does not lead to unintended negative consequences outweighed evidence of its harms. Although frequently examined (12 studies), evidence about the impact of public reporting on patient access (e.g., cream-skimming, cherry-picking) was of low quality and yielded mixed results. Some studies of long-term care (LTC) found evidence that public reporting created incentives for changing coding practices and readmitting patients to the hospital just before assessment for Nursing Home Compare. This was the most serious harm identified among the studies reviewed. No evidence was found that public reporting was associated with surgeons or health care organizations withdrawing from the market or with declines in the quality of unmeasured aspects of care (crowding out) (5 studies, moderate strength of evidence).

### Key Question 3: Does public reporting lead to change in health care delivery structures or processes (at levels of individual providers, groups, or organizations)?

Among the studies reviewed, both individual clinicians and health care organizations responded positively to public reporting, offering new services, changing policies, and increasing quality improvement activities (10 studies, moderate strength of evidence). One study found that poor-performing surgeons were more likely to leave surgical practice after public reporting (considered a positive outcome). In the LTC environment, nursing home administrators invested more in clinical care following public reporting (1 study), and those that took action following public reports demonstrated improvements in quality measures (1 study). Nursing home administrative actions in response to public reporting appeared to be motivated primarily by the expectation that those reports would influence professional referrals and the State survey process rather than patient and family selection of facilities.

### Key Question 4: Does public reporting lead to change in the behavior of patients, their representatives, or organizations that purchase care?

Results across studies and settings consistently showed that patients and their families or representatives did not use public reports when selecting health care providers: 10 studies found no or only weak evidence that public reporting influenced patient choice of provider. The few studies that reported evidence for an effect of public reporting on patient choice did so only for a subgroup of patients. Studies of contracting patterns found that public reports played only a minor role in guiding selection of providers (47 studies, moderate strength of evidence).

### Key Question 5: What characteristics of public reporting increase its impact on quality of care?

The review found very little evidence to address this Key Question; quantitative evidence was particularly lacking. Only 2 studies, both on public reporting of individual clinicians, examined the impact of report characteristics on quality of care. One study of poor quality found that use of email vs. mail influenced use of public reports, while message tone (risks vs. benefits) did not. Another study reported that information in public reports remained accurate and useful even when delayed by several years before release. No studies addressed this Key Question for hospitals, LTC, or health plans.

### Key Question 6: What contextual factors (population characteristics, decision type, and environmental) increase the impact of public reporting on quality of care?

Strong evidence suggests that public reporting leads to quality improvements more readily in competitive markets (7 studies, high strength of evidence). Providers and health care organizations with poor initial performance were more likely to make improvements following public reporting than those with better initial performance (5 studies, high strength of evidence). Characteristics of nursing homes did not predict how facilities responded to publicly reported quality information (6 studies, low strength of evidence), but some patient characteristics (i.e., age, health needs, insurance coverage) impacted use of publicly reported quality information when making health care choices. However, the strength of evidence for these 3 studies of LTC public reporting was low.

## 6. Prevention of Healthcare-Associated Infections

### What Are Healthcare-Associated Infections (HAI)?

The CDC defines a healthcare-associated infection as: “a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the acute care setting.”<sup>28</sup>

### What Is a Preventive Intervention?

For the purposes of this review, a preventive intervention is a specific infection-control practice that has been demonstrated to reduce the incidence of HAI. An example would be using maximal sterile barrier precautions when inserting a central line.

### What Is the Quality Gap Addressed by This Topic?

HAI are widespread and costly in the U.S. health care system. According to an estimate by the CDC, in 2002 there were 1.7 million HAI and 99,000 HAI-associated deaths in hospitals. More than 80 percent of these HAI were caused by the four most common categories: central line-associated bloodstream infections (CLABSI) (14 percent), ventilator-associated pneumonia (VAP) (15 percent), surgical site infections (SSI) (22 percent), and catheter-associated urinary tract infections (CAUTI) (32 percent).<sup>29</sup> Evidence-based strategies to eliminate HAI are known and endorsed by many professional societies,<sup>32</sup> but these preventive interventions have not been fully implemented into clinical practice throughout the United States. The 2003 Institute of Medicine report on priority areas included adherence to evidence-based HAI preventive interventions among its 20 priority conditions for which a gap remains between knowledge of the topic and integration of that knowledge into the clinical setting.<sup>2</sup> Information is needed about quality improvement strategies that lead to effective adoption of these preventive interventions. In light of much recent research on this topic, this review updates a previous review published in 2007,<sup>31</sup> and expands that review to include additional settings (e.g., ambulatory surgical centers, dialysis centers, and long-term care facilities) in addition to hospitals.

### Who Is Interested in the Topic?

Knowledge of the costs, benefits, effectiveness, and trade-offs of quality improvement strategies aimed at reducing HAI is essential when designing, selecting, and implementing improvement programs. This review will be of interest to individuals or organizations that wish to reduce HAI through quality improvement initiatives. This includes policymakers seeking to make measurable improvements in this national priority area; administrators of hospitals, ambulatory surgical centers, dialysis centers, long-term care facilities, and other health care organizations concerned about HAI among their patient population; and payers that wish to reduce the incidence of HAI, which account for substantial health care costs.<sup>32</sup>

### What Evidence Are Stakeholders Seeking?

The HAI reviewers for the Series sought to answer the following Key Questions:

- **HAI Key Question 1:** Which quality improvement strategies are effective in reducing the following HAI: central line-associated bloodstream infections, ventilator-associated pneumonia, surgical site infections, and catheter-associated urinary tract infections?

- **1a:** Which quality improvement strategies are effective in increasing adherence to evidence-based preventive interventions for the four HAI listed above?
- **1b:** What is the cost, return-on-investment, or cost-effectiveness for health care providers, and society as a whole, of quality improvement strategies to reduce these HAI?
- **1c:** Which factors are associated with the effectiveness of quality improvement strategies?
- **HAI Key Question 2:** What is the impact of health care context on the effectiveness of quality improvement strategies, including reducing infections and increasing adherence to preventive interventions?

### What Is the Scope of the Review?

**Population:** Patients at risk for CLABSI, VAP, SSI, or CAUTI in hospitals, ambulatory surgery centers, dialysis centers, or long-term care facilities.

**Outcomes analyzed:** Adherence to various preventive interventions, change in infection rates, costs, and return-on-investment.

**Literature reviewed:** The HAI reviewers searched for evidence published between January 2006 and January 2012 using the following databases: MEDLINE, CINAHL, and EMBASE®. The final review included 152 articles.

**Analyses performed:** The articles were divided into two categories: those with infection rates or adherence rates that were adjusted for confounding or temporal trends and those that adjusted for neither. Results for each category were synthesized separately in a qualitative manner.

### What Were the Key Findings?

Table A-6 summarizes the main results by Key Questions for this topic.

**Table A-6. Healthcare-Associated Infections (HAI) key findings**

<p><b>Key Questions 1 and 1a: Which quality improvement strategies are effective in reducing HAI—central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), surgical site infections (SSI), or catheter-associated urinary tract infections (CAUTI)—and improving adherence to evidence-based preventive interventions?</b></p>
<p>A majority of included studies (90%) used organizational change and/or provider education as a quality improvement strategy. There was insufficient evidence that these strategies (alone or in combination) improved infection rates or adherence. Because they were so common, all further analyses considered the effectiveness of adding additional strategies to these “base strategies.” The review found moderate evidence that both infection rates and adherence to evidence-based preventive interventions improved when audit and feedback combined with provider reminder systems, or audit and feedback alone, were employed in combination with the base strategies. There was also some evidence that provider reminder systems alone improved adherence and infection rates (low strength of evidence). In general, these results were consistent across the 4 HAI categories. Results for each of the four HAI categories are reported in <b>Table 47</b> of the full report.<sup>44</sup> Few studies reported on the effectiveness of financial incentives, regulation, or policy (n = 2) or patient education (n = 2) as additional quality improvement strategies. Although the review was intended to capture evidence from many different settings, no studies were found regarding effectiveness in settings other than the hospital.</p>



**Key Question 1b: What is the cost, return-on-investment, or cost-effectiveness for health care providers, and society as a whole, of quality improvement strategies to reduce these HAI?**

Overall, the strength of evidence addressing this question was judged to be insufficient due to a limited number of studies reporting economic outcomes (n = 14, of which 10 adjusted for confounding or secular trends), variation in the quality improvement initiatives used in those studies, and heterogeneity in economic metrics and analysis techniques used. Furthermore, no studies evaluated return-on-investment and only 1 study evaluated net savings of quality improvement strategies to reduce HAI. One study of audit and feedback combined with organizational change and provider and patient education reported that average intervention costs among 6 randomly selected hospitals were \$3,375 per infection avoided, and 47.9 infections were avoided per hospital during each year of the study.<sup>33</sup> Another study of the same combination of strategies estimated more than \$1.9 million in annual savings by reducing CLABSI infections by 43 cases per year.<sup>34</sup>

**Key Question 1c: Which factors are associated with the effectiveness of quality improvement strategies?**

The main factor analyzed in this review was the type of quality improvement strategy (e.g., audit and feedback, provider reminder system) employed. There was moderate evidence that combining audit and feedback and provider reminder systems with the base strategies of organizational change and provider education reduced infection rates (with 5 of 7 studies finding significant improvements) and increased adherence to evidence-based preventive interventions (22 of 35 studies). Moderate evidence also suggested that infection rates and adherence rates improved when using audit and feedback alone or in combination with the base strategies (11 studies). Evidence was mixed regarding use of provider reminder systems alone or in combination with the base strategies; all adherence rates improved among the 9 studies included in this analysis, but only 5 of the 9 showed an improvement in infection rates (low strength of evidence). Neither of the 2 high-quality studies showed reduced infection rates. These conclusions were limited to CAUTI due to limited data for the other categories of HAI. There was insufficient evidence to assess the impact of the base strategies alone. The review authors were unable to address additional factors such as duration of intervention, setting, or staffing due to limitations in the available literature.

**Key Question 2: What is the impact of health care context on the effectiveness of quality improvement strategies, including reducing infections and increasing adherence to preventive interventions?**

The review authors found great variability in what, if any, contextual factors were reported. Nearly all (97%) of the 72 studies analyzed reported at least 1 of 7 contextual factors examined in this review; 61 percent reported at least 3 factors. The 3 most commonly reported contextual factors were availability of implementation materials, followed by changes in responsibilities at the unit level and leadership at the unit level. There was also great variability in how contextual factors were used; some authors attempted to control for contextual factors in analyses, while others merely discussed them. Thus, the review authors did not attempt to synthesize evidence about how contextual factors impacted HAI rates or adherence to preventive interventions.

## **7. Measuring Outcomes of Care for People With Disabilities**

### **How Was Disability Defined for This Review?**

For the purposes of this review, people with disabilities were defined as those with physical, sensory, and/or mental health conditions that can be associated with a decrease in functioning in such day-to-day activities as bathing, walking, doing everyday chores, and/or engaging in work or social activities.<sup>1</sup>

### **What Is the Quality Gap Addressed by This Topic?**

The Agency for Healthcare Research and Quality identified people with disabilities as a priority population as part of their charge to continuously assess progress toward health care quality and to update the list of national priority areas identified in 2003 by the Institute of Medicine.<sup>2</sup> Disabilities, in particular those that are developmental or acquired, can complicate provision of health care. Challenges include exacerbation or complication of medical problems

by the disability or related medical, psychological, economic, and social problems or difficulties in management of medical conditions due to the particular characteristics of the disability. Furthermore, providing high-quality care requires that medical care be coordinated with a potentially wide range of social and support services. Outcomes measures are needed that can assess the effectiveness of quality improvement interventions (whether targeted to individuals with disabilities or to broader populations) while accounting for the special challenges in caring for people with disabilities. Measuring the effectiveness of care coordination programs will be further strengthened by including process measures that can detect coordination among medical and social services.

Although some efforts have been made to measure health care quality for individuals with disabilities,<sup>1,3</sup> there is as yet no consensus about whether outcomes related to medical care can be assessed in similar ways for patients with and without disabilities. Furthermore, methods for adjusting general population outcomes measures for use in disability populations, or in broader populations that include individuals with disabilities, have varied.

### **Who Is Interested in the Topic?**

This review aimed to lay the foundation for a shared understanding among researchers, clinicians, and policymakers about issues related to quality measurement for people with disabilities. It will be of interest to anyone who wishes to evaluate the effectiveness of quality improvement interventions that target care for people with disabilities or that target broader populations that include people with disabilities. It will also be of interest to State and Federal agencies with a responsibility for supporting the health and well-being of people with disabilities through medical coverage and social support programs (e.g., Medicaid programs). In addition, it may be of interest to organizations that advocate for people with disabilities, who will be better able to assess and address quality gaps when robust outcomes measures applicable to disability populations are available.

### **What Evidence Are Stakeholders Seeking?**

The Disability Outcomes reviewers for the series sought to answer the following Key Questions:

- **Disability Outcomes Key Question 1:** How are outcomes assessed for people with disabilities living in the community in terms of basic medical service needs?
  - **1a:** What general population outcomes have been validated on and/or adjusted to accommodate disabled populations?
  - **1b:** What types of modifiers or case-mix adjusters have been used with the general population outcomes to recognize the special circumstances of people with disabilities?
  - **1c:** What are key parameters for measuring processes related to basic service care access for people with disabilities?
- **Disability Outcomes Key Question 2:** What measures have been used to assess effectiveness of care for people with disabilities living in the community in the context of coordination among health providers?
- **Disability Outcomes Key Question 3:** What measures have been used to assess effectiveness of care for people with disabilities living in the community in the context of coordination between community organizations and health providers?

## What Is the Scope of the Review?

**Population:** Community-dwelling people of all ages who were diagnosed with and/or documented to have physical and cognitive disabilities. Individuals undergoing vocational rehabilitation only or with severe and persistent mental illness as the primary disabling condition were not included within the scope of this review.

**Settings:** Outpatient health; home- and community-based services.

**Scope:** To keep the project scope feasible, the review authors focused on measures that could be used to assess either (1) interventions aimed at specific medical needs for people with disabilities or (2) comprehensive programs designed to integrate medical and social services (care coordination). The specific medical needs included in this review are:

- Preventive dental care
- Preventive medical care (based on general recommendations of the U.S. Preventive Services Task Force)
- Medical care related to the following ambulatory-care-sensitive conditions:
  - Urinary tract infections
  - Pressure ulcers
  - Diabetes and diabetic complications
  - Pneumonia
  - Asthma
  - Gastroenteritis
  - Hypertension
  - Obesity

**Outcomes analyzed:** This review focused on outcomes, patient experience, and care coordination process measures that could be used for evaluating quality improvement interventions that target or include people with disabilities. It viewed disability as a complicating condition and thus focused on generic outcomes measures for the general population or for broad classes of disability rather than on disability-specific outcomes.

**Literature reviewed:** Peer-reviewed English-language articles published between 1990 and March 2012 and indexed in the MEDLINE, PsychINFO, Education Resources Information Center (ERIC), and Center for International Rehabilitation Research Information & Exchange (CIRRIE) databases. The review was limited to research from the United States and from the United Kingdom, Canada, Australia/New Zealand, and the Netherlands, where service delivery settings were more likely to be applicable to the United States. The review identified 15 articles that addressed Key Question 1 and 45 that addressed Key Questions 2 and 3.

**Analyses performed:** Results were synthesized qualitatively. When possible, the International Classification of Functioning, Disability and Health was used as an organizing principle.<sup>4</sup>

## What Were the Key Findings?

Table A-7 summarizes the main results by Key Questions for this topic.

**Table A-7. Disability Outcomes key findings**

<p><b>Key Question 1a: What general population outcomes have been validated on and/or adjusted to accommodate disabled populations?</b></p>
<p>The review found few examples of research that viewed disability as a complicating condition rather than as the main condition of focus. The 15 articles identified by the review that addressed this Key Question to some extent evaluated a total of 71 different outcomes measures for use in disability populations. Nearly half of these measures (48%) were evaluated by a single article that focused specifically on participation as an outcome among people with disabilities.<sup>5</sup> An additional 28 measures (39%) were identified from a series of 5 papers focused on the state of outcomes measurement for rehabilitation. The remaining articles identified 5 general population outcomes that have been adapted for use in disability populations (<b>Table 8 of full report</b>), 2 outcomes measures developed for 1 disability group that have been expanded for use in a different disability group (<b>Table 9 of full report</b>), and four newly developed measures (<b>Table 10 of full report</b>).<sup>6</sup> <b>Table 4 of the full report</b> lists all 71 outcomes measures and their source article.</p> <p>The review also identified a rehabilitation outcomes database (<a href="http://www.rehabmeasures.org">www.rehabmeasures.org</a>) that contains measures specifically for use in patients with stroke or spinal cord injuries and is currently being updated with measures for patients with traumatic brain injury. Another consensus-based measure development effort noted by the review authors is developing core measure sets aimed at specific chronic medical conditions for use in patients with disabilities.<sup>7</sup> Thus far, this effort has developed core measure sets for 14 conditions, ranging from breast cancer and depression to obesity and rheumatoid arthritis. The review also identified a compendium of 28 rehabilitation outcomes measures, culled from among 300 initially reviewed, for use in community settings. The set of measures may be found in <b>Table 7 of the full report</b>.</p>
<p><b>Key Question 1b: What types of modifiers or case-mix adjusters have been used with the general population outcomes to recognize the special circumstances of people with disabilities?</b></p>
<p>The review did not identify any studies that addressed this Key Question using a mixed-study sample that included both disabled and nondisabled participants.</p>
<p><b>Key Question 1c: What are key parameters for measuring processes related to basic service care access for people with disabilities?</b></p>
<p>The review also did not identify any studies that addressed this Key Question. The authors caution that the decision to limit the scope of this review to an illustrative set of medical conditions may have prevented them from identifying relevant literature that addresses other particular conditions.</p>
<p><b>Key Questions 2 and 3: What measures have been used to assess effectiveness of care for people with disabilities living in the community in the context of coordination among health providers and between community organizations and health providers?</b></p>
<p>The review identified 44 studies (from 45 articles) that addressed these research questions. The review authors synthesized evidence for these Key Questions together because most studies (77%) evaluated interventions that included both coordination among health care providers (Key Question 2) and coordination between health care providers and social support (Key Question 3).</p> <p>More than 100 different measures were used to evaluate care coordination interventions. Health and level of functioning, and costs or utilization were the most commonly used types of outcomes measures, but patient or caregiver experience of care was also commonly measured. The specific instruments used to measure these general types of outcomes varied widely. Some measures were developed for use in general populations, such as the Short Form (SF)-36 and SF-8 (measures of health and functioning), Patient Assessment of Care for Chronic Conditions (PACIC), Consumer Assessment of Healthcare Providers and Systems (CAHPS) (measures of experience of care), and the rate of emergency room visits or hospitalization (measures of utilization). Others were more specific to people with disabilities, such as measures of activities of daily living or instrumental activities of daily living dependencies, survival without institutionalization (measures of functioning), and rate or frequency of nursing home stays or use of adult daycare centers (measures of utilization).</p> <p>The review also identified the National Core Indicators collaborative as an important potential source of outcomes measures for people with disabilities. The initiative aims to develop a standard set of performance measures for use in evaluating the quality of developmental disability services. The complete set may be found in <b>Table 14 of the full report</b>.</p>

## 8. Interventions To Improve Health Care and Palliative Care for Advanced and Serious Illness

### What Is Palliative Care?

Palliative care is medical care focused on improving the quality of life of people facing serious or life-threatening illness, including end of life. It is often provided as a service or quality improvement intervention; emphasizes pain and symptom management, communication, and coordination; and can be delivered in any setting. This review also included end-of-life care and hospice, both subsets of palliative care:

- End-of-life care is care that is delivered to dying patients.
- Hospice is a care delivery system and insurance benefit for patients in the last months of life who have chosen quality of life as the primary goal of care. It is delivered wherever the patient resides; in the United States, this includes the home, special inpatient units, and nursing homes.

### What Is an Advanced or Serious Illness?

The review authors defined the population of interest as seriously ill patients and those with advanced disease (such as people living with advanced cancer or intensive care unit patients at high risk of dying) who are unlikely to be cured, recover, or be stabilized.

### What Is the Quality Gap Addressed by This Topic?

Evidence abounds that there is room for much improvement in the quality of palliative care for patients with advanced and serious illness. Pain remains undertreated for many patients. Despite effective therapies and clinical practice guidelines to facilitate pain management,<sup>19,20</sup> patients with terminal cancer frequently are not offered alternatives to chemotherapy, are not educated about the uncertain benefits of such treatment, or are unaware of their prognosis,<sup>21</sup> and in 2009, fewer than half of patients who died in the United States received any hospice care.<sup>22</sup> Furthermore, a previous systematic review of hospice care reported that family members experienced unmet needs for family support (18.2 percent) and emotional support (9.8 percent).<sup>23</sup> These gaps highlight the need for quality improvement interventions that improve outcomes for patients with advanced and serious illness and their caregivers. The review authors specifically targeted evidence regarding palliative care in hospice, where a previous systematic review identified quality gaps,<sup>23</sup> and in nursing homes, where prior systematic reviews related to end-of-life care are lacking.

### Who Is Interested in the Topic?

This review aimed to evaluate the effectiveness of palliative care quality improvement interventions for patients with advanced and serious illness. The results of the review will be of interest to organizations investing in palliative care quality improvement programs and to directors of and participants in such initiatives. Furthermore, it is likely to be of interest to providers working in palliative care and hospice programs or in settings with significant numbers of patients with advanced and serious illness (e.g., cancer centers, medicine inpatient units, nursing homes). Researchers and research funders with an interest in palliative care or this population will find information about evidence gaps and weaknesses that may help guide future research agendas and study design. Patient advocacy groups will find information that may be leveraged to encourage use of best practices.



## What Evidence Are Stakeholders Seeking?

The Palliative Care review authors sought to answer the following Key Questions:

- **Palliative Care Key Question 1:** What is the effectiveness of health care and palliative care interventions for key targets and settings relevant to palliative care?
  - **1a:** Specific targets: What is the effectiveness in terms of processes and outcomes for pain; communication and decisionmaking; continuity, coordination, and transitions of care; and patient and family distress in palliative care populations?
  - **1b:** Specific settings: What is the effectiveness of interventions for any target of palliative care within hospice programs or nursing homes?
- **Palliative Care Key Question 2:** What is the evidence for different quality improvement models for improving palliative care?
  - **2a:** What is the evidence for different types of quality improvement interventions?
  - **2b:** What is the evidence for different models in palliative care: integrative (palliative care principles and interventions embedded into daily practice) compared with consultative (use of palliative care consults)?

For each intervention target area (e.g., pain; communication and decisionmaking; continuity, coordination, and transitions of care; patient and family distress), the reviewers analyzed either Key Question 2a or 2b, but not both, depending on which question was more applicable.

## What Is the Scope of the Review?

**Population:** Patients with advanced and serious illness. (See definition above.)

**Outcomes analyzed:** Patient and family satisfaction/perceptions of palliative care; patient symptoms, needs, distress, and quality of life; health care utilization, such as hospital admissions or do-not-resuscitate orders (but not costs); quality-of-care measures, such as timeliness of response to pain and other symptoms; family/caregiver psychosocial symptoms, support, needs, quality of life, and grief/bereavement.

**Literature reviewed:** The review authors searched for evidence between 2000 and 2011 from the following databases: PubMed, CINAHL, PsycINFO, Cochrane, and DARE. The final review included 96 articles describing 90 studies. Twelve studies that addressed targets of continuity, coordination of care, and/or transitions in care were randomized controlled trials.

**Analyses performed:** Due to heterogeneity of interventions, outcomes, and outcome reporting, the data could not be synthesized and a meta-analysis was not conducted. Instead, the information was described in a systematic manner. The review authors categorized included studies by target and setting of the intervention, including a category for interventions that focused on multiple targets or targets other than the primary ones.

## What Were the Key Findings?

Table A-8 summarizes the main results by Key Questions for this topic.



**Table A-8. Palliative Care key findings**

<b>Key Question 1a: In palliative care populations, what is the effectiveness of health care and palliative care interventions that target pain; communication and decisionmaking; continuity, coordination, and transitions of care; and patient and family distress?</b>
Among palliative care populations, the review found evidence that interventions that targeted pain improved pain (moderate strength of evidence) but not quality of life (low strength of evidence). Nineteen of the 21 studies of pain focused on patients with cancer. Interventions that targeted communication and decisionmaking improved health care utilization (moderate strength of evidence), but not patient satisfaction (low strength of evidence) or family satisfaction (insufficient strength of evidence). Interventions that targeted continuity, coordination, and transitions of care improved patient and caregiver satisfaction (moderate strength of evidence) but not quality of life, overall symptoms, or health care utilization (low strength of evidence). There was only low strength of evidence that interventions targeting patient distress were effective, with 2 of 7 randomized controlled trials (RCTs) showing significant improvement.
<b>Key Question 1b: What is the effectiveness of interventions for any target of palliative care within hospice programs or nursing homes?</b>
Only a handful of studies for either setting were found for each intervention target, limiting the ability to draw conclusions. Altogether, only 2 studies were identified in the hospice setting and 9 in the nursing home setting. Of these 9 nursing home studies, 7 showed improvements in at least 1 outcome following palliative care interventions such as care pathways, pain assessment, and education. In 2 RCTs that focused on pain screening interventions among patients with end-stage dementia in nursing homes, both reported statistically significant improvement in pain-related outcomes (i.e., pain assessment and adherence to pain medication) with the intervention. One RCT that investigated an intervention to educate patients, providers, and families about advance directives found a statistically significant decrease in average hospital days among the intervention group (2.61 days vs. 5.86 days, $p = 0.01$ ). <sup>24</sup>
<b>Key Question 2a: What is the evidence for different types of quality improvement interventions improving palliative care?</b>
Six of 9 studies using patient-centered quality improvement interventions (patient/family/caregiver education and promotion of self-management) to target continuity, coordination of care, and transitions showed a significant improvement in patient satisfaction and quality of life. In contrast, none of 6 studies that used only provider-centered quality improvement interventions (i.e., provider reminder systems, facilitated relay of clinical data to providers, or provider education) without patient-centered interventions to target this area demonstrated improved quality of life or satisfaction. A majority of interventions targeting pain were patient centered (18 of 21), while only 14 percent were exclusively provider focused. Combining print and video material in patient-centered pain interventions seemed most effective; 4 of 6 such studies showed improvements in pain, while only 1 of 3 studies using only 1 modality (print or video but not both) showed improvement.
<b>Key Question 2b: What is the evidence for different models in palliative care (integrative vs. consultative) improving palliative care?</b>
This question was analyzed only for interventions targeting communication and decisionmaking. The review found some evidence supporting the effectiveness of both integrative care models (with 4 of 8 studies showing improvement) and consultative care models (with 6 of 8 studies showing improvement) for this target area.

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## Appendix B. Focus on Action: Key Messages for Improving Quality

In this appendix, we summarize how information learned through each review is useful for improving quality of health care. We organized this information according to key stakeholders because implications of the reviewed evidence may differ depending upon the audiences' perspective. These stakeholder groups are: patients or health care consumers and their caregivers, including patient advocacy organizations (Table B-1); clinicians and health care professionals, including physicians, nurses, pharmacists, social workers, and other clinical care providers (Table B-2); administrators of health delivery organizations, such as hospitals, outpatient clinics (primary or specialty care), and long-term care facilities (Table B-3); and policymakers (Table B-4). We present results for each potential audience separately.

### Messages for the Patient/Consumer/Caregiver Perspective

Regardless of the focus or target of quality improvement (QI) interventions, as the consumers and recipients of health care, patients have a direct interest in the success or failure of QI initiatives. As they help patients navigate the health care system and strive for optimal health, family members and other informal caregivers also have an interest in the quality of care received by their loved ones. An inefficient, chaotic, or inequitable system also poses many challenges to caregivers, who all too often bear the burden of overcoming these barriers to high-quality care. Patient advocacy organizations play an important role in aggregating individual experiences—good and bad—into collective insights about strengths and weaknesses of the current health care system and ways in which the system might better meet patient needs. Thus, from the perspective of patients and their caregivers and representatives, evidence about QI initiatives is a valuable window into the health system and may signal leverage points where their actions, whether through individual discussions with providers or through collective advocacy, can help improve the quality of their care experience. Table B-1 summarizes key messages for this audience by topic.

**Table B-1. Messages for improving quality for the patient/consumer/caregiver perspective**

Topic	Take-Home Messages Motivating Potential Actions
<b>Bundled Payment</b>	<b>The impact of bundled payment on quality of care is unknown.</b> Implementing bundled payment programs generally showed small changes in quality measures, but the direction and magnitude of those effects varied within and across studies. Thus, it is unknown which aspects of care might be improved through bundled payments and which might experience a detrimental change. There was no evidence about whether bundled payment programs lead to providers avoiding high-risk patients.
<b>Patient-Centered Medical Home</b>	<b>Small positive effects on patient experience were associated with PCMH.</b> The PCMH model holds promise for improving the experiences of patients, and potentially for improving care processes. The review found evidence of moderate strength indicating that interventions meeting PCMH criteria were associated with small improvements in patient experiences, both on overall measures of patient satisfaction and on measures of patient-reported/patient-perceived level of care coordination.
<b>Disparities</b>	<b>Very little research has focused on quality improvement strategies to reduce health care disparities.</b> Further advocacy may be needed to encourage progress in this area.

Topic	Take-Home Messages Motivating Potential Actions
<b>Medication Adherence</b>	<p><b>Reducing out-of-pocket medication costs improved adherence.</b> One of the most robust conclusions from this series underscores the important role that out-of-pocket costs play in medication adherence. This suggests the importance of assessing adequacy of pharmacy benefits in connection with adherence behaviors.</p>
<b>Public Reporting</b>	<p><b>Slight improvements in quality were associated with public reporting.</b> Most studies of hospital-level public reporting found a decrease in mortality (19 studies, moderate strength of evidence), and studies of public reporting for health plans or long-term care facilities generally found improvements in outcomes such as pain, pressure ulcers, and satisfaction with care.</p> <p><b>It is unclear whether public reporting limits patient access.</b> Evidence about the potential for health care providers to cherry-pick patients (thereby limiting access for sicker patients) was of low quality and yielded mixed results. One study found greater disparities between whites and blacks or Hispanics in receipt of coronary artery bypass graft surgery that persisted for 9 years following public reporting, but another study found that high-risk patients were more likely to see high-quality surgeons, contradicting the hypothesis that physicians might refuse to treat the highest risk patients to improve their performance on mortality and other patient outcomes measures.</p> <p><b>Public reporting had little impact on patient choice.</b> Results across studies and settings consistently showed that patients and their families or representatives did not use public reports when selecting hospitals, clinicians, health plans, or nursing homes. The few studies reporting evidence for an effect of public reporting on patient choice did so only for a subgroup of patients. Evidence from 12 qualitative studies suggested that patients were often unaware that quality information was available through public reporting (4 studies); considered other factors such as travel distance; recommendations by family, friends, or doctors; and financial considerations to be more important in choosing a provider (7 studies); or did not find the quality measures included in the reports to be relevant or understandable (2 studies).</p>
<b>Healthcare-Associated Infections</b>	<p><b>Little evidence is available about patients' roles in reducing HAI.</b> Patients and their caregivers may be able to encourage adherence to some preventive interventions if educated about good practices and empowered to voice concerns when their providers deviate from those practices. Yet this review found just 2 studies that examined patient education as a quality improvement strategy aimed at reducing HAI. Advocacy on behalf of patients may be needed to spur research in this area and further explore how the actions of patients and their caregivers may impact HAI rates or adherence to preventive interventions.</p>
<b>Disability Outcomes</b>	<p><b>There is a need to advocate for more inclusive research and engage in consensus efforts.</b> Much of the literature included in this review views disability as the main health concern rather than as a complicating condition. None of the studies reviewed included a mixed population of people with and without disabilities. Advocacy from the community of people with disabilities may help encourage more inclusion of disabled people in research studies, further a view of disability as a complicating condition, and broaden the scope of outcomes measures used in disability research. Efforts to develop consensus-based core measure sets should incorporate input from individuals with disabilities.</p>



Topic	Take-Home Messages Motivating Potential Actions
Palliative Care	<p><b>Interventions targeting continuity, coordination, and transitions of care improved patient and caregiver satisfaction.</b> Although these interventions did not improve quality of life or symptoms, or decrease health care utilization (low strength of evidence), patients and their caregivers reported higher satisfaction with care for interventions focused on providing continuity of care, well-coordinated care, and facilitated transitions (moderate strength of evidence).</p> <p><b>Interventions targeting communication and decisionmaking did not improve patient satisfaction.</b> Although these interventions decreased health care utilization (moderate strength of evidence), they did not improve patient or caregiver satisfaction (low strength of evidence), suggesting that this aspect of care may be less relevant to patients and their families.</p> <p><b>Little is known about interventions to decrease patient distress.</b> There was only low strength of evidence that interventions targeting patient distress were effective: 2 of 7 RCTs showed significant improvement.</p>

**Note:** HAI = healthcare-associated infections; PCMH = patient-centered medical home; RCT = randomized controlled trial.

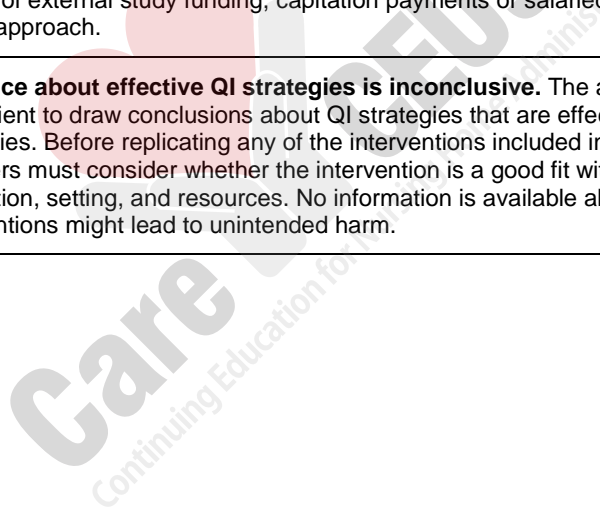
## Messages for the Clinician/Health Professional Perspective

As the direct providers of care, clinicians and health professionals, including physicians, nurses, social workers, and pharmacists, play a crucial role in ensuring the quality of care patients receive. Whether initiating and directing QI activities or participating in QI programs initiated at an organization or systems level, health care professionals will benefit from an understanding of the effectiveness of various interventions and the ways in which those interventions interact with patient, organization, system, and market factors. Health care professionals can also benefit from an understanding of some of the potential harms hypothesized to arise from improvement strategies, such as changes in coding practices in response to information uses, avoiding high-risk patients or selecting only low-risk patients, or shifting care to suboptimal alternative settings in response to incentive changes. Table B-2 summarizes key messages for clinicians and other health professionals by topic.

**Table B-2. Messages for improving quality for the clinician/health professional perspective**

Topic	Take-Home Messages Motivating Potential Actions
Bundled Payment	<p><b>Providers' response to bundled payment programs is largely unexplored.</b> Several unintended consequences of bundled payment programs have been hypothesized, including providers avoiding high-risk patients, changing coding practices to maximize reimbursement for bundles, or moving services in time or location to qualify for separate reimbursement. This review found no studies that specifically sought to assess changes in provider behavior in response to bundled payment programs. However, several studies reported postimplementation changes that suggested some potential gaming. Some evidence demonstrated increased patient risk following implementation of bundled payment programs, but it is unknown whether this was due to changes in coding practices or to actual changes in the level of risk among the patient population. In addition, several programs that blended bundled payments with fee-for-service reimbursement reported greater use of services that generate higher reimbursement than before bundling.</p>

Topic	Take-Home Messages Motivating Potential Actions
<p><b>Patient-Centered Medical Home</b></p>	<p><b>PCMH had small positive effects on staff experience.</b> The PCMH model holds promise for improving the experiences of staff. This review found evidence of low strength that PCMH implementation was associated with improved staff experiences. However, none of the studies reporting information on staff experiences were conducted in pediatric practices. Two of the 3 were conducted in an older adult population. None of the studies reported outcomes more than approximately 2 years following the implementation of the intervention under study. Relatively few practices and few clinicians have been involved in these studies, and these practices may not be representative of the wider primary care practices in the United States.</p> <p><b>The extent of unanticipated consequences of implementation is not known.</b> Unanticipated consequences such as increased provider burden, increased administrative time, and potential patient safety risks were not evaluated in the included studies.</p> <p><b>Various organizational learning and implementation strategies were used.</b> Implementation of PCMH required significant restructuring for most primary care practices. Eight of 9 PCMH studies and 11 of 13 functional PCMH studies used a formal learning collaborative (e.g., lectures and training sessions) and/or collaborative planning sessions (e.g., team meetings) to make practices more consistent with PCMH. The most commonly used implementation strategy was audit and feedback at either the provider or practice level.</p> <p><b>Various financial models have supported PCMH implementation.</b> Providers have concerns about costs for implementation and overall costs to the practice. Various strategies have been used to support PCMH implementation, including receipt of external study funding, capitation payments or salaried providers, or a hybrid approach.</p>
<p><b>Disparities</b></p>	<p><b>Evidence about effective QI strategies is inconclusive.</b> The available evidence is insufficient to draw conclusions about QI strategies that are effective at reducing disparities. Before replicating any of the interventions included in this review, providers must consider whether the intervention is a good fit with their particular population, setting, and resources. No information is available about whether the interventions might lead to unintended harm.</p>



Topic	Take-Home Messages Motivating Potential Actions
<p><b>Medication Adherence</b></p>	<p><b>Evidence for effectiveness varied considerably by patient condition.</b> It is unlikely that any single medication adherence intervention will be effective for all patients with chronic conditions. This poses a challenge for providers seeking to improve adherence among all their patients, particularly in the primary care setting, where providers care for patients with a wide range of conditions. Providers may need to target improvement efforts toward patient populations with the greatest potential to benefit (poorest adherence and/or greatest potential for improvement with better adherence) and where there is moderate evidence of effective interventions.</p> <p><b>Interventions improved medication adherence in most vulnerable populations studied.</b> Medication adherence improved for patients with major depression, severe depression, multiple chronic conditions, and depression with comorbid hypertension; black patients with coexisting depression and diabetes; and elderly patients with diabetes, hyperlipidemia, congestive heart failure, or hypertension.</p> <p><b>Choosing interventions for many patient populations will require extrapolation.</b> This review found evidence regarding medication adherence interventions for a limited number of chronic conditions. Depression, asthma, diabetes, hypertension, and hyperlipidemia were the most commonly studied. Only a few studies, yielding low or insufficient evidence, were available for each of several additional conditions, such as glaucoma, myocardial infarction, musculoskeletal disorders, and multiple sclerosis. No information was available about the effectiveness of interventions for other chronic disease groups. Particularly in the primary care setting, clinicians must consider how to apply disease-specific evidence from this limited set of conditions to other patient groups. For example, interventions that appeared to improve medication adherence for hypertension and hyperlipidemia may help improve adherence with medication for other conditions that are asymptomatic or that aim to prevent long-term complications.</p>
<p><b>Public Reporting</b></p>	<p><b>Limited evidence suggests that individual clinicians make positive changes in response to public reporting.</b> One study found that mortality rates declined following physician-level public reporting for cardiac surgery. Surgeons who stopped performing certain procedures after public reporting began were more likely to be poor performers (considered a positive change).</p> <p><b>Potential harms of public reporting were not confirmed.</b> There was no evidence that public reporting leads to overdiagnosis or inappropriate prescribing (defensive medicine). Few physicians reported withdrawing from practice due to public reporting (1 study). Qualitative studies based on surveys and interviews revealed widespread mistrust of public reporting by physicians. Many cited concerns that public reporting would motivate clinicians to decline treatment to high-risk patients, but this review found only mixed evidence of this practice.</p>
<p><b>Healthcare-Associated Infections</b></p>	<p><b>Methods to prevent HAI are known, but reducing HAI rates requires that providers consistently use those methods.</b> Although effective techniques to prevent HAI are well established, providers continue to lag in consistently applying these techniques, putting patients at unnecessary risk. Many QI strategies target provider behavior to increase their adherence to these evidence-based preventive interventions.</p> <p><b>Some combinations of QI strategies focusing on provider behavior work.</b> Although widely used, organizational change and provider education alone do not appear to be sufficient to improve HAI rates or adherence to evidence-based preventive interventions. The review found moderate strength of evidence that supplementing these base strategies with additional approaches that focused on providers, namely, audit and feedback with or without provider reminder systems, led to improvements. Two studies of CLABSI reported that simulation-based provider education was more effective than traditional passive learning techniques, but more research is needed to confirm this result.</p>

Topic	Take-Home Messages Motivating Potential Actions
Disability Outcomes	<b>Clinicians should be conscious of focus on disabilities relative to other health concerns.</b> The review found few examples of research that viewed disability as a complicating condition. Rather, the predominant view treated disability as the primary health concern in disabled populations, particularly for research from the medical paradigm. When treating patients with disabilities, health care providers should be conscious of how much they focus on the disability itself relative to other health concerns, particularly with respect to preventive care and chronic disease management. At the same time, further training may be necessary to develop a greater understanding of how to address medical issues, manage chronic disease, or deliver preventive care in the context of physical or intellectual disabilities.
Palliative Care	<b>Provider-centered interventions are not effective for continuity, coordination, and transitions.</b> None of 6 studies that used solely provider-centered QI interventions (provider reminder systems, facilitated relay of clinical data to providers, or provider education) without additional patient-centered interventions to target this area demonstrated improved quality of life or satisfaction.

**Note:** CLABSI = central line-associated bloodstream infections; HAI = healthcare-associated infections; PCMH = patient-centered medical home; QI = quality improvement.

## Messages for the Delivery Organization Perspective

Leaders of health delivery organizations play a crucial role in recognizing quality deficits within their organizations, identifying potential solutions, and driving QI activities. To guide these activities and make efficient use of limited improvement resources, these leaders need to know what works and what does not within a particular topic area. Table B-3 summarizes key messages for the health delivery organization perspective.

**Table B-3. Messages for improving quality for the delivery organization perspective**

Topic	Take-Home Messages Motivating Potential Actions
Bundled Payment	<b>Bundled payment programs lower utilization slightly.</b> Bundled payment was associated with between 5% and 15% lower utilization of services, in particular, shorter hospital length of stay. Utilization decreased to a greater extent for for-profit compared with not-for-profit providers. Although limited, some evidence suggested that bundled payment programs led to some care shifting to other settings.
Patient-Centered Medical Home	<b>The jury is still out about the impact of PCMH interventions on clinical process-of-care outcomes.</b> The review found evidence of low strength that PCMH may improve care processes, especially for preventive services. This is based on a combination of moderate evidence of an effect for preventive services and insufficient evidence to evaluate impacts on care for patients with chronic illness. <b>High variability in PCMH implementation confounds research conclusions.</b> Approaches to implementing the PCMH model varied greatly from one organization to another. While reflective of a rapidly innovating field, this variability limited the reviewers' ability to synthesize the research evidence and draw conclusions about what aspects of the PCMH model worked in what contexts and impacted which outcomes.
Disparities	<b>Evidence about effective QI strategies is inconclusive.</b> The available evidence is insufficient to draw conclusions about QI strategies that might be effective in reducing disparities. Before replicating any of the interventions included in this review, health delivery organizations must consider whether the intervention is a good fit with their particular population, setting, and resources. No information is available about whether the interventions might lead to unintended harm.

Topic	Take-Home Messages Motivating Potential Actions
<p><b>Medication Adherence</b></p>	<p><b>There is no single “silver bullet” for improving medication adherence.</b> This review found a wide variety of interventions that successfully improved medication adherence. Most of these interventions were multifaceted; over half were aimed at multiple targets, and most had multiple components, including several with multiple delivery modes. The diversity of interventions that demonstrated effectiveness suggests that there are many potential pathways for improving adherence. Until further evidence becomes available about specific intervention characteristics associated with improvements under particular circumstances, organizations may be well served by experimenting with various interventions and refining their approach over time.</p> <p><b>The evidence base points to some starting places for choosing an intervention.</b> The strongest evidence from this review points to several intervention approaches that were most often associated with success. Self-management approaches appeared to improve adherence with asthma medication, while case management improved adherence and symptoms for patients with depression. Pharmacist-led interventions improved both adherence and systolic blood pressure for patients with hypertension. Across conditions, consistent evidence supported the effectiveness of education, reminders, and pharmacist-led multicomponent interventions. Trials showing improvement in case management and educational interventions provided some evidence of improvement for other health outcomes as well.</p> <p><b>However, little is known about which intervention characteristics are likely to lead to success.</b> Even interventions with a similar approach (e.g., education, case management) varied greatly with respect to their target, agent, mode, intensity, and duration. Little information was available about which of these characteristics are associated with effectiveness and under what circumstances. In the absence of such information, organizations interested in improving adherence among their patients may wish to seek out and learn from peer organizations that have already implemented medication adherence interventions. Participating in improvement collaboratives focused on this topic would provide opportunities for this type of sharing and iterative learning. Some amount of trial and error with iterative refinement will likely be necessary to achieve success.</p>
<p><b>Public Reporting</b></p>	<p><b>Delivery organizations make positive changes in response to public reporting.</b> Although limited in number and setting, some studies reported that hospitals were more likely to offer new services, alter policies, and engage in QI activities following public reporting. Quality measures improved after public reporting for almost all HEDIS and CAHPS domains studied (5 studies). Evidence also supports improvements in other measures of quality, such as mortality (hospitals) and pain, pressure ulcers, and satisfaction with care (health plans, LTC facilities) following public reporting.</p> <p><b>Limited evidence exists of “gaming” of public reports in the LTC setting.</b> One study reported that, to improve performance measures, nursing homes may readmit postacute care patients to the hospital just before Nursing Home Compare assessment. Moderate evidence suggests nursing homes may be motivated to change coding practices to improve performance. There was no evidence that health plans withdrew from the market or experienced declines in other unmeasured areas following public reporting.</p> <p><b>Few patients used public reports to select health care providers.</b> Across settings, evidence consistently showed that patients, families, and their representatives rarely used publicly reported quality information to guide choice of health care providers. Qualitative studies indicated that public reports did not influence choice because of content (lack of relevant information), timing (not available at the time of decisionmaking), presentation, and awareness. Administrative actions seem to acknowledge this finding; in the LTC environment, administrative response to public reporting appeared to be motivated primarily by the expectation that those reports would influence professional referrals and the State survey process rather than patient and family selection of facilities.</p>

Topic	Take-Home Messages Motivating Potential Actions
<b>Healthcare-Associated Infections</b>	<p><b>Moderate strength of evidence exists for audit and feedback with or without provider reminder systems as an effective QI strategy.</b> Despite the great heterogeneity in studies, the review found evidence that, when combined with the base strategies of organizational change and/or provider education, using audit and feedback strategies alone or in combination with provider reminder systems improved infection rates and adherence to evidence-based preventive interventions. Evidence was insufficient that the base strategies alone improved these outcomes. <b>Key questions remain unanswered.</b> The above results were fairly consistent across the 4 categories of HAI (CLABSI, VAP, SSI, and CAUTI) but are applicable only to hospitals due to lack of evidence in other settings. Evidence was also lacking about contextual factors that may influence the effectiveness of these strategies and economic outcomes such as return-on-investment or net savings. Until such evidence becomes available, choice of QI strategy and implementation design will remain challenging.</p>
<b>Disability Outcomes</b>	<p><b>Access is a key concern for patients with disabilities.</b> Among more than 100 measures identified in this review, the review authors found only 9—all for use in children—that assessed access to care. Yet patients with disabilities frequently experience access barriers such as transportation issues; difficulty navigating clinics, getting on exam tables or into imaging equipment; or challenges in communicating with providers. Access may be further limited by providers who are unfamiliar with how to treat medical conditions in the context of a particular disability. Health delivery organizations should be conscious of these access barriers and consider how to measure outcomes related to access for people with disabilities as part of QI efforts.</p>
<b>Palliative Care</b>	<p><b>Patient-focused QI interventions can be used to improve patient-centered outcomes.</b> Six of 9 studies using patient-centered QI interventions to target continuity, coordination of care, and transitions showed a significant improvement in patient satisfaction and quality of life, while none of 6 studies using provider-centered QI interventions did so. A majority of interventions targeting pain were patient centered, and there was moderate evidence that pain-focused interventions improved outcomes related to pain.</p> <p><b>Some evidence supports both integrative and consultative palliative care models.</b> Although evidence was analyzed only for interventions targeting communication and decisionmaking, some evidence supported the effectiveness of both integrative care models (4 of 8 studies showing improvement) and consultative care models (6 of 8 studies showing improvement).</p>

**Note:** CAHPS = Consumer Assessment of Healthcare Providers and Systems; CAUTI = catheter-associated urinary tract infections; CLABSI = central line-associated bloodstream infections; HAI = healthcare-associated infections; HEDIS = Healthcare Effectiveness Data and Information Set; LTC = long-term care; PCMH = patient-centered medical home; QI = quality improvement; VAP = ventilator-associated pneumonia; SSI = surgical site infection.

## Messages for the Policymaker Perspective

Like health delivery organization leaders, policymakers influence quality at a system level, identifying quality gaps ripe for improvement and developing programs aimed at closing those gaps. They, too, need information about which QI interventions are effective in what contexts, and the resource implications of various QI choices. Furthermore, in their focus on systems-level effects, policymakers are also best situated to initiate changes that improve quality by reducing negative consequences of fragmentation of care, addressing needs of vulnerable populations, and weighing potential harms from QI activities. Table B-4 summarizes key messages for the policymaker perspective.



**Table B-4. Messages for improving quality for the policymaker perspective**

Topic	Take-Home Messages Motivating Potential Actions
<p><b>Bundled Payment</b></p>	<p><b>Bundled payments reduce spending and utilization slightly.</b> The available evidence showed consistently that bundled payment programs resulted in small (<math>\leq 10\%</math>) decreases in health care spending compared with cost-based or fee-for-service models. Bundled payment was also associated with between 5% and 15% lower utilization of services, in particular shorter hospital length of stay.</p> <p><b>The impact of bundled payment programs on quality of care is unclear.</b> Quality measures often showed change following implementation of bundled payment programs, but the direction and magnitude of the difference varied both within studies (i.e., different quality measures evaluating a single program) and across studies (i.e., similar measures evaluating different programs).</p> <p><b>Potential unintended consequences of bundled payment programs remain unexplored.</b> Studies rarely assessed unintended negative consequences of bundled payment, such as underutilization of effective services, avoiding high-risk patients, increasing the number of bundles reimbursed, changing coding practices to maximize reimbursement for bundles, or moving services in time or location to qualify for separate reimbursement. Studies of several programs reported that care shifted to other settings, suggesting that these programs may have broader impacts beyond the targeted settings and patient populations.</p>
<p><b>Patient-Centered Medical Home</b></p>	<p><b>Not much is conclusive yet regarding the impact of PCMH on clinical outcomes and care processes.</b> There is overall evidence of low strength that PCMH may improve care processes, especially for preventive services. This is based on a combination of moderate evidence of an effect for preventive services and insufficient evidence to evaluate impacts on care for patients with chronic illness.</p> <p><b>PCMH as a QI approach is still in its infancy. From studies to date, the medical home is not a magic bullet to solve America's high cost of providing health care.</b> Current evidence is insufficient to determine effects on clinical and most economic outcomes. The review found low strength of evidence that PCMH does not lead to uniformly lower utilization in two areas hypothesized to be affected: inpatient and emergency department utilization. Moreover, total costs were not consistently lowered in the reviewed studies.</p> <p><b>The amount of data that we have to bring to bear on this issue is expected to more than double in a few years.</b></p>
<p><b>Disparities</b></p>	<p><b>Additional study is warranted for collaborative care and patient education strategies.</b> Although limited, some evidence suggested that these strategies hold promise for reducing disparities. Combining language and literacy concordance with patient education also holds promise. Although there was no direct evidence of their effectiveness in reducing health care disparities, in the absence of further information, these strategies might be a useful starting place for efforts to reduce disparities.</p>
<p><b>Medication Adherence</b></p>	<p><b>Decreasing out-of-pocket costs can improve medication adherence for patients with cardiovascular disease and diabetes.</b> Although only 5 studies examined policy-level interventions, all found that reducing patients' out-of-pocket expenses for medications improved adherence, with the exception of adherence to inhaled corticosteroids (moderate strength of evidence). The mechanisms for reducing expenses varied across the studies, suggesting that how expenses are reduced is not as important as the reduction itself.</p> <p><b>Improved medication adherence does not necessarily mean improvement in other outcomes.</b> Only a subset of interventions that showed improved medication adherence also showed improvement in other outcomes, such as biomarkers, morbidity, mortality, quality of life, quality of care, patient satisfaction, health care utilization, and costs.</p>

Topic	Take-Home Messages Motivating Potential Actions
<p><b>Public Reporting</b></p>	<p><b>Current public reporting efforts are poorly matched to patient needs.</b> Patients and their representatives rarely used publicly reported quality information as the basis for choosing a provider; qualitative research suggested patients did not have access to quality information when they needed it, outcomes reported were not relevant to them, or they did not understand the information as presented. Thus, current public reporting initiatives are unlikely to motivate change through market forces. Future public reporting efforts aimed at patients must be better tailored to patients' needs with respect to timing, accessibility, content, format, and mode.</p> <p><b>Health delivery organizations are more responsive to public reporting than patients or clinicians.</b> Although mistrustful of public reporting, clinicians were somewhat responsive to publicly reported quality information; patients did not use information from public reporting. In contrast, health plans, hospitals, and especially nursing homes accepted public reporting and made changes to improve their performance. Except in the long-term care environment, little evidence was available about the motivation for these changes.</p> <p><b>Little evidence exists that public reporting leads to harm.</b> Potential harms from public reporting have been the subject of many commentaries. Indeed, this review found that the volume of editorials and discussion about potential harms outweighed the volume of research investigating those harms. Most studies that investigated potential unintended negative consequences of public reporting did not confirm the potential harm. However, the horizon scan revealed ongoing research that might show some negative consequences of public reporting for nursing homes; these results were not yet published at the time the review was completed.</p>
<p><b>Healthcare-Associated Infections</b></p>	<p><b>Meaningful reductions in HAI rates are possible through QI.</b> While questions remain about which QI strategies are most effective and cost-effective, particularly in different settings and contexts, the evidence shows potential for statistically and clinically meaningful reductions in HAI rates through various improvement strategies. Continued focus on this important area of patient safety, even in the absence of complete knowledge about improvement strategies, will likely lead to better patient care.</p>
<p><b>Disability Outcomes</b></p>	<p><b>Consensus around a core measure set is needed.</b> The wide range of measures used in disability research limits the ability to make comparisons and synthesize research evidence across studies. Many similar concepts—such as health, quality of life, functioning, and patient experience—were assessed by the measures identified in this study, but different definitions, tools, and measurement scales were used. A core measure set for disability research would help facilitate comparative synthesis, although the desire for standardization must be balanced with the need for measures that are customized to particular groups, conditions, and research questions.</p> <p><b>Collaboration among researchers from the medical (curative), rehabilitation (restorative), and social services (supportive) perspectives is essential for advancing the field of disability research.</b> Researchers' perspectives—whether trained and practicing in medicine, rehabilitation, or social services—have a profound impact on the ways in which care and life goals are conceptualized for people with disabilities. This influences and limits the types of outcomes selected for research, which has typically been performed in silos, with little cross-fertilization across professions. Multidisciplinary research will be essential to advance the field of disability research. It is crucial that any efforts to establish core measure sets for disability research include multiple perspectives.</p> <p><b>The choice of outcomes and populations can contribute to disparities.</b> People with disabilities often experience health care disparities, even while experiencing greater health care needs. Researchers contribute to these disparities when they systematically exclude people with disabilities from research studies or use measures that do not capture the full range of outcomes valued by people with disabilities.</p>

Topic	Take-Home Messages Motivating Potential Actions
<b>Palliative Care</b>	<p><b>Few intervention targets decrease health care utilization.</b> Of the four key intervention target areas examined in this review (pain; continuity, coordination, and transitions; communication and decisionmaking; and distress), only communication and decisionmaking appeared to decrease health care utilization (moderate strength of evidence).</p> <p><b>The effectiveness of policy-focused interventions is unknown.</b> Most research to date has investigated patient-focused, and to a lesser extent, provider-focused interventions. Research is needed to explore the impact of policy and regulatory interventions on patient-centered outcomes for palliative care.</p>

**Note:** HAI = healthcare-associated infections; PCMH = patient-centered medical home; QI = quality improvement.



# Appendix C. Advancing the Science: Key Messages for Informing Further Research

In this appendix, we summarize take-home lessons from each review that can help guide the direction, methods, or content of future research. These lessons were identified by the Evidence-based Practice Center topic teams who performed the reviews, as well as the Closing the Quality Gap series overview investigators. We summarize lessons separately for research gaps (Table C-1) and messages to researchers (Table C-2) and research funders (Table C-3). For all topics, information is lacking or limited for downstream effects, such as caregiver-related outcomes and financial consequences. In addition, the topic teams analyzed the applicability of their findings to settings, populations, and contexts of interest but not covered by primary studies in their reviews. Gaps and research needs often correspond to these analyses.

## Key Research Gaps

In addition to synthesizing evidence about a particular topic, systematic reviews provide valuable information about evidence gaps where further research is needed. This information can guide researchers and research funders in identifying key issues to address and developing research agendas. Table C-1 summarizes research gaps for each of the eight series topics.

**Table C-1. Research gaps**

Topic	Take-Home Messages To Inform Future Research
<b>Bundled Payment</b>	<p><b>Little is known about effects of multiple-setting bundled payment programs.</b> A majority of bundled payment programs in the studies included in this review pertained to single settings (e.g., inpatient hospitals, skilled nursing facilities, inpatient rehabilitation facilities) rather than multiple settings or provider types. Recently, interest in bundled payment has focused on this latter type, but thus far little evidence is available about the effects, unintended consequences, design, or context of multiple-setting bundled payment programs. As these programs are implemented, further research is needed to evaluate their effects on spending, quality of care, and other outcomes.</p> <p><b>Little evidence is available except in single-payer contexts.</b> Most research to date has focused on programs specific to single payers, such as Medicare or non-U.S. public insurance programs. Further research is also needed on bundled payment programs implemented in the context of the multiple-payer environment typical of the U.S. health care system.</p> <p><b>Effects on patient subgroups are unclear.</b> Evidence from a small number of studies suggests that the effects of bundled payment programs may vary for different patient subgroups. But few studies stratified analyses by patient population or type of service, leaving many questions unanswered.</p> <p><b>Almost no studies evaluated the impact of specific program design features or contextual factors on the effects of bundled payment programs.</b> This review found almost no evidence to address Key Questions 2 (effects of design features) and 3 (effects of context). This area is ripe for exploration as additional bundled payment programs are implemented and evaluated.</p>

Topic	Take-Home Messages To Inform Future Research
<b>Patient-Centered Medical Home</b>	<p><b>Research is needed on broader patient populations and outcomes.</b> Most studies evaluated effects in older adults with multiple chronic illnesses; few studies were conducted in pediatric or general adult primary care populations. Effects on quality indicators for chronic illness care and on clinical outcomes are uncertain. These are among the most important outcomes to patients, clinicians, and policymakers. Other gaps in evidence include the absence of data on staff retention, unintended consequences, and direct financial consequences to the practice implementing PCMH.</p>
<b>Disparities</b>	<p><b>The ability of QI strategies to reduce disparities is unknown.</b> Very little research to date has examined whether QI strategies can be used to reduce health care disparities. What little is available is insufficient to draw conclusions about effective strategies due to weaknesses in study design.</p> <p><b>Few disparities have been explored other than by racial and ethnic groups.</b> What little evidence is available about the effectiveness of QI strategies in reducing disparities has primarily focused on differences in racial and ethnic groups. Almost no information is available about reducing disparities that are based on other social or demographic characteristics, such as socioeconomic status, age, sex, or disability status.</p> <p><b>No evidence is available about potential harms from efforts to reduce disparities.</b> This review found no information to address Key Question 2, which focused on reports of unintended negative consequences resulting from efforts to reduce disparities through QI strategies.</p>
<b>Medication Adherence</b>	<p><b>Several key questions were rarely explored.</b> Few studies examined the medication adherence intervention characteristics that are associated with effectiveness, and only 3 studies examined unintended consequences of medication adherence interventions. Most studies of vulnerable populations focused on patients with particular high-risk conditions or coexisting conditions—in particular, depression with or without other chronic disease. No studies examined the differential impact of medication adherence interventions on racial and ethnic minority groups, low-income and underinsured or uninsured patients, or populations with low literacy.</p>
<b>Public Reporting</b>	<p><b>The research literature does not reflect the diversity of public reports.</b> Currently, the research literature is dominated by public reporting for cardiac procedures in three States (New York, Pennsylvania, and California) and for nursing homes using the Nursing Home Compare report. Research on these public reporting programs accounted for just under half of all quantitative studies included in this review. Research is needed on other public reports, settings, and geographic locations, particularly as public reporting becomes more common.</p> <p><b>The literature lacks needed detail about reports and reporting context.</b> Few if any details on the format or context of public reports were published in the literature, limiting analyses of how these factors impacted the effectiveness of public reporting as a QI strategy (Key Questions 5 and 6). Little information was available about how the effectiveness of public reporting varied in different settings and for different types of health care decisions.</p> <p><b>Greater rigor is needed in study design.</b> Most quantitative studies identified used a before-after design to compare public reporting with a period of time before it was implemented. Although population-based interventions such as public reporting can pose a challenge when selecting a comparison group, the field would be much advanced by development of statistical methods or study designs that enable investigation of when stakeholders (e.g., patients, referring clinicians, purchasers, policymakers) make use of public reports and for which types of decisions.</p> <p><b>Mechanisms through which public reporting leads to improvements in quality are understudied.</b> Most research on public reporting has focused on its potential harms and observed impact on quality. Few investigations have explored how public reporting motivates or facilitates improvements.</p>

Topic	Take-Home Messages To Inform Future Research
<b>Healthcare-Associated Infections</b>	<p><b>Evidence is lacking for settings outside the hospital.</b> Although this review aimed to identify evidence pertaining to additional settings, such as ambulatory surgery centers, dialysis centers, and long-term care facilities, no such evidence was identified.</p> <p><b>Continued gains in methodological rigor are needed.</b> Although the quality of research designs has improved markedly since the 2007 review on this subject,<sup>1</sup> a majority of the current evidence is still insufficient to support causal inferences. Greater use is needed of controlled trials and interrupted time series studies reporting data from multiple time points before and after the intervention.</p> <p><b>Reporting and analysis of contextual information are scarce.</b> Identifying what QI strategies work in which settings will require an understanding of how context impacts implementation. Yet information about many key contextual factors was often lacking in studies, and much of what was reported was anecdotal. Quantitative analyses including contextual factors were relatively rare.</p> <p><b>Economic impact was rarely studied; methods were inconsistent across studies.</b> Key Question 1b sought to assess the cost, return-on-investment, or cost-effectiveness of QI strategies aimed to reduce HAI, but the strength of evidence addressing this question was insufficient. Methods of reporting costs or savings varied widely. No studies reported return-on-investment; only 1 reported net savings. This question needs greater investigation, given the importance of this information in guiding selection and implementation of QI strategies. More consistency in economic outcomes, greater methodological rigor in analyses, and more detailed reports of methods are needed to enable synthesis across studies.</p>
<b>Disability Outcomes</b>	<p><b>Research primarily treats disability as the main health concern, rarely as a complication.</b> The review found few examples of research that viewed disability as a complicating condition rather than as the main condition of focus. This indicates that research adopting the perspective of disability as a complicating condition is still emerging; increased awareness is needed in the research and health care communities about newer models that view individuals with disabilities as living with disability, but not defined by it.</p> <p><b>Key questions remain unanswered.</b> The review found no studies that addressed Key Questions 1b (modifiers of general population measures for use in disabled populations) or 1c (parameters for measuring processes related to basic service care access for people with disabilities). No studies used a mixed population of people with and without disabilities, highlighting a gap in the equity of health care research in this area. This likely relates to the predominant view within the research literature that disability is the central health concern for disabled people, rather than a complicating condition. However, the review authors cautioned that their results represent a sample of the literature on outcomes for people with disabilities, and more sensitive and specific search strategies might find studies missed by their broad search strategy.</p>
<b>Palliative Care</b>	<p><b>Little is known about palliative care in hospice or nursing homes.</b> Although hospice is designed to focus on the needs of patients at the end of life, this review found very little research on palliative care interventions in this setting. Evidence about such interventions in nursing homes was also scant, even though many patients with advanced and serious illness receive care in this setting.</p> <p><b>Studies of cancer patients predominate.</b> Few studies have focused on pediatric populations or specific disease groups beyond cancer. Studies focused on reducing disparities in palliative care were entirely lacking, despite evidence that disparities exist.</p> <p><b>The effectiveness of policy-focused interventions is unknown.</b> Most research to date has investigated patient-focused, and to a lesser extent, provider-focused interventions. Research is needed that explores the impact of policy and regulatory interventions on patient-centered outcomes for palliative care.</p>

**Note:** HAI = healthcare-associated infections; PCMH = patient-centered medical home; QI = quality improvement.



## Messages for Researchers

The evidence base about what works and what does not work to improve health care quality is built on individual investigations of quality improvement interventions and publication of program evaluations. In their choice of questions, analytic approaches, and publication priorities, researchers help fill evidence gaps, replicate important findings, improve study quality, and develop theoretical models. Systematic reviews play a crucial role in informing these choices by developing critical questions, aggregating evidence across studies, identifying lessons learned from previous studies, and revealing knowledge gaps. Table C-2 summarizes key messages for researchers by topic.

**Table C-2. Messages for researchers**

Topic	Take-Home Messages To Inform Future Research
<b>Bundled Payment</b>	<p><b>Employ more robust evaluation designs.</b> The evidence base for bundled payment will be strengthened if future studies employ more robust designs, such as difference-in-differences analyses with randomized intervention and control groups to reduce the risk of bias. Longer follow-up after implementation and reporting of outcomes at several time points will also improve the evidence base. Because evidence about the effects of bundled payment programs is urgently needed, the field will benefit if the results of longer term followup are reported separately so that publication of short-term results is not delayed. Finally, consider natural experiments or quasi-experimental research designs.</p> <p><b>Harmonize cost and quality outcomes.</b> Studies varied widely in the cost and quality outcomes used to evaluate bundled payment programs, limiting the ability to synthesize results across studies. Use of more standardized measures will facilitate future evidence synthesis. Collaboratives of bundled payment evaluators could help facilitate the harmonization of measures across evaluations.</p> <p><b>Incorporate measures of program design and context into evaluations.</b> Both quantitative and qualitative measures of design features and contextual factors should be incorporated into program evaluations to provide information about how to scale up programs for broader implementation. Program design features to measure include the definition of the bundle (i.e., number of providers, time window, specific services included and excluded), methods of limiting financial risk (e.g., risk adjustment and outlier payments), use of quality measurement, and methods for distributing payments among providers. Contextual factors to measure include the degree of integration in the delivery setting and the degree of financial pressure on participating delivery organizations. It will also be important to evaluate differential impacts on patient subgroups.</p>
<b>Patient-Centered Medical Home</b>	<p><b>Describe interventions in detail.</b> Given such variety in how the PCMH model has been implemented, reports of PCMH interventions need to be described in detail. When possible, researchers ought to map elements of the intervention to the core PCMH components. This would facilitate evidence synthesis in the future and allow researchers to draw conclusions about elements of interventions and the PCMH model that are associated with key outcomes. Consider reporting complete details of PCMH interventions in separate publications.</p> <p><b>Address key knowledge gaps.</b> We encourage investigators to adjust for clustering when appropriate, report meaningful quality indicators for chronic illness (both processes and clinical outcomes), and provide data related to the impact of PCMH on staff. We also encourage long-term followup of results. Outcomes examined in this report rarely had followup periods longer than 2 years. Furthermore, because PCMH has the potential to reduce health disparities, evaluating effects in subgroups such as the socioeconomically disadvantaged will be important.</p>

Topic	Take-Home Messages To Inform Future Research
<p><b>Disparities</b></p>	<p><b>Design studies that specifically address the effectiveness of QI interventions in reducing disparities.</b> Evidence identified through this review stemmed from post hoc analyses, limiting the ability to link any observed changes in disparities with the specific QI intervention under study. To demonstrate an intervention’s effectiveness in reducing disparities, future studies must first demonstrate the effectiveness of the intervention on the outcome(s) of interest (e.g., reducing blood pressure) using a nonintervention control group <i>and</i> must also demonstrate that the disparity in outcome between two patient groups was reduced in the intervention but not the comparison group.</p> <p><b>Investigate additional disparities.</b> Most research to date about how to reduce health care disparities has focused on differences by racial and ethnic groups. More research is needed for additional types of health care disparities, such as disparities by socioeconomic status, insurance status, language preference, health literacy, age, sex, and geographic region. Furthermore, future studies should consider clustering of disparities (e.g., low-income minorities living in inner-city areas).</p> <p><b>Potential harms resulting from efforts to reduce disparities need exploration.</b> No studies identified in this review addressed potential harms that might arise from efforts to reduce disparities through QI strategies. Future studies should look for evidence of harms.</p>
<p><b>Medication Adherence</b></p>	<p><b>Greater consistency in outcomes would strengthen the evidence base.</b> Although medication adherence was an outcome in all studies reviewed, it was defined in myriad ways, making it difficult to synthesize evidence across studies. This and other study heterogeneity (e.g., included patient population, research design) precluded a quantitative meta-analysis. Although a single definition of medication adherence may not be applicable to all studies, use of a smaller number of adherence outcome definitions—ideally derived from consensus among researchers in this field—would facilitate comparative synthesis and strengthen the evidence base. More consistent terminology in describing interventions would also facilitate future evidence synthesis.</p> <p><b>Examine mechanisms of effectiveness.</b> Investigations are needed into what characteristics of interventions, under what circumstances (patient population, disease, medications, settings), are associated with improved medication adherence and additional outcomes. More complete and specific descriptions of interventions would facilitate comparative synthesis to address this question, but well-designed, sufficiently powered studies focused specifically on addressing these questions are also needed. Theoretical models about the mechanisms through which such interventions operate would help guide this line of investigation.</p> <p><b>Include additional outcomes beyond medication adherence.</b> This study found little evidence linking medication adherence with other outcomes, such as biomarkers, morbidity, mortality, quality of life, quality of care, patient satisfaction, health care utilization, or costs. Routinely including additional outcomes beyond adherence will provide further evidence on which to assess the relationship between adherence and key measures of health care quality and patient well-being.</p>
<p><b>Public Reporting</b></p>	<p><b>Specify reporting format and context in research publications.</b> Information about the format of public reports (e.g., Web, print, email) and context of public reporting (e.g., patient population, users, decision type) ought to be included in research publications. To inform QI and implementation of public reporting, it will be particularly important to specify who used (or was expected to use) public reports, at what time, and for what purposes.</p> <p><b>Investigate the full range of public reporting programs.</b> To date, a majority of studies of public reporting have focused on cardiac surgeries in just a few States and on nursing homes, reflecting only a portion of current and upcoming public reporting efforts. Future investigations should address the full range of current and developing public reporting programs. Investigations should also consider all potential users, motivations, and goals of public reporting when selecting evaluation criteria.</p>

Topic	Take-Home Messages To Inform Future Research
<p><b>Healthcare-Associated Infections</b></p>	<p><b>Preintervention data are critical to strengthen the evidence base.</b> Many studies contributed only low strength of evidence because they lacked preintervention data to enable analysis of temporal trends. Given the many factors that can affect infection rates and adherence to preventive interventions, such analysis is important for understanding the impact of specific QI strategies on those outcomes. Rather than simple before-after designs, studies can use an interrupted time series design (when controlled trials are not feasible), reporting data from at least 3 time points both before and after the intervention and conducting formal time series statistical analyses.</p> <p><b>Include contextual factors in reports; investigations of the role of context are needed.</b> A key evidence gap identified by this review is the role that context plays in the outcome and success of QI strategies. At a minimum, reporting contextual factors will enable future reviews to better evaluate the role of context. Analyses that control for or evaluate the role of contextual factors will contribute much-needed evidence.</p>
<p><b>Disability Outcomes</b></p>	<p><b>More focused searches are needed for comprehensive review.</b> The review authors caution that their results represent a sample of the literature on outcomes for people with disabilities. The broad scope of this review, which lacked search terms for particular outcomes measures, diseases, or disabilities, led to a search strategy that lacked both sensitivity and specificity. However, findings from this review may help guide future, more narrowly focused efforts.</p> <p><b>Measures identified in this review are a starting place for choosing research instruments.</b> Although a detailed review of instruments sufficient to guide measure choice was beyond the scope of this review, the lists of measures, source articles, and databases and collaborative measure set development efforts identified in this review offer researchers a starting place for identifying instruments for use in their research. Measure selection would be greatly simplified in the future if a core set of outcomes measures were identified for use in research involving people with disabilities.</p> <p><b>The choice of outcomes and populations can contribute to disparities.</b> People with disabilities often experience health care disparities, even while experiencing greater health care needs. Researchers contribute to these disparities when they systematically exclude people with disabilities from research studies or use measures that do not capture the full range of outcomes valued by people with disabilities. Researchers ought to be aware of these harms when designing studies and strive for multidisciplinary work that incorporates the perspectives of the medical, rehabilitation, and social services professions.</p> <p><b>Conduct research that is multidisciplinary and inclusive.</b> Multidisciplinary research will help bridge silos and widen the range of measures used to include the full range of outcomes valued by people with disabilities.</p>

Topic	Take-Home Messages To Inform Future Research
<b>Palliative Care</b>	<p><b>Include broader populations.</b> This review found very little research in the hospice setting, among pediatric populations, or focusing on patient or caregiver distress. Much of the research to date has focused on the hospital intensive care unit setting and patients with cancer. Investigations are needed in additional settings—in particular, hospice and nursing homes—and additional patient populations, such as those with heart failure.</p> <p><b>Focus on key research gaps.</b> Further development is needed of instruments to measure key patient-centered outcomes for this population, such as quality of life and caregiver burden. Other areas with robust instruments, such as pain, would benefit from standards for how the instruments are used and reported to better enable comparative synthesis across studies. Focus on recruitment and retention efforts to assure adequate sample sizes and describe interventions more fully in research publications. Pilot testing of outcomes measures to ensure that they are appropriate to the intervention under study would help strengthen many studies.</p> <p><b>Integrate QI into palliative care interventions.</b> Few studies identified in this review used QI theory or methods such as collaboratives, Plan-Do-Study-Act cycles, or audit and feedback as part of the intervention. Applying knowledge and techniques from the robust and rapidly developing field of QI could strengthen the palliative care evidence base.</p>

Note: PCMH = patient-centered medical home; QI = quality improvement.

## Messages for Research Funders

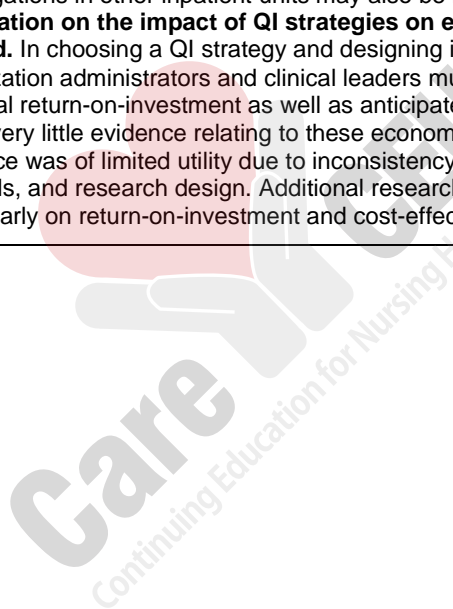
In supporting, and at times motivating, investigations, research funders also have a crucial role to play in advancing any given field. They shape research agendas through their role as gatekeepers of research support and can help advance the field by directing that funding toward the most robust study designs, most important research questions, and highest priority patient populations or care processes. They can also help encourage—or require—harmonization of measures across studies and development of theory to foster innovative approaches to improvement efforts. Systematic reviews provide a valuable tool to help research funders understand the questions and research tools that will help advance the field. The initial Closing the Quality Gap series cultivated such advancements, serving as a foundation for further evidence synthesis and continued evolution of the science of quality improvement, as demonstrated in this new series. Table C-3 summarizes key messages for research funders by topic.

**Table C-3. Messages for research funders**

Topic	Take-Home Messages To Inform Future Research
<b>Bundled Payment</b>	<p><b>Encourage use of harmonized outcomes measures.</b> Greater consistency is needed in the cost and quality outcomes used to evaluate bundled payment programs. Encouraging researchers to incorporate a set of key harmonized outcomes measures into evaluations would help facilitate future research. This set could be supplemented with additional program-specific measures as needed.</p> <p><b>Support evaluation of unintended consequences.</b> Very few studies attempted to evaluate the effect of bundled payment programs beyond the specific setting or patient group targeted by the intervention. However, results from those studies suggest that bundling payments has broader impacts. Much more research is needed to explore unintended consequences of bundled payment programs.</p>

Topic	Take-Home Messages To Inform Future Research
<p><b>Patient-Centered Medical Home</b></p>	<p><b>Continue investigating impacts on mortality.</b> A single good-quality observational study found a mortality benefit at 1 year that was no longer significant at 2 years. This finding, along with nonsignificant findings of a good-quality randomized controlled trial with results in the direction of a mortality benefit and a poor-quality observational study that reported functional decline via a measure that includes mortality, points to the potential benefit of continuing to examine intensive PCMH-type interventions targeting frail seniors and the impact on mortality.</p> <p><b>Support or require more consistent nomenclature, outcomes, and measures related to PCMH.</b> Within the next 2 years, the evidence base regarding PCMH is expected to more than double. An updated systematic review could be valuable, and researchers would be better able to leverage this evidence base if PCMH interventions were described more fully using common terminology. The evidence base would be further strengthened by more consistent use of measures of PCMH components and outcomes.</p> <p><b>The relative impact of PCMH components is key for applications.</b> As the evidence base expands, analyses of the relative impact of PCMH components will be important for clarifying the key approaches for implementation. This knowledge could also inform certifying agencies' criteria for medical home practices. Clinical practices and policymakers also need better information on the financial context and implementation strategies required for successful spread and sustainability of the PCMH model.</p>
<p><b>Disparities</b></p>	<p><b>Support more robust study designs to facilitate conclusive research.</b> Although complicated and therefore requiring more resources for support, studies that are designed to detect changes in both effectiveness outcomes and disparity between at least two groups of patients are extraordinarily important.</p> <p><b>Additional study is warranted on collaborative care and patient education strategies.</b> Although limited, some evidence suggests that these strategies hold promise for reducing disparities. Further research—particularly using robust study designs—is needed to confirm these preliminary findings.</p> <p><b>Support research on a broader set of health care disparities.</b> Most research to date about how to reduce health care disparities has focused on differences by racial and ethnic groups. More research is needed for additional types of health care disparities.</p> <p><b>Encourage researchers to explore potential harms.</b> No studies identified in this review addressed potential harms that might arise from efforts to reduce disparities through QI strategies. Future studies should look for evidence of harms.</p>
<p><b>Medication Adherence</b></p>	<p><b>Medication adherence interventions are a “black box.”</b> This review identified a myriad of interventions aimed at improving medication adherence. The interventions varied widely with respect to the key characteristics of target, agent, mode, intensity, duration, and components. Yet few studies examined how these characteristics impacted the effectiveness of the interventions with respect to medication adherence or other outcomes. This area is ripe for further investigation. Knowledge about specific characteristics that are most effective, and under what circumstances they are effective (which populations, diseases, medications, settings, etc.) will be of critical importance in guiding the design and implementation of QI interventions aimed at improving medication adherence, and potentially interventions with broader goals as well.</p>

Topic	Take-Home Messages To Inform Future Research
<p><b>Public Reporting</b></p>	<p><b>Focus future research on advancing the science.</b> Future research should leverage knowledge from past investigations and focus on developing the science rather than repeating past approaches that produced limited information. In conjunction with the producers of public reports and researchers, research sponsors need to identify key issues for the field and support investigations that target these areas.</p> <p><b>Focus attention on public reporting interventions and context.</b> Rather than focusing exclusively on efficacy (does public reporting work?), future research should address effectiveness—for whom it works and in what situations. Furthermore, theoretical models are needed for how public reporting achieves its impacts, followed by research to test and refine those models.</p> <p><b>Support research on the full range of public reporting initiatives.</b> Research is needed that expands investigation of public reporting beyond the much-studied settings of cardiac care (especially cardiac surgery) and nursing homes.</p>
<p><b>Healthcare-Associated Infections</b></p>	<p><b>Effective strategies outside the hospital setting are unknown.</b> Research is needed on the effectiveness and cost-effectiveness of QI strategies employed in ambulatory surgery centers, dialysis centers, long-term care facilities, and other settings outside the hospital where patients are at risk for HAI. Much of the research to date has focused specifically on the hospital intensive care unit setting; investigations in other inpatient units may also be beneficial.</p> <p><b>Information on the impact of QI strategies on economic outcomes is urgently needed.</b> In choosing a QI strategy and designing implementation, health delivery organization administrators and clinical leaders must consider costs, savings, and potential return-on-investment as well as anticipated effectiveness. This review found very little evidence relating to these economic outcomes. The available evidence was of limited utility due to inconsistency in choice of outcome, analytic methods, and research design. Additional research in this area is needed, particularly on return-on-investment and cost-effectiveness.</p>





Topic	Take-Home Messages To Inform Future Research
<p><b>Disability Outcomes</b></p>	<p><b>More focused, narrow searches are needed in the future.</b> As a starting place in tackling the topic of quality measurement for people with disabilities, this review was purposely broad in scope. However, this breadth resulted in search strategies that lacked sensitivity and specificity, yielding a sample rather than a comprehensive review of the available literature. The authors expect that literature could be identified to answer each of the Key Questions addressed by this review if more focused, narrow searches were undertaken. However, given the breadth of this field, several such reviews, each homing in on a separate area, would likely be needed.</p> <p><b>Further efforts are needed to assemble and assess measurement tools.</b> This review identified several collaborative efforts to review large numbers of measurement tools, critically assess their applicability for research involving various disability populations, and assemble those tools into consensus-based core measure sets or databases. However, the efforts to date have focused either on narrow populations (e.g., patients who experienced stroke, frail elderly individuals, patients with spinal cord or traumatic brain injuries) or limited aspects of care (e.g., rehabilitation, developmental disability services). While these are important early steps, further work is needed to establish measure sets that address the full spectrum of QI and care coordination research related to people with disabilities. Further coordination among such efforts would also benefit the field.</p> <p><b>Support research that is inclusive and multidisciplinary.</b> Researchers contribute to health care disparities for people with disabilities when they systematically exclude people with disabilities from research studies or use measures that do not capture the full range of outcomes valued by people with disabilities. Ideally, rather than isolating disabled populations in studies focusing exclusively on disability (the predominant disability-as-core-concern model) and excluding them from studies of the general population, future research incentives are needed for studies that include a mix of disabled and nondisabled people within study samples with appropriate adjustment for the disability as a complicating condition. Multidisciplinary research will help bridge silos and widen the range of measures used to include the full range of outcomes valued by people with disabilities.</p>
<p><b>Palliative Care</b></p>	<p><b>Key knowledge gaps require further research.</b> Research funding is needed to support well-designed studies that evaluate QI and policy interventions, particularly in areas that are advancing rapidly in health care policy (e.g., audit and feedback and financial and regulatory interventions) but that have not been rigorously evaluated with regard to palliative care. Broadening research on palliative care interventions to a wider group of patients (current research being heavily focused on patients with cancer) and health care settings (beyond the intensive care unit) would yield valuable new knowledge. More research is needed to understand the effectiveness of both integrative and consultative palliative care models. This review found no studies that compared the two models directly.</p>

**Note:** HAI = healthcare-associated infections; PCMH = patient-centered medical home; QI = quality improvement.

## Reference

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# Appendix D. Taxonomy of Quality Improvement Strategies

In this methods report, we discuss results for intervention-focused topics with respect to the taxonomy of quality improvement (QI) strategies developed for the original Closing the Quality Gap series. Below, we provide details of that taxonomy, abstracted from the original series report. Further details, including examples of each type, may be found in the original Closing the Quality Gap series overview and methodology report.<sup>1</sup>

**1. Provider reminder systems**—The investigators defined a reminder system as any patient- or clinical encounter-specific information provided orally, in writing, or by computer intended to prompt a clinician to recall information or intended to prompt consideration of a specific process of care (e.g., “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, whereby clinicians typically receive performance summaries relative to a process or outcome of care spanning multiple encounters (e.g., all patients with type 2 diabetes seen by the clinician during the past 6 months).

**2. Facilitated relay of clinical data to providers**—“Facilitated relay” is 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 (e.g., the telephone transmission of a patient's blood pressure measurements from a specialist's office). The Effective Practice and Organisation of Care (EPOC) group uses the term “patient mediated” to describe such interventions,<sup>2</sup> but the authors regard the label “facilitated relay” 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 HbA1c 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**—“Provider education” is used to describe a variety of interventions including educational workshops; meetings such as traditional Continuing Medical Education (CME); lectures (in person or computer based); and 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 prerecorded) 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 single intervention, along with its relative effects on a variety of chronic diseases.

**6. Promotion of self-management**—This strategy includes the distribution of materials (e.g., 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 HbA1c 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**—This term is 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., adding 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., giving a clinic nurse a more active role in patient management); or simply adding more nurses, pharmacists, or physicians to a clinical setting.

(c) Communications, case discussions, and the exchange of treatment information between distant health professionals (e.g., telemedicine).

(d) Total Quality Management (TQM) or Continuous Quality Improvement (CQI) techniques for measuring quality problems, designing interventions, and implementation of interventions, along with process remeasurements.

(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 (organizational change) is consistent with prior reviews, 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 a target patient outcome).
- (b) Positive or negative financial incentives directed at patients.
- (c) Systemwide 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.

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