Advancing Quality Improvement Research: Challenges and Opportunities - Workshop Summary

Samantha Chao, Rapporteur, Forum on the Science of Health Care Quality Improvement and Implementation

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ADVANCING QUALITY IMPROVEMENT RESEARCH

CHALLENGES AND OPPORTUNITIES

WORKSHOP SUMMARY

Samantha Chao, *Rapporteur*

Forum on the Science of Health Care Quality Improvement and Implementation

Board on Health Care Services

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by coordinator **ARTHUR A. LEVIN,** of the Center for Medical Consumers, New York. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the author and the institution.

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Summary*

The Institute of Medicine's Forum on the Science of Health Care Quality Improvement and Implementation held a workshop on January 16, 2007, in Washington, DC. The workshop had its roots in an earlier forum meeting when forum members discussed what is meant by the terms "quality improvement" and "implementation science" and became convinced that they mean different things to different people. At the time, the members also discussed the need to identify barriers to quality improvement research and to implementation science. Thus the purpose of this workshop was to bring people together from various arenas to discuss what quality improvement is, and what barriers exist in the health care industry to quality improvement and also to research about quality improvement.

The summary that ensues is thus limited to the presentations and discussions during the workshop itself. We realize that there is a broader scope of issues pertaining to this subject area but are unable to address them in this summary document.

*The Forum's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop.

LESSONS IN QUALITY IMPROVEMENT

The workshop's first session was devoted to experiences that various institutions have had with quality improvement. Recognizing the wealth of experiences available outside of health care services, the workshop included presenters from outside the health care service industry as well as from inside. This includes discussions from a variety of perspectives: non-health care services, health plans, hospitals, and nursing. It was not possible, however, to include examples from all settings, including smaller physician practice settings and long-term care settings.

Non-Health Care Service Sector

Although improving quality requires the use of specific tools, developing those tools and putting them to use is only part of the challenge. As Scot Webster of Medtronic, a manufacturer of medical devices, explained, the larger part of improvement is actually changing culture and driving change.

Webster focused on three barriers to operating with high quality and efficiency: lead time, external variability, and internal variability. *Lead time* is the period of time from the beginning to the end of a process. *Variability* refers to differences in conditions or in how a process is performed; *external variability* refers to differences that cannot be controlled by the process's operator, while *internal variability* refers to processes that can be. Many tools exist to improve quality and to deal with these barriers. Medtronic chose to combine the tools of Six Sigma and Lean in an innovative technique called Lean Sigma, which has positively affected Medtronic's business. Although it can produce impressive results, Lean Sigma should not be seen as the answer for all quality problems, Webster cautioned. Quality improvement is 30 percent application of various tools and 70 percent working together to create a culture of continual change, he said, and to sustain quality improvement, institutions need to incorporate it into their culture.

Lean Sigma is also not a replacement for creativity or the experience of health care providers, Webster said. While health care has a high ratio of external to internal variability, and external variability is by definition outside of one's ability to control, Lean Sigma could still be used as a tool to support the performance of health care professionals, he said.

Integrated Health Care Delivery System

As an integrated health care delivery system, Kaiser Permanente has a unique approach to quality improvement, Scott Young of Kaiser's Care Management Institute said. Quality is integrated into every level at Kaiser, from medical centers to the national program office. Kaiser views quality, safety, service, and cost as the four dimensions that lead to improvements in care.

One of the factors underlying differences in health care outcomes is the uneven application of evidence-based care, which results in unwanted variations. These variations can often be linked to missed opportunities to improve quality and—at the extreme—to safety issues, close calls, and near misses that occur every day. These in turn, Young explained, are the basis for poor outcomes, adverse events, increased morbidity and mortality, and potential increased medical liability. Collectively, he said, these issues are viewed as the "iceberg of safety," with increased morbidity and mortality and potential increased medical liability at the tip of the iceberg. Quality improvement programs can help prevent patient safety issues in health care.

The task of improving quality is made possible by support systems available throughout Kaiser, such as its electronic medical-record system called KP HealthConnect, its care-management programs, the KP Elder Care Network, and the use of evidence-based medicine. There are six components to the company's approach to quality: measurement and evaluation, care management, evidence-based medicine, health information technology, innovative practice models, and team-based care.

Hospital Perspective

Craig Miller of Baptist Health Care System described how this hospital system changed its culture. In 1997, Miller said, Baptist was a place that provided poor quality care. Once the hospital leadership recognized that change was necessary to improve employee satisfaction and to solve financial problems, Baptist began to focus its efforts on the people associated with the system—the patients and the employees. With this focus, Baptist transformed itself into a hospital system that now provides excellent quality care, as evidenced by the system winning the 2003 Baldrige Quality Award.

Baptist built its vision of change around five pillars of excellence: people, service, quality, growth, and finance. In addition to these pillars, Baptist used the Baldrige criteria for excellence to transform

itself.[1] To operationalize the changes required to achieve their vision, Baptist adopted five keys: create and maintain a great culture; select and retain great employees; commit to service excellence; continuously develop great leaders; and hardwire success with systems of accountability.

Nursing Perspective

Nurses are central to improving the quality of health care delivery, said Marita Titler of the University of Iowa Hospitals and Clinics. Titler presented four major points to illustrate the role of nurses in quality improvement, including an overview of the quality improvement program at the university, strategies used to implement performance improvement, challenges in improving quality, and markers of success. The University of Iowa Hospitals and Clinics bases its implementation of new processes and procedures on seven principles, Titler said. The first of these principles is that education is necessary but not sufficient in order to change practice behaviors. The second is that implementation is not necessarily sustainable; constant tracking and improvement are required to improve the likelihood that a change will be sustained. The third principle is to facilitate doing the right things. The fourth is that data need to be effectively transformed into useable and actionable information. The fifth principle is to have a clear focus for implementation. The sixth is coordination among all players, which is especially useful in complex interventions. The seventh principle is to pilot or try the intervention prior to implementing the change system-wide. Improving care requires a number of strategies that integrate these seven principles and at the center of them is engaging the workforce, Titler said.

APPROACHES TO QUALITY IMPROVEMENT RESEARCH

There is a lack of understanding of how to connect the different strategies available for improving quality, said Paul Batalden of Dartmouth. He offered the following formula as a way of thinking about how the various factors of quality improvement fit together:

[1]Baldrige criteria are: leadership; strategic planning; focus on patients, other customers, and markets; measurement, analysis, and knowledge management; workforce focus; process management; and results (Baldrige National Quality Program, 2007).

Generalizable scientific evidence	+	Particular context	→	Measured performance improvement

Generalizable scientific evidence and particular contexts link together in a cycle that is a form of experiential learning. This cycle not only describes how a large majority of evidence-based medicine is developed, but it also captures how evidence-based medicine is integrated into practice. Thus, Batalden suggested, experiential learning can be seen as one of the underpinnings of quality improvement and quality improvement research.

Jeremy Grimshaw of the Ottawa Health Research Institute offered a different approach to quality improvement research. Implementation research[2] can be described as studies of how the uptake of research findings is promoted. Implementation research focuses on the challenge of delivering evidence-based care to patients, specifically on the technical aspects of care. The aim is to develop a generalizable evidence base that can be used to improve the implementation of research findings and enhance decision making at the local level. This research is inherently interdisciplinary, involving health care professionals, organization scientists, engineers, and others.

Despite the suggestion by some attendees that these approaches to quality improvement research oppose one another, others thought that the discussion revealed more similarities than differences. In particular, Batalden and Grimshaw agreed on the purpose of quality improvement research and also agreed that the evidence base needs to be developed to the point that it can build on itself. Batalden and Grimshaw stated that both approaches were necessary to develop the needed body of knowledge.

Methods

Quality improvement is analyzed using a variety of study designs, including systematic reviews, controlled trials, case reports, and hybrid quantitative/qualitative reports, Batalden said. These different methods have different strengths, each with its own set of advantages and disadvantages.

There is disagreement in the field about the use of what some believe to be the "gold standard," randomized controlled trials

[2]Implementation research is the term used in Europe to refer to quality improvement research, noted Grimshaw. They are not identical, but cover many of the same areas.

(RCTs). Some people do not believe that RCTs are useful in complex social contexts, such as quality improvement processes, while others believe RCTs to be an extremely valuable method for evaluating these interventions. Given that different interventions lend themselves to specific evaluation methods, Grimshaw and Batalden concluded that one should always attempt to choose the best possible study design, given the individual circumstances.

BARRIERS TO QUALITY IMPROVEMENT AND QUALITY IMPROVEMENT RESEARCH

There is very little data available to guide the development of quality improvement research, of health sciences research, and of medicine in general, said Harold Pincus of Columbia University and New York-Presbyterian Hospital. This lack of data is closely related to the eight major barriers to quality improvement and to quality improvement research that workshop participants identified.

The first barrier is that quality improvement efforts can have many divergent purposes. Some see the purpose as improving performance, a process that occurs mainly through experiential learning. This process differs significantly from scientific research, whose purpose is to discover generalizable truths through hypothesis testing, noted Frank Davidoff of the Institute for Healthcare Improvement.

A second barrier is the role of specific contexts. Understanding the effects of specific local contexts and characteristics of what is generalizable across settings is extremely valuable in the implementation of interventions, Grimshaw said.

The third barrier is the lack of agreement about which academic area should be home to quality improvement research, Pincus said. Quality improvement research could potentially be considered an interdisciplinary research field, serving as a bridge between multiple disciplines. While many agree with the concept of interdisciplinary research in theory, it is extremely difficult to put into practice.

The fourth barrier is the "mismatch" between training and practice: Most people doing medical quality improvement projects have little or no research training, while most people with research training are not doing quality improvement projects. Different strategies will need to be developed for recruitment in different audiences.

Fifth, ethical oversight in quality improvement remains largely ambiguous and can be a large obstacle for many researchers. Quality improvement can be seen either as an intrinsic element of clinical care and medicine or as a form of clinical research. This in turn leads to questions as to whether quality improvement research should be

considered human subjects research, which would require ethics review and institutional review board (IRB) approval.

The sixth barrier identified during the workshop is the existence of methodological differences between the biological sciences and the social sciences. Quality improvement research faces the same challenges—such as biases, confounders, and difficulties with measurement—that clinical research does. However, quality improvement studies are not subject to the tightly controlled conditions of clinical interventions. It is therefore difficult to know if "proven interventions" are generalizable.

The seventh difficulty facing the development of quality improvement research is that much of what is published is poorly conducted. Because of a variety of factors, only a relatively small amount of quality improvement research is actually published, Davidoff said, and much of what is published is not generalizable and so fails to provide a basis for future efforts upon which to build.

The last barrier identified during the workshop was the barrier of communication. The lack of a common vocabulary for quality improvement and implementation research terms has hindered further progress, Grimshaw said.

OPPORTUNITIES

Both short-term and long-term opportunities exist for strengthening the science of quality improvement. In the short term, the opportunities identified by workshop participants centered on strengthening the evidence base for quality improvement. This can be achieved by using the most rigorous methods possible to assess interventions and by clarifying the focus of quality improvement projects. Long-term opportunities include creating strategies to improve professional development and effect cultural change among all stakeholders.

GENERAL REACTIONS

General reactions to the workshop discussions were given at the end of the day by both forum members and audience members. Many of their comments focused on the need to leverage experiences from other disciplines. The role of context should also be more carefully studied, as well as communication between researchers and between researchers and implementers. Other areas for the forum to pursue were also proposed.

Introduction

With its Forum on the Science of Health Care Quality Improvement and Implementation, the Institute of Medicine (IOM) convenes representatives from academia, clinical practice, government, and industry in a neutral setting where they can discuss various ideas about improving the science behind health care quality improvement and implementation. Through these discussions, forum members attain a better understanding of what the needs of the science are, and they begin breaking down the communication barriers that prevent advances in the field.

The workshop "The Path to Quality Improvement: Approaches and Barriers" was held on January 16, 2007, in Washington, D.C. It was the result of a forum conversation that had taken place in December 2006. The forum had identified a need to understand what was meant by the terms "quality improvement" and "implementation science," and during the ensuing discussion it became clear to forum participants that these terms mean different things to different people. Forum participants also discussed the need to identify the barriers to quality improvement research and to implementation science. The purpose of this workshop was therefore to bring people together from various arenas to discuss the scope of quality improvement in a broad sense. The forum members felt it would be valuable to hear about lessons learned not only from within health care settings but from outside of health care as well. Because of the limited time available at this workshop, not all relevant perspectives

and issues could be discussed. The forum members plan to integrate other views and topics in its future activities.

The following chapters describe and summarize the presentations and discussions that took place during that workshop, and the content is therefore limited to what was presented and discussed during the workshop itself. We realize that there is a broader scope of issues pertaining to this subject area, but we are unable to address them in this summary.

1

Lessons in Quality Improvement*

This section includes discussions from a variety of perspectives: non-health care services, health plans, hospitals, and nursing. It was not possible, however, to include examples from all settings, such as smaller physician practice settings and long-term care settings.

NON-HEALTH CARE SERVICE SECTOR

Although improving quality requires the use of specific tools, developing these tools and putting them to use is only part of the challenge. As Scot Webster of Medtronic explained, the larger part of improvement is changing culture and driving change.

Webster offered Medtronic's experience with quality improvement as an example. Medtronic manufactures a wide variety of medical devices, including pacemakers and insulin pumps. Every five seconds, Webster said, somewhere around the world a Medtronic device is implanted. In 2006 Medtronic's net sales were $11.3 billion; the company spends approximately 10 percent to 15 percent of its revenue each year on research and development. The quality of its products is imperative, but as Medtronic is a high-volume company,

*The Forum's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop.

the efficiency of its operations and the flow of its processes are also critical factors in its success.

For these reasons Medtronic set itself the goals of assuring that it produced high-quality products while at the same time increasing efficiency and improving flow. Webster highlighted three issues that Medtronic found to be important in reaching these goals: lead time, external variability, and internal variability. *Lead time* is the period of time from the beginning to the end of a process. A patient who must sit in the waiting room of an emergency room for three hours is an example of a need to reduce lead time. *Variability* refers to differences in conditions or in how a process is performed; *external variability* refers to differences that cannot be controlled by the process's operator, while *internal variability* refers to processes that can be. An epidemic would be an example of external variability, Webster said, while incorrect prescriptions would be an example of internal variability. If an organization can reduce lead time and internal variability, he said, it can gain the flexibility it needs to manage external variability, which in turn will lead to improved customer experiences and reduced costs. These three issues—lead time, external variability, and internal variability—are important not just in manufacturing, Webster said, but in health care as well.

There are a number of tools that can be used to improve quality and focus on the problems of lead time and variability, Webster said. In its efforts to maximize profits, Medtronic chose two: Six Sigma and Lean. In particular, Medtronic combined the two tools to create an innovative technique it called Lean Sigma. The company created Lean Sigma for three reasons, Webster said.

The first reason was that the goals of both of these tools are to decrease error and reduce waste from processes. Six Sigma focuses on the efficiency of a single process, using standard deviations as a measure to track performance. The methodology Six Sigma follows is called DMAIC, for Define, Measure, Analyze, Improve, and Control. The first step is to characterize problems with products or outcomes by defining what the problems are and then finding ways to measure performance. After measuring performance, these resulting data undergo statistical analyses to identify the problem with the process. Only when the process problem is identified can the process be improved, whether through automation or perhaps by something as simple as turning off a knob. The last step of DMAIC is control, which refers to the need to sustain change so that the problem does not recur. Statistical testing and evidence are two essential components of Six Sigma, Webster noted.

Lean also follows the DMAIC methodology, Webster explained,

but its focus is on the flow of multiple processes as opposed to the efficiency of a single process. Lean is a tool for improving quality, as guided by customer demands and the desire to minimize waste, while also allowing for flexibility. A central part of Lean is the balancing of resources. In a hospital setting, for example, that could mean that when a nurse in one department has spare time, he can be retasked to help out in another area. In a factory, machines can be moved around so that the flow of parts from one machine to another may require less time. If each process in a system takes the same amount of time, Webster argued, patients would not wait unnecessarily in a hospital and inventory would not sit idle between processes in a factory. In Lean, Webster said, all inputs are measured so that customer requirements can be met with minimal wasted resources.

Webster estimated that Medtronic currently is running over 1,000 Lean Sigma projects, with some dramatic results. For example, a factory in Galway, Ireland that manufactures stents reduced its lead time from 17 hours to 1.7 hours and at the same time increased output from 500 units per shift to 800 units while using approximately the same number of employees. The factory used Lean to balance flow and production and Six Sigma to reduce variability in many of the processes.

The second reason Medtronic chose to use Lean Sigma, Webster said, is because Lean and Six Sigma complement each other well. Depending on the problem, either Lean or Six Sigma can be used, he said, and some situations will require the use of both.

The third reason Medtronic combined Lean and Six Sigma is because of their ability to form a science out of process. Analyzing processes in order to identify reasons for variability and to determine which processes statistically yield better outcomes requires that data be accumulated about those process, and through Lean Sigma, Medtronic has developed an evidence base that it uses for improvement. The DMAIC methodology and the science of Lean Sigma apply to all systems with processes, Webster said. In particular, they are not limited to the manufacturing world and would make sense to apply in health care.

But quality improvement is more than just tools, Webster said. Indeed, he estimated it to be only about 30 percent application of various tools and 70 percent working to create a culture of continual change. Once an improvement event has occurred, the operators have been equipped with the tools needed to improve, but sustaining the improvement demands that the operators incorporate quality improvement as part of their own culture. Medtronic has

experienced this transformation, as demonstrated by the thousands of employees who now focus on quality, Webster said. "You have to get it in the DNA. You have got to get it in the culture. It is not about being good at the projects. It is about having this as the way we lead." Once quality improvement is embedded in the culture, Webster said, quality experts are no longer necessary because improvement is self-sustaining. By embedding quality improvement in its culture, Medtronic is developing its future leaders, he said.

At Medtronic, each business runs itself without a high level of corporate command, which has allowed each business to develop its own culture and its own priorities. Each business must then independently find the need to use tools such as Lean Sigma.

In offering advice to the health-care industry, Webster first cautioned that Lean Sigma should not be seen as the answer for all quality problems. There are many problems that require a "just do it" approach, for instance, smaller projects that do not require Lean Sigma. Webster suggested keeping the focus of quality improvement efforts small at first. Involvement in other operations could distract from the focus of process improvement, as the goal of improvement should not be to improve margins or technology, but to produce better outcomes. Lean Sigma should be used to support the creativity and experience of health care providers, not as a replacement.

INTEGRATED HEALTH CARE DELIVERY SYSTEM

As an integrated health care delivery system, Kaiser Permanente has a unique approach to quality improvement, said Scott Young of Kaiser's Care Management Institute. The communities Kaiser serves and its 8.6 million members are at the center of Kaiser's mission. Having an integrated delivery system means that Kaiser's multispecialty group practices, its hospitals, and its insurance are all affiliated. This allows the company to coordinate care across its members' lives; to be accountable for the quality, cost, safety, and service of its members; to have a unified medical record that enables capabilities to measure and improve care; and to directly link coverage design and services rendered, Young said.

Quality is integrated into every level at Kaiser, from medical centers to the national program office, Young said. Kaiser views quality, safety, cost, and service as the four dimensions that lead to improvements in care. The quality of care received around the country is uneven, Young said, using a chart of 30-day mortality after acute heart attack (Figure 1) to demonstrate his point. The 30-day mortality of Kaiser patients averaged 8 percent, with values

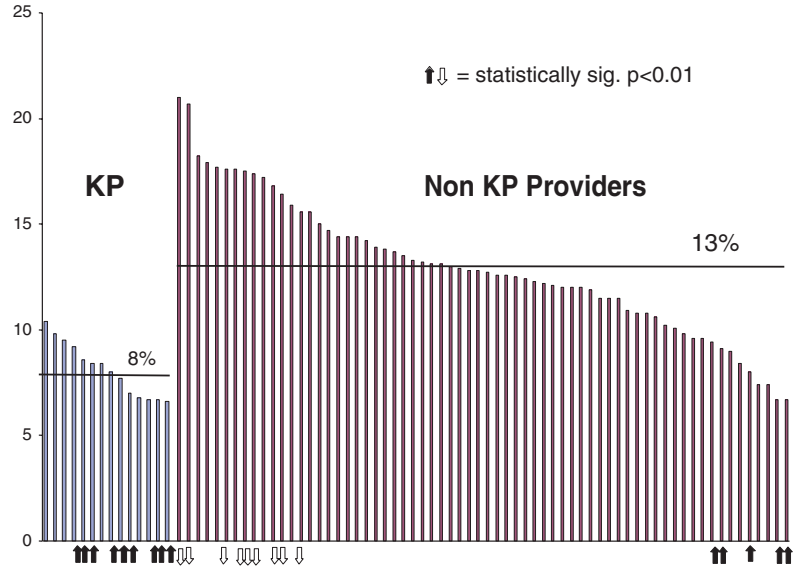

FIGURE 1 Comparison of 30-day mortality rates after acute heart attack. Kaiser Permanente members have a significantly greater chance of survival from heart attacks than non-members. The study, released in February 2002, showed that the survival of heart attack patients at all Kaiser Permanente hospitals was better than the statewide average. Overall mortality was 8 percent versus the statewide average of 12 percent.
SOURCE: 2002 study by the California Office of Statewide Health Planning and Development (OSHPD).

ranging from 7 percent to 10 percent. This is in marked contrast to other providers, which had an average mortality rate of 13 percent and a much higher range.

Underlying this difference in outcomes, Young said, are uneven applications of evidence-based care, which result in unwanted variations. In particular, these variations can often be linked to missed opportunities to improve quality and—at the extreme—to safety issues, close calls, and near misses that occur every day. These safety issues and near misses can often result in poor outcomes and adverse events. These are the basis for what Young views to be the "iceberg of safety," with increased morbidity and mortality and potential increased medical liability at the tip of the iceberg. Too often the underlying reasons for increased morbidity and mortality go unnoticed. Quality improvement programs can help prevent patient safety issues in health care.

At Kaiser, 1 percent of members are associated with approximately 30 percent of total costs, Young said. The majority of these high-cost individuals are members living with multiple chronic conditions. Service is the dimension supporting the other three dimensions of quality, safety, and cost. It is Kaiser's belief that there is a need to make care patient-centric, to address critical needs for its communities, and to meet both member and purchaser expectations. Meeting goals in these four dimensions, Young said, is Kaiser's key to improving the quality of care for patients.

The task of improving quality is made possible by support systems available throughout Kaiser, such as its electronic medical record system called KP HealthConnect, care management programs, KP Elder Care Network, and the use of evidence-based medicine. There are six components to the company's approach to quality: measurement and evaluation, care management, evidence-based medicine, health information technology, innovative practice models, and team-based care.

Young noted that improvement can only be made in areas that can be measured. To evaluate its progress, Kaiser measures its performance with common metrics, such as the Health Plan Employer Data and Information Set (HEDIS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as tracks progress in safety, service, and efficiency. Data can be viewed nationally, by region, or by individual medical center.

Kaiser's care management programs are focused on making the right thing to do the easy thing to do. Young described the need to use tools such as guidelines, effective and innovative care models, support teams of professionals, and technology. An important part of Kaiser's care management programs is to provide care that is personal, effective, and efficient to members with chronic illness. An example Young used is an improvement program aimed at diabetic members and other members at risk for cardiovascular disease. Improvements were seen in those patients prescribed a specific drug regimen, including the use of aspirin, angiotensin-converting-enzyme inhibitors (ACE-I) or angiotensin-receptor blockers (ARBs), plus lipid-lowering drugs. The care these members received was noted in select provider panels, and the effect of the regimen was studied. Kaiser modeled the effects of the drug combination, which showed significant reductions in cardiovascular disease and lower costs. The drug regimen is currently being rolled out in all eight of Kaiser's regions, noted Young.

Kaiser has invested heavily in its health information technology programs, which consist of an integrated electronic health record (KP

HealthConnect), kp.org (personal health record available to all members), and support tools to coordinate care for patients with ongoing and chronic illnesses. For the electronic health record alone, Kaiser will invest $4 billion. These programs have made possible more effective use of evidence, improved provider and member communication, and better support for providers in the delivery of care.

Evidence-based medicine is being embedded into KP HealthConnect to help integrate proven and effective care into the delivery systems in a real-time manner. Evidence-based medicine in this capacity exists in a variety of forms, such as clinical guidelines, preventive services, clinical libraries, outcomes reports, best practice alerts, and health maintenance reminders. These highly actionable tools are currently being integrated into clinical work streams and serve as a significant component in Kaiser's quality improvement efforts, Young said. These implementation efforts involve providers and staff at all levels, from national guideline directors to frontline clinicians. However, gaps in the evidence base must be filled in order to produce better care, noted Young.

Team-based care has long been a fixture at Kaiser. The multispecialty groups there strive to provide a host of physical and virtual services to best serve members' needs. These capabilities now include email and virtual provider visits and electronic pharmacy and lab services. As health care shifts more toward the home, virtual, and self-care environments, more innovative care models will need to be developed, Young concluded.

HOSPITAL PERSPECTIVE

Craig Miller of Baptist Health Care System described how this particular hospital system changed its culture. Baptist is a four-hospital system in northern Florida and southern Alabama. In 1997, Miller said, Baptist was a place that provided poor quality care and had low employee morale, below-average physician satisfaction, and poor patient satisfaction. When the hospital leadership realized that change was necessary to improve employee satisfaction and to solve financial problems, Baptist began to focus its efforts on the people associated with the system—the patients and the employees. With this focus, Baptist transformed into a hospital system that now provides excellent quality care, as evidenced by the system winning the 2003 Baldrige Quality Award.

Baptist built its vision of change around five pillars of excellence, Miller said: people, service, quality, growth, and finance. In addition to these pillars, Baptist focused on the Baldrige criteria for excel-

lence to transform itself.[1] To operationalize the changes required to achieve their vision, Baptist adopted five keys: create and maintain a great culture; select and retain great employees; commit to service excellence; continuously develop great leaders; and hardwire success with systems of accountability.

Miller said that the first key—create and maintain a great culture—is based on strong communication. This communication is enabled by involving all of Baptist's employees in feedback, education, surveys, and employee forums. To make this meaningful and engaging, Baptist changed its culture and began in a structured manner to share stories about patients, innovations by individual providers, and patient-provider interactions.

Employees are the foundation of the organization, Miller said, and many improvements begin as innovations by employees. Therefore, Baptist's second key to excellence is selecting and retaining great employees. Employees are given a sense of ownership over the selection process. For example, interviewees are asked questions by their potential peers during the interview process. Baptist also focused on retaining employees. Management personally recognizes those individuals who exemplify desired behaviors, and every quarter outstanding employees are acknowledged for being exceptional leaders by the company's legends and champions program. One particular focus of this second key to excellence is engaging physicians. By making physicians a central part of the culture change, Baptist was able to improve both clinical aspects of care and employee morale. It was noted that although employee satisfaction does not necessarily result in delivery of high quality care, employee satisfaction is used as a quality indicator. Employee morale has improved tremendously and turnover has decreased, leading to cost savings at Baptist.

A commitment to service is the third key to excellence. An example Miller used here is a strategy called scripting, where employees are given scripts to follow during particular situations. By using scripting, a consistent level of service performance can be ensured, Miller said. Furthermore, hospital leaders are constantly going on rounds, making themselves available to their employees and patients so they can address problems firsthand. Apologizing for mistakes and then learning from them has become a large part of Baptist's culture, Miller added.

[1]Baldrige criteria are: leadership; strategic planning; focus on patients, other customers, and markets; measurement, analysis, and knowledge management; workforce focus; process management; and results (Baldrige National Quality Program, 2007).

The fourth key to excellence is continuous development of great leaders. Baptist puts a lot of effort into developing its leaders. "The big difference between winners and losers, whether they are organizations or individuals, is that winners understand that learning, teaching, and leading are inextricably intertwined," Miller said, quoting Noel Tichy, director of Global Business Partnership at the University of Michigan. Baptist teaches its leaders how to learn and listen, skills that are disseminated to other employees through what Miller calls "cascade learnings."

Hardwiring success through implementing systems of accountability is the fifth key. An important element of this is having 90 day-work plans that require action to help reach a system goal. These plans require each pillar of excellence to be addressed, establishing goals and objectives, identifying responsible individuals, and providing measurable outcomes for each. Transparency in communication and goals is critical, explained Miller.

Baptist's focus on quality has led it to become one of Fortune's 100 Best Companies to Work For for the sixth straight year. The quality of care provided has improved dramatically, Miller said. Its journey led it to the Baldrige National Quality Award. Its journey began by making changes within.

NURSING PERSPECTIVE

Nurses are central to improving the quality of health care delivery, said Marita Titler of the University of Iowa Hospitals and Clinics. In her facility, the department of nursing has a quality management committee. The group has broad representation, bringing together nurses from each clinical division and from other areas of focus, such as infection control. Work groups have also been put in place that report to the quality-management committee to target specific, interdisciplinary issues, such as pain, skin care, fall prevention, and medication management.

Improvements are driven by data. Issues that data are collected on include medication errors, falls, pain indicators, and the Centers for Medicare and Medicaid Services indicators, such as discharge instructions for heart failure patients. Interdisciplinary approaches are often required to make improvements, Titler said.

The University of Iowa Hospitals and Clinics bases its implementation of new processes and procedures on seven principles, Titler said. The first of these principles is that education is necessary but not sufficient in order to change practice behaviors. The second is that implementation is not necessarily sustainable; constant track-

ing and improvement is required to improve the likelihood that a change will be sustained. The third principle is to facilitate doing the right things. The fourth is that data need to be effectively transformed into useable and actionable information. The fifth principle is to have a clear focus for implementation. The sixth is coordination among all players, which is especially useful in complex interventions. And the seventh principle is to pilot or try the intervention prior to implementing the change systemwide.

Improving care requires a number of strategies that integrate these seven principles, and at the center of them is engaging the workforce, Titler said. Data are necessary for making care evidence based, and data should be collected not only for outcomes of care but also for the care processes that contribute to those outcomes. Data should be analyzed before, during, and following implementation of evidence-based practice changes to understand the impact of the improved care delivery.

Presenting data at the patient care unit or clinic level using statistical tools is helpful for nurse managers, and facilitates staff involvement in process improvements. Such tools include statistical process control charts, run charts, and Pareto charts. Other important strategies for improving care include listening to staff, presenting and discussing the evidence base for clinical practices such as fall prevention, and engaging unit-based change champions in process improvement and point-of-care coaching. The work of evidence-based practice improvement must be made visible through mechanisms such as internal newsletters, publications, and senior leadership reports. Interdisciplinary and interdepartmental collaboration are essential and the role of leaders is critical in engaging employees in change, Titler said. Leaders need to develop action plans to increase transparency, such as defining accountable persons, identifying an intervention's effect on patient care, and making sure the plan for implementation is well understood. Without a leader's vision and guidance, effective and well-planned practice improvements are unlikely to be sustained. Key questions for evaluating the success of quality improvement programs include: Have goals of the prior year been achieved? Are core metrics improving? Are people working collaboratively across departments and disciplines to improve patient care? Are staff seeking out quality improvement personnel for guidance? Challenges in improving quality of care, Titler said, include system issues such as using clinical documentation systems, competing demands by various external agencies, and using a mechanistic rather than a complex adaptive system approach. Improving systems and care processes is the role of all involved in health care.

2

Approaches to Quality Improvement Research

Although a number of different quality improvement strategies exist, Paul Batalden of Dartmouth noted that overall there is a lack of understanding of how to connect these different strategies in efforts to improve quality. Thus Batalden set forth a framework for connecting various strategies in quality improvement and quality improvement research. That framework, Batalden said, rests on three assumptions. First, the overall goal is to achieve better health care. Second, better health care should be based on as much knowledge as possible. And third, improving the quality of health and of health care is not as easy as it first seems (Batalden and Davidoff, 2007).

Batalden defined quality improvement as "the combined and unceasing efforts of everyone—health care professionals, patients and their families, researchers, payers, planners, educators—to make changes that will lead to better patient outcome, better system performance, and better professional development" (Batalden and Davidoff, 2007, p. 2). If quality improvement efforts are to be sustainable, Batalden said, all three of these goals must be focused on, not just one or two. Unfortunately, he said, in most cases the three goals are pursued independently, not collectively. For example, efforts are often made to improve patient outcomes and system performance, but the formative process of how health care professionals are trained and how to achieve better health care through

improvements in the quality of this training has generally received little attention.

Batalden offered the following formula as a way of thinking about how the various factors of quality improvement fit together:

Generalizable scientific evidence	+	Particular context	→	Measured performance improvement

In short, by taking general scientific understandings and applying them to a particular context, one should be able to achieve a measurable improvement in performance. There are five distinct knowledge systems underlying this formula, Batalden explained. The first relates to generalizable scientific evidence, which Batalden described as understanding how to minimize the effect of context. The second system of knowledge focuses on understanding the specific variables that define a particular context. The third involves measuring the stability of change over time; this system of knowledge underlies measured performance improvement, which is the outcome—that is, the right-hand side—of the above formula. While Batalden stresses the importance of measurements over time, such measures often do not exist; instead, it is often the case that only discrete pre-and post-intervention measurements are taken. The fourth system of knowledge is implied in the plus sign in the formula: It is the knowledge involved in choosing the correct evidence to a particular context. The fifth system of knowledge, which Batalden calls the knowledge of execution, is the formula's arrow.

Generalizable scientific evidence and particular contexts link together, creating a cycle that is a form of experiential learning. The cycle begins with testing the implications of concepts in new situations, Batalden explained. These tests lead to concrete experiences, and observations and reflections made from these experiences are then analyzed to form new abstract concepts and generalizations, which can then be tested in new situations, beginning another cycle. Without further testing and analysis, however, this is just experience. This cycle not only describes how a large majority of evidence-based medicine is developed, but it also captures how evidence-based medicine is largely integrated into practice. In fact, Batalden said, the quality improvement field has been substantially handicapped by the idea that only one method to control quality can be used at a time to affect change. While a lot can be learned from studying the effects of individual quality improvements, much can also be learned experientially from a multitude of efforts to improve health

care. Thus, Batalden suggested, experiential learning can be seen as one of the underpinnings of quality improvement.

Jeremy Grimshaw of the Ottawa Health Research Institute offered a different approach to quality improvement research. There is a consistent failure to translate research findings into clinical practice, as evidenced by studies showing 30 percent to 40 percent of patients not receiving the care they should (McGlynn et al., 2003) and 20 percent to 25 percent of patients receiving unnecessary or potentially harmful care (Grol, 2001), and, Grimshaw said, overcoming this failure is a major focus of health care quality improvement. One way to fix this failure, he suggested, would be to instill evidence into clinical practice at a variety of levels: the structural, the organizational, the group or team, and the individual health professional levels (Ferlie and Shortell, 2001). To target the stakeholders at the various levels, different interventions would be needed, depending on the identified barriers. The challenge, Grimshaw said, will be to equip health care providers with the correct tools to properly deliver evidence-based treatments.

Implementation research[1] can be described as studies of how the uptake of research findings is promoted, explained Grimshaw. Implementation research focuses on the challenge of delivering evidence-based care to patients. The aim is to develop a generalizable evidence base that can be used to improve the implementation of research findings and enhance decision making at the local level. This research is inherently interdisciplinary, involving health care professionals, organization scientists, engineers, and others, Grimshaw noted.

Some workshop attendees questioned just how much these two views of quality improvement research differ. Despite the suggestion by some attendees that these approaches to quality improvement research oppose each other, others thought that the discussion revealed more similarities than differences. In particular, Batalden and Grimshaw agreed on the purpose of quality improvement research and also agreed that the evidence base needs to be developed to the point that it can build on itself.

[1]Implementation research is the term used in Europe to refer to quality improvement research, noted Grimshaw. These terms are not equal, but they cover many of the same areas.

METHODS

Quality improvement is analyzed using a variety of methods, Batalden said. These include systematic reviews, controlled trials, case reports, and hybrid quantitative/qualitative reports. These different methods have different strengths. The workshop discussions focused only on systematic reviews and randomized controlled trials.

Rigorous evaluations add valuable information to the overall knowledge base and provide a solid base of research that can be built upon, Grimshaw said. The majority of such evaluation approaches today emphasize a diagnostic process that first identifies barriers, then addresses the most important barriers with specific interventions, and, finally, evaluates the effects of the different interventions through rigorous evaluation designs.

Randomized controlled trials (RCTs) and other such rigorous research methods can provide better evidence of effectiveness than other types of methods when assessing specific questions, Grimshaw argued. RCTs should be used to evaluate such questions as what the likelihood is that an intervention will yield the desired effect, what the direct effects will be of that intervention and of its alternatives, under what circumstances the intervention will succeed or fail, and what resources are required to do the intervention, he said.

Grimshaw described the disagreement in the field about the use of what some believe to be the "gold standard," RCTs, when making evaluations of the effectiveness and efficiency of interventions. There is some antipathy to the use of RCTs in complex social contexts, such as quality improvement processes, while others believe RCTs to be an extremely valuable method of evaluating these interventions. Responding to those who do not believe in using RCTs for quality improvement, Grimshaw said that there are many misconceptions about RCTs. It is often assumed by critics, for instance, that all randomized trials use the methods of explanatory (focused on efficacy) drug trials that require tight inclusion criteria, that they largely ignore context, and that they are expensive. But this is not necessarily true, Grimshaw argued. Randomized trials of quality improvement interventions tend to be pragmatic (focused on effectiveness) and attempt to elucidate whether an intervention will be effective in a real-world setting, not in an optimal one. Such RCTs frequently have broad inclusion criteria and can be designed to gain better understanding of the influence of context on the effectiveness of quality improvement interventions and why changes occurred. One method of achieving this, for instance, is to use observational

approaches in conjunction with data from RCTs to test multilevel hypotheses about which interventions work and which do not.

Quasi-experimental trials are another method of evaluating interventions, Grimshaw said. Additionally, uncontrolled before-and-after studies, controlled before-and-after studies, and interrupted time-series analyses are all frequently used alternatives to RCTs. However, many of the criticisms of RCTs also apply to these other methods. RCTs build on the knowledge generated by observational studies and case studies, Grimshaw said.

Grimshaw and Batalden agreed that the best method to evaluate a given intervention will depend on the specifics of that intervention, and one should always attempt to choose a mixture of the best possible method, given the individual circumstances.

AREAS WHERE MORE KNOWLEDGE IS NEEDED

Based on Batalden's proposed model of quality improvement, many areas exist where more knowledge is needed to achieve better patient outcomes, system performance, and professional development. To improve patient and population outcomes, examples of areas where knowledge is needed include better measures of outcomes, improved confidence in these measures, and understanding of the causes of variation in both outcomes and measurement. Improving system performance will require enhanced measures, a better understanding of the various evaluation methods used, and an understanding of the role of standards in introducing change. Better professional development requires a more comprehensive understanding of such issues as competence, accreditation and licensure, and fostering of cooperation among professionals. Another area of knowledge that needs building, Batalden said, is how employees are trained, developed, and held accountable. Two other areas that are not well understood are the roles that leadership and governing boards play in quality improvement. Building this body of research knowledge will demand developments in many areas, Grimshaw said. Theoretical developments are needed to provide frameworks and predictive theories for creating generalizable research, such as understanding how interventions are chosen and interpreted and how to change individual and organizational behaviors. Methodological developments are also required, as well as exploratory studies aimed at understanding the experiential learning that takes place in individual settings and organizations. Rigorous evaluations need to be undertaken of the effectiveness and efficiency of interventions,

Grimshaw said; these bodies of knowledge can be synthesized to determine the generalizability of findings.

Finally, Grimshaw noted that partnerships are needed to encourage communication among various stakeholders, such as theorists, researchers, and implementers. Such partnerships are necessary in order to understand what types of knowledge are needed and how that knowledge can best be developed; but, he said, few such partnerships exist today.

3

Barriers to Quality Improvement and Quality Improvement Research

In the early 1990s, a number of hospitals created rapid-response teams or medical-emergency teams to identify and intervene early in the care of clinically critical patients. The promise of these teams was that they could help provide better care to many of a hospital's most at-risk patients, and in some instances the rates of cardiac arrest, post-surgical complications, and overall mortality were shown to have improved, at least informally. Over time, rapid-response teams became increasingly popular. In 2003 there were about 100 such teams in U.S. hospitals, and by 2005 there were a couple of thousand teams, said Frank Davidoff of the Institute for Healthcare Improvement.

This widespread adoption, however, was not accompanied by a strong evidence base. Between 1992 and 2004, Davidoff said, only 17 reasonably creditable accounts of rapid-response teams were published. In fact, the strength of evidence regarding the effectiveness of rapid-response teams remains only moderate. The question that must be raised, Davidoff commented, is this: Why has the evidence taken so long to develop?

There is very little data available to guide the development of quality improvement research, of health sciences research, and of medicine in general, stated Harold Pincus of Columbia University and New York-Presbyterian Hospital. The lack of data, coupled with the insufficient development of the basic science of quality improvement research, Jeremy Grimshaw described, has led to a situation

where quality improvement has not been guided by evidence-based learning. Quality improvement has been based largely on experiential learning, but this knowledge has yet to be adequately captured in the literature. The spread of ideas from experiential learning has thus been poor.

This session of the workshop was devoted to discussing the barriers to quality improvement and, in particular, to developing an evidence base for use in quality improvement and in quality improvement research.

BARRIER OF FOCUS

Many workshop speakers emphasized the need to concentrate on the particular purpose of quality improvement projects and research. Davidoff noted that quality improvement efforts can have many divergent purposes. Some believe the purpose is improving performance, a process that occurs mainly through experiential learning and which differs significantly from scientific research, whose purpose, Davidoff noted, is to discover generalizable truths through hypothesis testing.

The emphasis on experiential learning that has evolved may lead to the conclusion that many of those doing quality improvements are uninterested in studying and writing about their experiences, Davidoff said. For them, discovering the generalizable truths about the efficacy and effectiveness of quality improvement interventions may be largely a secondary consideration.

THE ROLE OF CONTEXT

Understanding specific contexts and what is generalizable across settings is extremely valuable in the implementation of interventions, Grimshaw said. He also stated that work in the field attempts to generate evidence while considering context and its effect on processes.

If local contexts are not considered, then the lessons learned from interventions will not be generalizable and will fail to improve the health care system, Batalden cautioned. For example, the practice of health care policy is local, while the policy of health care is not, Batalden added. The local uptake of health care policies, thus, must be considered when working to improve care. Active research and knowledge development are needed, both locally and across local settings.

WHERE DOES IT BELONG?

Contributing to the infrastructure problem is lack of an agreed academic area for where quality improvement research should be taught, researched, and developed, noted Pincus. While the field could be part of schools or hospitals, it is unclear what school—i.e., public health, medicine, or nursing—or department would be most appropriate to hold it. One answer might be that health care quality improvement research should be considered an interdisciplinary research field, serving as a bridge between multiple disciplines. As an interdisciplinary field, Pincus suggested, it could potentially become a discipline of its own, following the precedent set by other fields, such as neuroscience.

But while many agree in theory with the concept of interdisciplinary research, it is extremely difficult in practice, Pincus said. Disincentives to interdisciplinary research outnumber incentives. In particular, Pincus identified three disincentives to interdisciplinary research: conceptual, procedural, and structural and financial. The conceptual barriers include the lack of common understanding and language across different disciplines. "When people with completely different scientific backgrounds get together to solve a common problem, they have to learn a different way of speaking, a different language," Pincus quoted Nobel Prize Winner Alan MacDiarmid. Procedural barriers include disincentives in career development, for example the time it takes to learn about all these various areas of study. The inherent departmental nature of academic medicine raises questions about whether a department will sponsor faculty who receive grants technically falling into other departments. This, along with issues concerning how indirect costs will be shared, are examples of structural and financial barriers. All of these, Pincus said, must be considered in identifying strategies for enhancing and expanding quality improvement research.

RESOURCE BARRIERS

Limited data exist about the resources allocated to health care quality improvement. According to the Coalition for Health Services Research, an estimated $1.5 billion of federal funding was spent on health services research in fiscal year 2006 (Coalition for Health Services Research, 2006). In another study, about 1.5 percent of 2002 biomedical research funding was in health services and policy research, equating to less than 0.1 percent of total U.S. health care expenditures (Moses et al., 2005), cited Pincus. Because these statistics refer to funding for all of health services research, not just

quality improvement research, even less is actually spent on understanding what works to improve performance. In countries outside the United States, Grimshaw said, the situation is no better, with funding policies that are often insufficient and inconsistent.

A related issue, Pincus said, is stakeholders' lack of motivation to build the infrastructure that is needed to attract health services researchers. The main sources of funding for health services research include several federal agencies such as the Agency for Healthcare Research and Quality (AHRQ), the U.S Department of Veterans Affairs (VA), and the Centers for Medicare and Medicaid Services (CMS), foundations, and to a lesser degree, the National Institutes of Health (NIH). Very little funding comes from industry (i.e., hospitals, insurance, and pharmaceuticals) and voluntary health organizations, Pincus said. Thus it is important to develop strategies for diversifying funding sources and enhancing contributions from both industry and the NIH.

During the discussion, Richard Kahn of the American Diabetes Association (ADA) noted that as a voluntary health organization, the ADA does not receive many applications for quality improvement research grants. The applications that it does receive tend not to be well put together and are not of highly sophisticated research designs. Despite the general feeling that the organization awards few grants for quality improvement research, Kahn said that more funding would be provided if better applications were received.

BARRIERS TO RECRUITMENT AND TRAINING

Davidoff characterized the following "mismatch" between training and practice: Most people doing medical quality improvement projects have little or no research training, while most people with research training are not doing quality improvement projects. Furthermore, he observed, few people know how to study quality effectively. Quality improvement research is unfamiliar to most practitioners, mainly because quality improvement is, at its core, more a social process of behavior and organization change than a biological or physical process.[1] This mismatch is a large barrier to improving the state of quality improvement research, Davidoff said.

[1]The roles of behavior and organization change are extremely relevant to the understanding of quality improvement and implementation science, but because of the scope of the workshop, discussion of these issues was limited.

Recruitment

The science behind recruiting and training researchers to study quality improvement is not well understood, Pincus said. There is some evidence that such strategies as involving people in research during medical school or before, undertaking full-time research fellowships, protecting faculty time, and training people in research-intensive departments can help produce successful researchers, Pincus said. In particular, exposure to research experiences is critical to the recruitment of future researchers.

Another issue is how potential quality improvement and patient safety researchers should be recruited into an interdisciplinary field. Pincus likened it to marketing and the strategy of market segmentation. Different strategies are needed for involving and recruiting different audiences—undergraduates as opposed to residents and post-doctoral students or health professionals versus those in fields outside of the health professions.

The problem of ownership presents yet another barrier to recruitment. It is often difficult to attribute ideas and quality improvement interventions to one specific person. Additionally, rewarding a single person for an idea may not be appropriate because quality improvement has to become part of the culture, and therefore belongs to everyone, noted Jay Berkelhamer of Children's Healthcare of Atlanta. This is a problem, and reward systems are yet to be built and may indeed reward multiple people, Davidoff agreed. Pincus also noted the trend of moving toward a "team science" approach.

One further difficulty is building a critical mass of interested people, Davidoff said. Although it is not clear whether a critical mass has yet been reached in quality improvement research, there are at least some examples of movement toward that goal. For example, Davidoff said, the Institute for Healthcare Improvement's annual meetings gathers around 6,000 people, and both Batalden and Davidoff commented on the number of residents they have seen who are interested in this work. Quality improvement is now also on the agendas of many medical specialty certifying boards, said David Stevens of the Association of American Medical Colleges. Andrea Kabcenell of the Institute for Healthcare Improvement commented that getting involved in quality improvement needs to be made more democratic and accessible. However, recruitment is confounded by the problems of publication and lack of career opportunities.

Training

The types of training needed to be successful in quality improvement have not been specified, but before evidence can be accumulated on the issue, Pincus said, it will be necessary to develop an infrastructure to train and develop people to go into the field of quality improvement research. There are a few models for this type of training, such as the VA Quality Scholars Program and the Robert Wood Johnson Foundation's Clinical Scholars Program. Curricula should be developed, Pincus suggested, by focusing on those skills currently believed to be important for quality improvement researchers. Values, mentorship, research opportunities, and flexibility must be part of the environment provided. People should also be taught practical skills, such as tips on conducting successful research and receiving grants. And, Pincus said, if quality improvement is to be treated as an interdisciplinary field, special attention should be given to the criteria for how promotion and tenure should be executed.

Quality improvement research involves not only those researchers who will become principal investigators but also many other professionals, such as clinician educators and administrators, whose roles and development must also be considered. When developing training strategies, professionals from other disciplines should be included. Early recruitment and proper training are well-supported strategies, but difficult to implement, Pincus said.

LEVERS FOR STRENGTHENING QUALITY IMPROVEMENT RESEARCH

Pincus identified three levers to improve quality improvement research. The first is humanistic—that is, the research will ultimately result in better care for patients. The second lever is in the policy arena. Policy levers, such as accreditation or payors providing matching funds for quality improvement research, must be utilized. Quality improvement research can also be leveraged by strategies focused on individual researchers, for example, providing salary support for protected research time or altering tenure and promotion policies to respond to the special barriers of interdisciplinary research.

BARRIERS TO PERFORMING QUALITY IMPROVEMENT AND QUALITY IMPROVEMENT RESEARCH

Ethics

Ethical oversight in quality improvement remains largely ambiguous. For example, Davidoff, citing the work of continuing education expert Philip Nowlen, said that what distinguishes professionals from other people is "the obligation of professionals to 'move unceasingly toward new levels of performance.'" From this perspective, quality improvement can be seen as an intrinsic element of clinical care. Others, however, believe quality improvement to be a form of clinical research, which raises the question of whether quality improvement research is human-subjects research. This is an important question because human-subjects research requires ethics review and institutional review board (IRB) approval.

The purpose of IRB approval is not to decide whether clinical care is ethical, Davidoff said, but the prospect of undergoing IRB approval, which can be extremely slow and inconsistent, has deterred some people from studying quality improvement. At the heart of this issue is determining whether a project falls under the rubric of quality improvement, which would not be subject to an ethics review, or whether it is research that would require ethics review. Currently, the distinction between these types of projects is not well delineated, Davidoff said. Constructs need to be developed that can help sharpen the distinction.

One member of the audience brought up the issue of confidentiality, asking how the Health Insurance Portability and Accountability Act (HIPAA) impedes researchers' abilities to collect data. Davidoff responded that HIPAA does not prevent quality improvement research from being conducted, although there are many rules that need to be followed, referencing the more complete discussion of this issue in a report from the Hastings Center (The Hastings Center, 2006).

These concerns argue, Davidoff said, that it would be best if the health care system itself developed ethical guidelines for quality improvement instead of allowing the task to be subsumed by the administrative structure responsible for clinical research ethics.

Methodology

Methodological differences between the biological sciences and the social sciences offer another barrier, Davidoff said. Quality improvement research faces the same challenges—such as biases,

confounders, and difficulties with measurement—that clinical research does, but there are also methodological problems specific to quality improvement research. For example, clinical interventions are often studies of efficacy that are conducted in highly controlled environments with rigorous population sampling and close monitoring of response rates. By contrast, quality improvement studies are not performed under such tightly controlled conditions. This is by design, Davidoff noted, but it makes it difficult to know if "proven interventions" in quality improvement research are generalizable and actually yield improved outcomes.

Another common challenge in methodology, which is compounded in quality improvement studies, is containing the intervention. As Davidoff explained, if individual participants or small sections of single large institutions are the units of study, they need to be prevented from sharing ideas with others in the organization to the greatest extent possible, so as not to "contaminate" the trial. This is extremely difficult to accomplish; an alternative, Davidoff said, is to let the unit of study be entire organizations (cluster trials), but that gives rise to another problem: that of heterogeneity. In this approach, all types of care settings—large, medium, or small; teaching or nonteaching; rural or urban—would be included in the trial. This may increase generalizability, but it would also decrease the internal validity of such a trial.

Such methodological problems have caused many studies of quality improvement to be methodologically flawed, Davidoff concluded.

Publication

Publication is seldom seen as an essential element of quality improvement, Davidoff said, because quality improvement studies are often dependent on local context and do not identify and share generalizable truths. Furthermore, Grimshaw said, much of what is published is poorly reported. This stems from a lack of writing experience by those doing quality improvement work, Davidoff suggested. When writing about complex systems and social processes, the need for writing experience becomes even more pronounced. Unfortunately, there is limited guidance as to how published articles documenting quality improvement efforts should be structured. One exception is an article written by Davidoff and Batalden that proposes guidelines for how write-ups of quality improvement studies should be structured in an effort to improve them in the eyes of reviewers, editors, and readers (Davidoff and Batalden, 2005).

Journals should begin to be more active in and receptive to quality improvement research, which would in turn help stimulate interest in the field by future researchers. Journals need to begin to rethink some of what is published, Davidoff said, offering the section in *Annals of Internal Medicine* on improving patient care as an example.

Collectively, these issues of role and structure result in a relatively small amount of learning being published, Davidoff said, and much of what is published is not generalizable and so fails to provide a basis upon which to base future efforts.

Communication

The lack of a common vocabulary for quality improvement and implementation research terms is a barrier to further progress. This is compounded by the fact that frameworks for how this research should be approached are not widely known. The result, Grimshaw concluded, is that those doing research in these areas have difficulty communicating with each other, which contributes to the problem of studies not building on previous findings, as discussed previously. The difficulties are augmented when the research is performed in an interdisciplinary setting, Pincus added.

BARRIER OF SUSTAINABILITY

Scot Webster spoke of the important role that culture change plays in improving quality. In particular, Webster noted Medtronic's culture of grass roots, bottom-up sustainability. Due to this corporate culture, individual employees and units are able to initiate improvement projects on their own. If the employees did not believe in quality improvement as part of their culture, sustained change would not occur, Webster said.

Marita Titler observed that overcoming problems with employee engagement requires addressing the false notion that interventions and improving the quality of care do not affect employees. This means that employees must understand why interventions are important. Otherwise, interventions are at risk of being seen merely as additional short-term projects adding to workloads, and not as priorities. People have to believe in the improvements, not just see them as short-term solutions, Webster agreed, adding that culture change and change management must be included as areas of focus.

Titler also emphasized the barriers caused by problems at the system level. System-level issues that can potentially detract from

advances in quality improvement include accounting for change, managing competing demands, and understanding that change is complex. Purely mechanistic approaches for change in complex systems are often inadequate; instead, more complex, adaptive approaches may be necessary. These barriers must be addressed in order to induce change, Titler concluded.

4

Opportunities

The many barriers described in the previous section can be translated into areas of opportunity for quality improvement research. As Scott Young of Kaiser's Care Management Institute noted, future quality improvement efforts will need to take into account improvements in care for those with multiple chronic conditions, transitions in care, new technologies, robust evidence-based medicine, and innovative care environments.

SHORT TERM

There are a number of concrete actions that can be taken to make quality improvement and quality improvement studies better in the short term. One area of focus, for example, is the development of an evidence base. And as Frank Davidoff of the Institute for Healthcare Improvement said, managing the heterogeneity of research will require that the goals of quality improvement projects be more focused. Heterogeneity cannot be ignored, but there are ways to control it within the constraints of the real world. Adapting a lesson from randomized trial advocate Tom Chalmers, Davidoff proposed quality improvement interventions be assessed using the most rigorous methods possible immediately after the intervention has been introduced. In this way, the strength of study results may increase due to the ability to randomize.

Additionally, randomized controlled trials should build on previous work that characterized context and intervention development, Batalden said. The gap between technical knowledge limits and the needs of the particular applications of knowledge must be bridged.

The focus of quality improvement projects should also be clarified, suggested Davidoff. Projects often do not distinguish between the goals of determining the efficacy of the clinical intervention itself and of assessing the effectiveness of the care system in delivering the intervention. Different types of evidence may be required for the different goals, Davidoff noted. With a greater emphasis on clearly defining the focus of studies, the field could produce useful, generalizable knowledge that is actually needed, Grimshaw said.

Understanding the ethical issues is also an important, tangible change that can help improve the state of quality improvement research, Davidoff said.

LONG TERM

One long-term solution to improving quality improvement and quality improvement research would be to provide training in research methods to people doing work in quality improvement, Davidoff suggested. This could help fix the aforementioned mismatch between training and practice. Davidoff also noted that changes should be made to professional education. Examples of such changes would include teaching collaborative skills, training physicians in the manner that health care should be delivered, and encouraging provider partnerships.

Academic and editorial cultures also need to change in order for quality improvement and quality improvement research to develop. These stakeholders need to recognize the social and intellectual values of quality improvement work, Davidoff said. Other opportunities include learning more about experiential learning and leveraging other research disciplines. Davidoff noted that other research disciplines, such as social sciences and economics, could be useful in moving forward. One important step in achieving this could be recognizing that quality improvement research, as an interdisciplinary field, will require special attention, Pincus noted.

THE IMPORTANCE OF STRATEGIES FOR CHANGE

Strategies should be developed to take action on these opportunities, Pincus said. He proposed six strategies to help advance

quality improvement research: an infusion of new dollars, diversification of funding sources, creation of institutional homes for quality improvement research, recognition of the need for diverse strategies for different audiences, exposure to future researchers at multiple and early points in academic development, and enhancement of data about what strategies are most effective in engaging investigators and developing substantial programs. While these strategies are all important, a prioritization was not offered. Indeed, as Titler noted, because of the complexity of the health care system and the often conflicting needs of various stakeholders, it is extremely difficult to prioritize among strategies to develop quality improvement and quality improvement research.

5

General Reactions

The following general reactions were offered by members of the forum as well as members of the audience during the last session of the workshop.

LEVERAGING OTHER INDUSTRIES

Thomas Boat of the University of Cincinnati commented on the need to learn from industry about how to market one's efforts. Reducing variation in health care practices will be a challenge, but may potentially yield great results.

In response to Boat's comments, Jay Berkelhamer of Children's Healthcare of Atlanta offered the example of mass-customization automobile manufacturer Maserati, which produces between 5,000 and 10,000 cars a year (Cropley, 2007). No two Maseratis are alike, as they are all made to specification, but the production of the cars is standardized. Lessons may potentially be learned about how to standardize while allowing for individual differences, Berkelhamer said.

Judith Gueron of Manpower Demonstration Research Corporation also discussed lessons learned from other industries. For example, she pointed out that 40 years ago educational reforms were suggested, with the recommendation that changes take place in schools of education, but significant advances have yet to be seen. Applying that lesson to health care, Gueron suggested that medical schools might not be the best place to focus reform efforts.

Laura Leviton of the Robert Wood Johnson Foundation discussed positive deviance and similar methods from other areas. In education literature, for example, the term "school improvement methods" is used. Some of these methods have been successfully implemented in other fields and could be useful in health care, Leviton said.

CONTEXT

The difficult portion of reducing variation, Boat said, will be allowing medical practices to account for context while treating individual patients and understanding the various confounders of genomic background, environmental exposures, and psychosocial contexts.

Ignatius Bau of the California Endowment agreed that the discussion of context is critical. There is the assumption that context does not matter in quality improvement, he said, but this assumption conflicts with the research agenda that attempts to produce generalizable processes. What is known about changing culture, such as changing provider behavior and changing processes of care in team-based environments, should be a necessary component of this conversation. Bau also discussed the need to understand both resistance to change and why, according to performance measures, best practices are not followed every time a patient is treated.

AREAS FOR FURTHER DISCUSSION

There is a large co-occurrence of mental, addictive, and general health conditions, Pincus said, citing the findings of the IOM report *Improving the Quality of Health Care for Mental and Substance-Use Conditions* (Institute of Medicine, 2006). But resource investment in a quality improvement infrastructure and improvements in quality that have been made in health care have not been paralleled in mental health care. Partnerships, among other strategies, should also be considered, he said. AHRQ's Integrated Delivery System Research Network[1] could be applied in mental health settings, for example. Quality improvement methods have not yet permeated the areas of mental health and substance use, where they could potentially have a great impact.

[1]The Integrated Delivery System Research Network is a research model, connecting top researchers and health care systems (Agency for Healthcare Research and Quality, 2002).

David Introcaso of the Department of Health and Human Services noted that the forum could benefit from listening to the perspectives of patient advocates and hearing about the disease burdens of vulnerable populations. There is a great need to think about innovation and how to guide innovation, Introcaso said, and a model should be developed of how research is created, how knowledge is created, and how knowledge is transferred.

The questions of how to define and develop a discipline are complicated, but they are ones that should be considered by the forum, said Alex Ommaya of the Department of Veterans Affairs.

Anthony Rosner of the Foundation for Chiropractic Education and Research remarked on the future challenges chronic conditions will bring, asking the forum to address health promotion and prevention in future discussions. Boat also urged the forum to consider the large variety of settings in which health care is delivered.

CLARIFYING COMMUNICATION

Marshall Chin and Jeremy Grimshaw recognized the many complementarities discussed during the workshop. The workshop also reflected the plethora of activities around quality improvement and quality improvement research throughout the country and the world. In order to build on all these efforts, there is a need to become more specific in writing about these efforts. Researchers also must be cognizant of describing the level at which an intervention is acting, Grimshaw said.

Berkelhamer commented that those institutions in the academic community doing the research are not necessarily those doing well in practice centers.

Titler described the current state of communication in the field. For the most part, implementers and researchers work in silos and do not communicate well with each other. This lack of communication perhaps signals the need for these groups to move away from these distinctions and work together, Titler said.

THE NEED FOR FURTHER KNOWLEDGE

Kahn emphasized the role of leadership. The presentations made in the morning sessions largely reflected much of what is already known to work, noted Kahn. The questions that naturally arise are: Why did it take so long to adopt? Why isn't everybody doing it? What are the environmental characteristics that allow people to improve?

Davidoff discussed the need to understand *dynamic knowledge*, or knowledge in action. This is the knowledge that people harness in doing their jobs, but it is generally not articulated well. Gueron responded that dynamic knowledge comes from a different conceptual base for innovation and leadership than static knowledge.

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Appendix A

Workshop Agenda

THE PATH TO QUALITY IMPROVEMENT: APPROACHES AND BARRIERS

Sponsored by
The Institute of Medicine's
Forum on the Science of Health Care Quality
Improvement and Implementation
The National Academies Keck Building
Washington, D.C.

8:15 a.m. **Welcome**

8:20 a.m. **Lessons in Quality Improvement from Outside Health-Care Services**
— Scot Webster, Medtronic
— Q&A
Moderator: Tom Boat

9:25 a.m. **Break**

9:40 a.m. **Quality Improvement in Medical Systems**
— Scott Young, Kaiser Care Management Institute
— Craig Miller, Baptist Hospital Inc.
— Marita Titler, University of Iowa City Health Care System
— Q&A
Moderator: Jay Berkelhamer

12:15 p.m. **Lunch**

1:00 p.m. **Perspectives on Quality Improvement and Quality-Improvement Research**
— Paul Batalden, Health Care Improvement Leadership Development, Dartmouth Medical School
— Jeremy Grimshaw, Ottawa Health Research Institute
— Q&A
Moderator: Brian Mittman

3:00 p.m. **Break**

3:15 p.m. **Barriers to Quality Improvement and Quality-Improvement Research**
— Harold Pincus, Columbia University and New York Presbyterian Hospital
— Frank Davidoff, Institute for Healthcare Improvement
— Q&A
Moderator: Jerome Grossman

5:15 p.m. **General Reactions from the Forum**
Moderator: Tom Boat

6:00 p.m. **Adjourn**

Appendix B

Workshop Participants

Pamela Ballou-Nelson
Adventist Midwest Management Services

Mara Benner
Gentiva Health Services

Emily Devoto

Louis Diamond
Thomson Healthcare

Antoniya Dimova
Varna University of Medicine, Bulgaria

Molla Donaldson
George Washington University School of Medicine & Health Services

Denise Dougherty
Agency for Healthcare Research and Quality

Suzanne Felt-Lisk
Mathematica Policy Research

Nagla Fetouh
Christine Mirzayan Fellowships
The National Academies

Veronica M. Friel
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Jenissa Haidari
American Academy of Otolaryngology

Michael Halpern
American Cancer Society

Michael Harrison
Agency for Healthcare Research and Quality

Alex Hathaway
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Nkemdiri Iruka
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