The State of Quality Improvement and Implementation Research: Expert Views, Workshop Summary

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

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THE STATE OF QUALITY IMPROVEMENT AND IMPLEMENTATION RESEARCH

EXPERT VIEWS

WORKSHOP SUMMARY

Samantha Chao, *Rapporteur*

Forum on the Science of Health Care Quality Improvement and Implementation

Board on Health Care Services

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

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Reviewers

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 **JACK C. EBELER,** of Ebeler Consulting. Appointed by the Institute of Medicine, he was responsible for

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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 authoring committee and the institution.

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Introduction

The Institute of Medicine (IOM) workshop "The Conduct of Health Care Quality Improvement and Implementation Research" was held on May 24–25, 2007, in Irvine, CA. The purpose of this workshop was to gain a better understanding of what is known and not known about quality improvement and implementation research. Experts were asked to identify current methods and best practices as well as areas where future efforts should be concentrated to propel the field. As with its previous workshop, the Forum on the Science of Health Care Quality Improvement and Implementation invited speakers from other disciplines to share their experiences in their respective fields. Although many disciplines are relevant to this topic, not all views could be incorporated because of workshop time constraints, but will be incorporated in the forum's future activities.

The following chapters describe and summarize workshop presentations and discussions. Therefore, the content is limited to the views presented and discussed during the workshop itself and is not intended to be a comprehensive assessment. The broader scope of issues pertaining to this subject area is recognized but could not be addressed in this summary. Appendix A is the workshop agenda and Appendix B contains a list of workshop participants. Speakers were invited to submit written responses prior to the workshop; those are included in Appendix C.

The forum is used by the IOM to convene representatives from

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academia, government, and industry. In bringing together this wide group of stakeholders with diverse views, the forum provides a neutral setting where issues related to improving the science behind health care quality improvement and implementation can be discussed. Through their discussions, forum members attain a better understanding of what the needs are and begin crossing the communication barriers that prevent advances in the field.

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1

Persistent Problems with Quality*

Persistent problems exist in the quality of health care, preventing it from being as high quality and as effective as it could be. To help illustrate problems in health care and explain why quality improvement and quality improvement research is important in the advancement of health care, two perspectives were presented: value and patient.

VALUE PROPOSITION

Forum co-chair Paul O'Neill acknowledged that quality of health care can be conceptualized in many ways. Addressing the overuse, misuse, and underuse of clinical care is an important aspect of improving quality in health care, but can be limited in its impact. O'Neill's perspective of quality in health care considers the value proposition and thus has a broader goal—to improve the way health and medical care is provided so that the right care can be delivered every time. Practicing health care in this manner could reduce the cost of health and medical care by an estimated 50 percent or $1 trillion while making great improvements in patient outcomes.

One example O'Neill cited was the adequate stocking of Pyxis

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

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machines, which nurses use to automatically dispense medications. Improper stocking of medications (known as stock outages) leads to wasted time and resources to find medications that should be there. A hospital O'Neill observed had 57 Pyxis machines and incurred 983 stock outages in a single month. In a disaggregated form, these numbers might not mean anything. However, when compared to a perfect health care system without stock outages, the inadequate supply of medications should be viewed as a systems failure, leading to extra work and wasted resources. In another example, an equivalent of 11 full-time nurses was used to look for equipment in a single year, instead of using their knowledge and skills to treat patients, O'Neill said. Many other examples exist that yield similar value propositions that can help improve the value of health and medical care without challenging medical knowledge.

PATIENT PERSPECTIVE

Denise Dougherty of the Agency for Healthcare Research and Quality (AHRQ) provided the complementary patient perspective of problems with quality during clinical care. To characterize the urgency of the problems, Dougherty provided national snapshots of issues in quality based on data from AHRQ's National Healthcare Quality and Disparities Reports, which identified many variations in care. Quality and quality improvement rates varied by delivery setting (e.g., hospitals saw more improvement than ambulatory care centers, nursing homes, and home health care) and by state without a good explanation for why these variations occur. For example, the worst performing state admits five times as many children for asthma into its hospitals than the best performing state. Although we know that a proportion of these hospitalizations could be prevented with appropriate and timely ambulatory care, benchmarks are unknown and need to be developed. Through the lens of the IOM's six aims for quality—safety, effectiveness, timeliness, patient centered, efficient, and equitable—one can easily identify many more deficiencies in care. Based on the data, progress has been made in many areas of health care quality (overall improvement rate was 3.1 percent between 2005 and 2006[1]), but improvement has been slow. Acceleration of improvements and reductions in disparities in quality are necessary to better serve patients and increase the value of health care to patients and payers.

[1]This was determined by averaging improvement rates of core measures of the National Healthcare Quality Report.

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2

Spread in Health Care

Paul Plsek of Paul E. Plsek & Associates addressed the spread of ideas in health care quality and the barriers to spread. Plsek discussed the following three questions: What do we know about how improvement spreads? Why is spread so problematic in health care compared to other industries? How do we increase the likelihood of something actually spreading? These questions were asked to help give context for the importance of quality improvement research, which will be discussed in the next chapter. To address these questions, Plsek quoted Albert Einstein, stating, "We can't solve problems by using the same kind of thinking we used when we created them."

Plsek presented a systems perspective, stating that every system is perfectly designed to achieve the results it yields; to get different results, the system must be changed. The first step to transforming the system, Plsek said, is to be able to clearly see the system. He likened the problem to walking through a forest in circles: Getting out of the forest would be much easier if all the paths could be viewed from above. Previous attempts to spread improvements in health care have not revolutionized the system, perhaps because they have suffered from walking in circles by repeatedly using the same types of interventions. Examples might include repeatedly presenting the results of studies showing the effectiveness of specific treatments, with the hope that key individuals will see the need for change, or always assuming that certain individuals, such as chief medical

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officers or chief executive officers, are the best ones to lead change. But more profound change is clearly needed.

An adequate characterization of the health care system is needed to identify opportunities for improvement. There are three types of systems: simple, complicated, and complex. A simple system follows a standard recipe to yield results. A complicated system involves combining multiple subsystems and can be recreated by following the same procedures (e.g., sending a rocket to the moon). A complex system is made up of multiple subsystems, but each application is unique (e.g., raising a child). Health care is sometimes mischaracterized as a complicated system. In reality, health care is a complex system, and the spread of improvement both inside and outside health care is complex as well, Plsek said.

Much is known about complex adaptive systems and spread of innovations within such systems,[1] Plsek said, referencing the work of Trish Greenhalgh (Greenhalgh et al., 2004; Plsek and Greenhalgh, 2001) and others. Spread of improvement and innovation within a complex system combines characteristics of the innovation itself, characteristics of the system, characteristics of the people adopting the innovation, and characteristics defining the context of the system. Plsek pointed out that while there are many characteristics of complex systems, three that are particularly important in understanding how improvements spread are the nature of relationships and coordination; attractors, described as the underlying motivating factors for the behaviors we observe in ourselves and others; and the interactions among structures, processes, and patterns.

The first characteristic of complex systems is that relationships and coordination are often more important than the parts of a system, Plsek said. Management expert Henry Mintzberg identified six basic mechanisms of coordination in organizations: mutual adjustment, direct supervision, standardization of work processes, standardization of outputs, standardization of skills/professions, and standardization of norms (Mintzberg, 1989). The particular mechanisms driving health care are the standardization of skills/professions, mutual adjustment, and standardization of norms. Professional organizations—the term Mintzberg uses to describe health care, law firms, and other such entities—coordinate naturally through professional standards such as education and regulation, at the heart of which is

[1]A complex adaptive system is a collection of individual agents that have the freedom to act in ways that are not always predictable and whose actions are interconnected such that one agent's actions changes the context for other agents (IOM, 2001).

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mutual adjustment, Plsek said. Professional organizations also coordinate under the standardization of norms mechanism, so that an understanding of the norm exists (e.g., having a zero infection rate). To achieve the end goals, the people leading change—the change agents—have the choice of either attempting to force organizations to work against their natural coordination mechanisms or reframing the needed change in a way that takes advantage of these natural mechanisms.

Second, behavior in complex adaptive systems can largely be explained by attractors. Again, change agents have two choices: attempting to directly confront and change others' behaviors and motivators, or reframing the needed change in ways that leverage people's innate reasons for doing what they do.

The third characteristic of complex systems is that integrated changes in structures, processes, and patterns are required for sustainable transformation. Structures refer to the physical environment and policies; processes may be guidelines and protocols; and patterns reflect behaviors and the nature of relationships, decision making, conflict, power, and learning. Understanding of all three is necessary for transformation to occur. For example, adoption of electronic medical records would be a structural change, which must be accompanied by processes such as guidelines. However, improvements may not be sustainable if people do not feel included in decision making, or if conflict avoidance behavior occurs when certain powerful individuals refuse to use the system as it was designed.

Answering the questions mentioned in the beginning of his talk, Plsek said the spread of improvement is complex. Improvement in health care spreads much slower in comparison to other industries. Perhaps this is because the coordination strategies that work in other industries do not necessarily apply in health care. Finally, with respect to what can be done to enhance the likelihood of spread, Plsek said that spread cannot be forced and that context plays a large role. People conducting interventions need to be more conscious of the interventions so that factors contributing to spread can be identified. Storytelling is as important as evidence-based research findings to improve spread of ideas. People have to be willing to change, and change has to start somewhere in the current culture of the organization (the mechanism of mutual adjustment). People also have to be willing to adapt, while the leadership of an organization must be willing to "muddle through," which, Plsek said, has been an effective strategy in complex systems.

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3

State of the Science of Quality Improvement Research

To get a better sense of how quality improvement research is being conducted, the workshop convened six panelists from a variety of perspectives to address the following six questions:

1. With respect to quality improvement, what kinds of research/evaluation projects have you undertaken/funded/reviewed? In which contexts (e.g., settings, types of patients)? With whom do you work to both study and implement interventions? For what audience?
2. How do you/does your organization approach quality improvement research/evaluation? What research designs/methods are employed? What types of measures are needed for evaluation? Are the needed measures available? Is the infrastructure (e.g., information technology) able to support optimal research designs?
3. What quality improvement strategies have you identified as effective as a result of your research?
4. Do you think the type of evidence required for evaluating quality improvement interventions is fundamentally different from that required for interventions in clinical medicine?
    a. If you think the type of evidence required for quality improvement differs from that in the rest of medicine, is it because you think that quality improvement interventions

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intrinsically require less testing or that the need for action trumps the need for evidence?

b. Does this answer depend on variations in context (e.g., across patients, clinical microsystems, health plans, regions)? Other contextual factors? Which aspects of context, if any, do you measure as part of quality improvement research?

5. Do you have suggestions for appropriately matching research approaches to research questions?

6. What additional research is needed to help policy makers/practitioners improve quality of care?

Some panelists submitted written responses to these questions; those responses are included in Appendix C.

EVIDENCE-BASED PRACTICE CENTER

Paul Heidenreich of both the Palo Alto Veterans Administration (VA) Hospital and Stanford Evidence-based Practice Center (EPC) presented the EPC's approach to evaluating quality improvement research. The EPC, a collaborative effort between Stanford and University of California, San Francisco (UCSF), is one of 13 EPCs funded by AHRQ to provide evidence-based reports and disseminate the findings of those reports.[1] The Stanford–UCSF EPC has authored a series of reports titled "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies." These reports attempt to provide guidance to those doing quality improvement and assess the effectiveness of various quality improvement strategies under specific circumstances. A secondary goal is to advance review methodology. The series has evaluated a variety of issues in health care, including diabetes and medication management. Each evaluation studies the effects of the same quality improvement strategies, such as provider reminders and techniques to promote self-management (Table 3-1). The studies are all conducted using one of three evaluation designs: randomized trials, concurrent trials, and interrupted time series.

The EPC employs a "strength of evidence" scale to rate studies on three factors: impact, study strength, and effect size. The level of difficulty to implement an intervention is also considered, focusing on cost barriers and complexity. The strength of evidence and diffi-

[1]Topics for reports are typically requested by AHRQ, and the EPC will develop a framework to address it. The EPC will also identify experts and stakeholders to be involved in the report before proceeding.

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TABLE 3-1 Crossing the Quality Gap Series Overview

Evaluations	Quality Improvement Strategies	Methods Used
Diabetes	Provider reminders	Randomized trials
Hypertension	Facilitated relay of clinical data to providers	Concurrent trials
Medication management–antibiotic use	Audit and feedback	Interrupted time series[a]
Asthma	Provider education	
Care coordination	Patient education	
Nosocomial infections	Patient reminder systems	
Heart failure	Organizational change	
	Promotion of self-management	
	Disease or case management	
	Team or personnel changes	
	Changes to medical record systems	
	Financial incentives	

[a]These studies collected data at least three times before the intervention and three times after the intervention

culty of implementation are used in conjunction during evaluations. Using this scale, the reports were able to glean some findings about which quality improvement strategies work and which do not. For example, nearly all the quality improvement strategies had a positive impact in the hypertension evaluation, with an average reduction of 4.5 mmHg. Specific quality improvement strategies, such as organizational change and patient education, had greater impacts than others, Heidenreich said. The hypertension evaluation also concluded that it was difficult to distinguish the individual effects of components of multicomponent interventions. This is in contrast with the results from the diabetes evaluation, which found that more complex interventions yielded greater effects. Overall, the reports also found consistent results between the randomized controlled trials (RCTs) and the controlled before-and-after study designs.

The reports also highlighted some limitations in the literature. For example, study strategies were often not well described, particularly those assessing organizational change and studies using combinations of quality improvement strategies, Heidenreich said.

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Without being able to identify the key components of a strategy, attribution of effects to specific interventions was difficult.

Heidenreich said he did not believe there was a difference between the evidence required for clinical medicine and for quality improvement. The difference, he said, is between the potential harm and cost of quality improvement and clinical medicine. For example, the potential harm patients face if every diabetic does not receive foot exams may be minimal when compared to the potential harm patients may encounter from drug trials. The need for evidence is fundamentally the same, Heidenreich said.

Areas for further research include the need to separate the components of multidimensional interventions. Additionally, the implementation of interventions should be evaluated.

COCHRANE EPOC

The Cochrane Effective Practice and Organisation of Care Group (EPOC) conducts systematic reviews. EPOC has completed 39 reviews and is developing 39 more, said Jeremy Grimshaw of the University of Ottawa. Through its work, EPOC has identified more than 5,000 randomized studies or well-designed, quasi-experimental studies for evaluating health care quality. In reviewing the literature, the challenge Grimshaw posed to the group was as follows: How do we get the most information out of these studies?

Quality improvement and quality improvement research are similar, but have many differences. Quality improvement aims to improve the quality of care delivered in a specific setting, requiring highly contextualized experiential learning. Quality improvement may demonstrate change but does not focus on evaluating causal relationships between the improvement activity and the magnitude of improvement. A common problem with current quality improvement efforts is that potential solutions are often tested before the problem is well understood. In contrast, quality improvement research generates generalizable knowledge by evaluating the effects of and exploring the mechanism of action and potential effect modifiers of different quality improvement interventions across a range of settings. Its goal is to make strong causal inferences, which requires use of a broad range of study designs.

Grimshaw defined quality improvement research as the scientific study of the determinants, processes, and outcomes of quality improvement, including the following:

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- synthesis of knowledge (identify knowledge base and various approaches);
- identification of knowledge to action gaps;
- development of methods to assess barriers and facilitators to quality improvement;
- development of methods for optimizing quality improvement strategies;
- evaluations of the effectiveness and efficiency of quality improvement strategies; and
- development of quality improvement theories and research methods.

Quality improvement research should be actionable in a policy sense by being predictive, allowing for conclusions to be drawn, such as "if X intervention is implemented, Y benefits are likely to occur." Quality improvement research requires use of diverse methods, such as ways to create and appraise clinical practice guidelines and cluster randomized trials in implementation research. Rigorous evaluations, such as RCTs, are needed to provide evidence of effectiveness to ensure that the effects are not a result of secular change. In the end, the methods used depend on the question being asked.

Grimshaw then described an increasingly common approach to quality improvement research, where initial research focuses on an assessment of barriers and supports in the practice environment. This is followed with the identification of strategies to overcome those barriers, leading to improvements in processes and outcomes of care.

The literature generally supports the notion that changing provider behavior and improving quality is possible. Frequently quality improvement interventions lead to modest results that are still potentially important from a population perspective. For example, the average absolute improvement in compliance with evidence-based recommendations across 118 RCTs of audit-and-feedback is around 5 percent, but this comes with a substantial amount of variability (–2 to +71 percent). Further there is considerable evidence that low-intensity interventions may be effective in improving quality. The need is not for new methods, Grimshaw argued, but for new approaches.

A great deal still needs to be answered by quality improvement research, such as the generalizability of interventions and their mechanisms. Additionally, researchers need to better understand the likely confounders of quality improvement in order to balance the unknown confounders. Understanding the effects of economic issues, such as the opportunity costs of disseminating ineffective or

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inefficient interventions, is one such confounder. Quality improvement research should use an interdisciplinary approach and introduce different perspectives and methods from other disciplines (e.g., behavioral and psychological theorists). Priorities for future research include developing methods of barrier identification, optimizing interventions, and evaluating effectiveness and efficiency of different strategies.

MULTIPLE RESEARCH METHODS

Whereas Heidenreich and Grimshaw discussed methods of working with the complexity of and barriers to quality improvement research, Trish Greenhalgh of University College London discussed the problem that quality improvement research is undertheorized. As examples of how theories can be used in quality improvement research, Greenhalgh described two approaches to quality improvement undertaken by her own team: language interpretation services and electronic medical records. (See Appendix C for submitted response to answers.)

In her first example, Greenhalgh said she had worked with a local service provider in London who had identified their biggest problem as the poor state of language interpretation services in primary care. To better understand the problem, Greenhalgh applied a qualitative design study to interview patients, doctors, interpreters, and managers about their stories of interpreted consultations. The focus of these interviews and subsequent analyses was the person's own narrative of the interpreted consultation as he saw it. Because the narrative serves as a window to the wider organizational context, Greenhalgh's team was able to use participants' stories to elucidate organizational routines, defined by organizational sociologist Martha Feldman as "repetitive, recognizable patterns of interdependent actions, carried out by multiple actors" (Feldman and Pentland, 2003). In the study of organizational routines, a useful unit of analysis is often the handover between two people, a common occurrence in contemporary health care. By studying the routines associated with the provision of professional interpreters, Greenhalgh was able to compare organizations having strong routines with those having weak routines. Those organizations with weak routines in this area tended to rarely use interpreting services (or to use them inefficiently) and thus were lower performers. In organizations with well-developed routines, junior administrative staff often were responsible for refining and applying the routines; thus, apparently low-status and "unimportant" staff had a high degree of agency and influence in whether the interpreting service

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was actually available in the organization. Greenhalgh found that improvement was often driven by the creativity of individual staff to shape organizational routines.

Greenhalgh's second example was the research and evaluation of the new Summary Care Record, an online version of the electronic patient record accessible to any United Kingdom health professional. Two parallel studies, funded by separate organizations (the Medical Research Council and the Department of Health), are underway that focus on the research and the service evaluation components of implementing the Summary Care Record. The studies focus on the various parts of a system required to implement electronic patient records, including the receptionists, nurses, and physicians as well as the routines to determine how work is constrained by the electronic records. A particular point of focus is "workarounds," the informal actions people take to make complex interventions work in practice when there is a mismatch between what is supposed to happen and what is practical or possible. As discussed in the above two examples, research projects with built-in evaluations must be linked with making improvements in quality, Greenhalgh recommended.

A second recommendation was to explore the use of stories to capture the complexity of health care services, including the implementation of interventions, as well as the creativity of staff to stimulate improvement. Finally, Greenhalgh recommended the strengthening of theory to better understand organizational-level data. Although RCTs have a place in quality improvement research, other methods also must be employed to get a full picture.

VETERANS ADMINISTRATION

Brian Mittman of the VA and the journal *Implementation Science* spoke about his experiences with quality improvement research, in particular the VA's Quality Enhancement Research Initiative (QUERI). The QUERI program is designed to maximize validity and rigor, while also recognizing practical importance. To achieve this, QUERI focuses on meeting the needs of clinicians, managers, and researchers using a two-pronged approach addressing both practice improvement goals and research goals. An additional goal is to balance internal and external validity. Formal frameworks guide the planning and design of research projects. With respect to the rigor of research design and method, QUERI's approach stays away from designs that do not adequately allow for the realization of secular trends, such as single case studies and before-and-after studies. However, the approach does respect context, heterogeneity, and the importance of change processes and mechanisms.

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The VA's highly developed information technology system, its research-supportive management and culture, and its strong levels of funding for research-based quality improvement, Mittman concluded, are a result of the VA's infrastructure, heralded as one of the best prepared systems to support quality improvement research.

In response to a question about the effectiveness of quality improvement strategies identified by the VA, Mittman noted that such strategies do not lead to clear decisions regarding effectiveness. This notion is derived from the idea that a strategy's effectiveness is highly dependent on the setting and context for implementation. In fact, Mittman said, some researchers believe that what drives change is not the specific quality improvement strategy itself, but the manner in which it is implemented. The actual effects of a quality improvement strategy may not always be as useful as the derived observations of the change processes. Based on this thinking, selecting an improvement strategy based solely on an intervention's effects in other settings may not be very useful; the organizational and contextual features (e.g., local circumstances, resources, and training) of implementing the strategy must be considered. Echoing sentiments from Grimshaw, Mittman stated that success in quality improvement will likely require multifaceted, multilevel campaigns. However, more effective ways to disseminate knowledge are needed. Although written documentation is necessary, it is not sufficient.

Is the evidence needed for quality improvement fundamentally different from that required for clinical medicine? Mittman said the evidence for quality improvement is very different and that the overreliance on using the methods and approaches from clinical medicine has hindered the advancement of quality improvement research. This is driven largely by the heterogeneity seen in both interventions and contexts. The evidence requirements also differ in that quality improvement focuses more on the data and analyses of processes than the impact and outcomes data. In quality improvement research, the need for implicit knowledge is greater than the need for explicit knowledge, the guiding framework for clinical research as exemplified by RCTs. Although RCTs are important, emphasis on use of other methods for data collection and analysis are necessary to develop other types of evidence.

Quality improvement research should be supported by social scientists, Mittman said. Additionally, quality improvement researchers should have some minimum level of training in the social and clinical sciences. Researchers need to be trained to understand the nature of the kind of evidence that needs to be produced.

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PRACTICE-BASED RESEARCH NETWORKS

Bill Tierney of Indiana University and the Regenstrief Institute reviewed methods used in quality improvement research: RCTs, prospective cohort studies, retrospective cohort studies, and cross-sectional studies. RCTs are often the most desired method, Tierney said, because of their rigor and having fewer biases. However, RCTs also have drawbacks, which include being time consuming, expensive, and difficult to perform. Perhaps most importantly, findings from RCTs may be the least generalizable. Prospective cohort studies are often the next best alternative because they are quicker, cheaper, and easier to conduct. Similar to RCTs, prospective cohorts offer the advantage of capturing the most relevant measures for answering the question at hand. Even easier and less expensive to conduct are retrospective studies that rely on existing measures of everyday care and management. Although retrospective studies are good for understanding patterns of care and generating hypotheses, they are subject to severe observational bias and rarely provide definitive answers. Qualitative studies employ cross-sectional methods that provide data as snapshots in time. Firm conclusions are difficult to draw because findings often cannot be generalized, but they can help understand the extent and define the problem(s) needing more rigorous study. However, results from cross-sectional studies are highly actionable in the local environments in which they are conducted. Researchers must use the most appropriate research methods when RCTs are not possible.

In addition to the wide range of methods, a variety of measures are used to study quality improvement. For example, use of health care services, vital signs, and test results are easily derived from electronic medical records. However, aspects of care important to patients—how they feel, their quality of life, functional status, and preferences in care—are more difficult to measure, are not routinely recorded by health care providers, and therefore are often left out of quality improvement efforts. These types of data can only be collected from questionnaires completed by providers or patients.

In turn, collecting data on measures of quality requires adequate infrastructure. One formal structure is the Practice-Based Research Network (PBRN).[2] Indiana's PBRN includes both inner-city community health centers and suburban office practices. The PBRN collects data through a citywide network of hospitals and an electronic

[2]Practice-Based Research Networks are groups of ambulatory practices organized to understand and improve primary care from both clinical and organizational perspectives (AHRQ, 2001).

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medical records system employed by Indiana University for more than 35 years. Information is shared through a health information exchange that gathers information from a great number of hospitals, freestanding labs and x-ray facilities, and physicians in central Indiana to encourage community-based studies. Arguably the most important piece of infrastructure, however, is for clinical leadership to be committed to research in quality improvement and safety.

Tierney presented some of his own research findings based on his background in internal medicine, geriatrics, and informatics. Tierney has performed numerous types of research, including RCTs (e.g., evaluating multidisciplinary care management in geriatrics and internal medicine in areas such as depression, dementia, and computer decision support systems), cohort studies (e.g., assessing weight management in elders), retrospective cohort studies (e.g., comparing electronic medical records with chart audit programs for quality indicators), and cross-sectional studies. To study quality improvement, researchers at Indiana University have also used an approach called appreciative inquiry, a method that allows people to share stories and provide insights into parts of interventions not currently measurable, such as characteristics of organizational context. In comparing these stories, researchers can identify the values, barriers, and facilitators affecting quality of care.

In his research, Tierney has found computer decision support for preventive care to be effective. However, this approach has not been able to reliably yield improvements in chronic disease management. Prevention and chronic disease management are different problems that must be approached in different ways, Tierney said. Qualitative research is also largely underused. To more effectively use qualitative research and to have the greatest impact on provider and patient activities, behavioral scientists need to be more involved in the study of health care quality improvement.

Variability also exists by site. For example, Tierney and Indiana University have established a PBRN in western Kenya that delivers HIV/AIDS care to more than 55,000 patients at 20 sites. Strategies found to be effective in Kenya may work only in Kenya and East Africa and may not generalize to practices in the United States. Additionally, some quality improvement interventions, such as multidisciplinary case management, may be effective in some contexts and diseases, but they may be too costly to implement broadly in resource-constrained practices in the United States or elsewhere. The effectiveness of an intervention is difficult to predict. Interventions have been proven to be effective in areas thought to be difficult, such as keeping frail elders out of institutions and managing dementia.

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But interventions in other areas originally believed to improve quality were not successful, such as managing chronic renal insufficiency using accepted evidence-based practices.

These findings suggest that more extensive research efforts are needed to establish useful approaches to improving quality and study their effects. For example, it must be determined how to incorporate health-related quality-of-life measures into everyday health care and quality improvement research. Although useful quality-of-life measures exist, using them in everyday care is not widely taught in U.S. medical schools. Another area of research needed is the engineering of clinical decision support tools that physicians will use, particularly in disease management. These tools should become a standard part of care processes and medical records, but must be meaningful and target the correct actor (e.g., develop tools to be used by nurses to support functions nurses handle). People must be able to see improvement tools as methods to help themselves change instead of the system forcing change. Finally, appropriate measures of costs should be developed.

PATIENT SAFETY

Kaveh Shojania of the Ottawa Hospital and the University of Ottawa spoke about quality improvement research from the patient safety perspective. (See Appendix C for responses to questions.) No quality improvement strategies have been proven to be very effective, Shojania said. General improvements have been made, but they are small in magnitude and often cannot be generalized; major breakthroughs are lacking. For example, during a review of 11 various quality improvement interventions for diabetes, hemoglobin A_1c levels improved by an average of 0.42 percent across 66 trials, which would result in questionable effects on clinical care (Shojania et al., 2006). Although processes of care are often improved, processes do not usually translate into meaningful improvements in outcomes of care. There are no magic bullets, Shojania concluded.

Many question the model for approaching quality improvement in health care because of its lack of major breakthroughs over the past 20 years of research, but Shojania proposed that the expectations may be too high. The majority of clinical therapies yield mostly small to modest benefits. Improvements of 3 to 4 percent in breast cancer treatments supported by trillions of dollars of research often make headlines. The war on cancer has been fought for more than 30 years with steady, incremental improvements. Comparing quality improvement of health care to the basic sciences of cancer biology,

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far less is known about quality improvement yet the investments have not been made. Therefore, Shojania does not believe that quality improvement requires different types of research than clinical research.

Common arguments for suggesting quality improvement research must respond to different standards of evidence, including the following: the urgency for evidence; the complexity of quality improvement; the understanding that some solutions do not require evidence; the evaluation of quality improvement interventions is too costly; and the side effects of quality improvement interventions are not the cause of major problems. Shojania refuted each argument to maintain that quality improvement research actually should not require separate standards of evidence.

The first argument derives from the notion that too many unnecessary deaths occur and that the problem is too urgent to wait for a large, convincing body of evidence to develop. However, medical errors reportedly were the eighth leading cause of death (IOM, 1999), and should be held to the same standards of evaluation as those applied to the top seven, Shojania said.

A second argument for quality improvement requiring different standards of evidence is that quality improvement is too complex to study adequately with even the most rigorous methods, such as RCTs. The purpose of RCTs, however, is to balance unknown factors between control and intervention subjects. In fact, there are more unknown factors of quality improvement as compared to clinical science. RCTs are thus well suited to the study of quality improvement and have been found to be very useful in the identification of ineffective strategies (e.g., an RCT of continuous quality improvement combined with the chronic care model found that while the process was successfully implemented, outcomes failed to improve). RCTs can help identify where resources should be concentrated.

The third argument refers to the notion that some ideas are so logical that evidence is not needed. A tongue-in-cheek article in the *British Medical Journal*, a systematic review of RCTs to determine the effectiveness of parachute use to prevent death and trauma, which (not surprisingly) found that no such RCTs had ever been conducted (Smith and Pell, 2003), reflects this view. However, Shojania pointed out that even if efficacy is taken for granted, implementing even the most apparently simple or straightforward intervention can be complex. For example, hand washing represents an incredibly basic patient safety strategy, yet increasing adherence to this widely recommended parachute equivalent tends to be extraordinarily diffi-

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cult. Although the goal is not questioned, the most effective method for achieving the goal remains unclear.

The fourth argument for having different standards of evidence in quality improvement is that evaluating quality improvement interventions is too costly, citing a cost of more than $1 million for trials of computerized provider order entry systems (CPOE) (Leape et al., 2002). These systems themselves cost more than $20 million each and will have little return on investment if implementation problems occur, if many clinicians do not use the system, or if the system introduces new problems, all examples that have been documented. Given that billions of dollars are at stake for hospitals across the country to implement CPOE, spending several million dollars to confirm effectiveness for various systems and identify optimal implementation strategies seems quite cost-effective, Shojania said. Reducing work hours and mandating medication reconciliations are other examples of costly interventions that have relatively low returns on investment because the strategies for how best to implement them remain unknown.

The fifth argument Shojania rebutted was the idea that the side effects produced by quality improvement and patient safety are not of great consequence. Shojania dismissed that notion as false for two reasons. First, quality improvement interventions generally increase the amount of care people receive, giving rise to the known side effects of medications and other treatments involved. Second, changes in complex systems often result in unintended consequences. This was exemplified in articles reporting new errors in care that were introduced by CPOE, bar coding, work-hour reductions, and infection control isolation protocols. Based on these arguments, Shojania concluded that quality improvement tends to have more in common with the rest of clinical medicine than is generally recognized.

Shojania presented a framework for evaluation (Figure 3-1). Although the benefit of some interventions is self-evident, their implementation should be monitored to ensure no adverse unintended consequences arise. Most interventions, however, are not self-evident. For these interventions, it must be asked if an RCT should be conducted. If an RCT is not feasible, rigorous prospective study designs such as controlled before-and-after studies or multivariate modeling should be used. These evaluative models are used throughout health services research and are appropriate for quality improvement, Shojania said. Lessons from other disciplines, such as cognitive psychology, sociology, and qualitative research, should be employed in studying quality improvement. The need is not for

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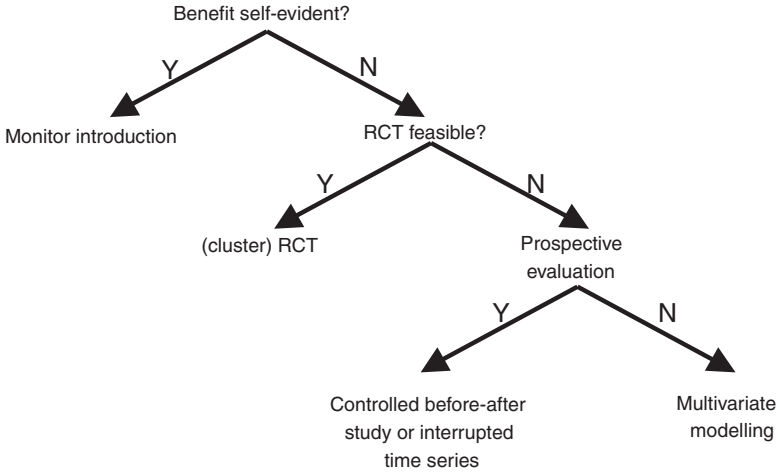

FIGURE 3-1 Framework for evaluation of interventions.
RCT = randomized controlled trial.
SOURCE: Adapted from Lilford (2005).

new models of evidence in quality improvement research, but for investments comparable to other areas in medicine in terms of time, money, and human resources.

OPEN DISCUSSION

An open discussion followed speaker presentations where members of the audience were invited to ask panel members questions. This section summarizes those discussions.

Panel members were asked to discuss the applicability of community-based participatory research methods in quality improvement. Greenhalgh responded by saying that those methods are extremely valuable because community members have high buy-in into studies when they help develop interventions. The downside, however, is that when participatory methods are used, participants may resist being randomized because the flip-side of buy-in is lack of equipoise stemming from a firm belief that the locally developed program is useful and that standard care is a lesser option. Mittman noted that similar methods are being used at the VA, likening the VA approach to health system–based participatory research, where the leadership of the VA health system serves in partnership with researchers. Grimshaw said one of his key conclusions from the forum

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thus far is the need for use of multiple methods and a good framework. There are various stages for evaluating complex interventions: theory building, modeling approaches, and exploratory trials that are followed by definitive large-scale randomized trials. A range of methods is available for each stage; the challenge is to determine which method is most appropriate in individual circumstances, Grimshaw said.

Another question posed was whether one could identify specific factors and characteristics in people who successfully implement quality improvement interventions, and if so, whether people could be trained to be more successful. Tierney said successful implementation requires collaboration between clinical leadership and multidisciplinary researchers. With respect to whether people could be trained, Tierney said it is possible, but it must occur under an apprenticeship model: doing and showing the trainee effective approaches rather than telling the trainee what to do. Mittman agreed, adding that experience is critical to successfully researching and implementing quality improvement because of its complexity. Grimshaw said that whether better training can accelerate effective leadership remains unknown. The field needs to evaluate whether current leaders are equipped to bring the field forward and whether future leaders will be able to effect change.

Another question was whether quality improvement research should undergo ethics review. Tierney, a member of an institutional review board (IRB),[3] said not all quality improvement projects should be considered human subjects research. For example, quality improvement studies aimed at improving care delivery in specific hospitals and practices *without generating new knowledge* should not need IRB approval. However, as an editor of a medical journal, Tierney acknowledged that most journals require studies to be reviewed by an IRB, and this might drive quality improvement researchers to obtain IRB approval for their studies that otherwise might not require such approval. Many mechanisms exist to address quality improvement research in IRBs, such as expedited and exempt review processes, discrediting common beliefs that IRB approval requires large investments in time and effort. Tierney encouraged quality improvement researchers to serve on IRBs to educate both themselves of IRB processes and educate other IRB members about quality improvement research through their participation. Heidenreich agreed with Tierney's point that many

[3]Institutional review boards are groups whose purpose is to oversee the ethical conduct of research to protect the rights of research subjects.

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mechanisms exist to attain approval and that if research is being conducted, the study should undergo the IRB process. Greenhalgh said similar issues are being discussed in the United Kingdom, and research ethics application forms are not often designed for quality improvement projects. Greenhalgh recommended that researchers describe the uncertainties and parameters of projects in the notes sections of ethics forms and not send junior staff to defend complex projects. Many panelists noted they had not been subject to major delays or problems in attaining IRB approval.

When asked whether patients themselves should be randomized, Heidenreich said it depended on the intervention, but for the majority of cases, the point of randomization should be the physician or facility. Grimshaw agreed, noting that quality improvement interventions, and thus quality improvement research, often operate at the level of the provider or organization and not the level of individual patients.

Panelists were asked what types of research they would like to see going forward. Shojania replied by emphasizing the need for qualitative research to generate hypotheses, which should be followed up by empiric studies of effectiveness. Heidenreich called for analyses of the implementation of quality improvement as postmarked surveillance as well as analyses of the conduct of RCTs of different implementation methods. Grimshaw said building a common taxonomy was of primary importance and would involve input from a variety of stakeholders and researchers in other disciplines (e.g., organizational science, psychology, and clinicians). Grimshaw also said the basic science of quality improvement needs to become better developed, while building on existing knowledge in the social sciences. Mittman hoped for the creation of a road map identifying the theoretical frameworks and foundations for determining the most appropriate sequence of research projects. Greenhalgh hoped to see better publication standards for methods sections (where the details of interventions should be explained), noting that information currently gleaned from literature is often limited by restrictions on the length of methods sections allowed in journals. Tierney identified three specific needs: (1) to incorporate qualitative research into rigorous trials (in agreement with Heidenreich); (2) to involve industrial engineers and human factors engineers; and (3) to introduce more health services research into HIV/AIDS care in sub-Saharan Africa, where a large portion of the more than $30 billion investment has been spent inefficiently because of inadequate knowledge of proper care delivery in resource-poor countries.

In summary, there is no magic bullet to improve quality. As

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many of the speakers suggested, all available research methods are valuable and researchers must learn which methods are most appropriate in answering different questions. The result will likely be multifaceted, multilevel research approaches and will require input from a number of disciplines. Speakers also largely recognized the need to not only understand what works, but also why an intervention does or does not work. This reflects the need for research studies to better discuss the roles of organizational and contextual factors, such as the role of leadership. Better understandings of these factors will help identify what improvements are not specific to an individual hospital or clinic but can be generalized to larger audiences.

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4

Priorities for Change

This session was open to all workshop attendees to discuss what is known about effective strategies for quality improvement research and spread. As starting points for discussion, everyone was asked to identify high-priority effective strategies as the basis for developing a spread agenda, and high-priority unanswered questions about quality improvement strategies as the basis for developing a research/evaluation agenda. No conclusions identifying top priorities were drawn during the session.

INTERVENTION-LEVEL PRIORITIES

As discussed in the previous chapter, how a quality improvement intervention is implemented may be equally important as what quality improvement interventions "work." However, little is known about which interventions are effective. It was mentioned that reminders for immunizations have been shown in the literature as a practice ready for widespread use, with the average number of patients receiving immunizations nearly doubling, as shown in 30–40 RCTs. The field needs to better understand generalizability. Workshop attendees suggested ways studies could be more actionable and could provide greater insights to interventions. For example, audit-and-feedback mechanisms generally yield improvement, but vary widely in terms of magnitude of impact. To better understand this variation, it was suggested that head-to-head comparisons of

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audit-and-feedback mechanisms be conducted instead of the current intervention group versus control group comparisons. It was also suggested that a process of implementing and evaluating effective quality improvement strategies be developed so that the implementing organization would have more knowledge of the intervention before attempting to spread to other organizations.

Current efforts around variations in health care were noted as attempting to narrow disparities. Instead, variations should be studied. Partnerships should form to help study why variations exist, help identify characteristics of variations, and help study the components of variations.

Addressing the more technical side of interventions, a few attendees called for a stronger technical infrastructure to support quality improvement efforts. It was noted that measures of health care must be standardized. Currently measures are defined in a variety of ways (e.g., some measures of breast cancer care include women aged 40–60, while others include women aged 35–55), making meta-analyses difficult to conduct because data cannot easily be aggregated, much like comparing apples to oranges. Others noted that a greater emphasis needs to be placed on developing outcomes measures that could be used to drive improvement efforts. Patient satisfaction measures also need to be developed and more widely incorporated in improvement efforts.

Another concern is the lack of comprehensive databases to use to make decisions about interventions. Such a tool could be very useful in sharing best strategies and lessons learned.

ORGANIZATIONAL-LEVEL PRIORITIES

Another major focus is the need for knowledge about organizational change and cultural change in health care. The role of leadership is critical, but it is unclear how to engage top levels of leadership in quality improvement efforts. One response was to provide top leadership with motivation for incremental change. Implementing one or two small, moderately successful interventions could be the basis for widespread change. However, change does not occur only from the top, but must be integrated from levels throughout the entire organization. For example, the receptionist, a patient's first point of contact, could be a key leader for change and should be as involved as the office manager.

Strategies for approaching change should also be considered. For example, finding ways to improve average providers may be more of a motivating factor for change than improving top perform-

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ers, one participant said. It was noted that spread is often seen as a two-dimensional S-shaped curve[1] and is different from transformation. Perhaps cultural change in health care should not be viewed as an issue of spread, but rather transformation, requiring a multidimensional approach.

The ways in which culture and leadership are currently approached may need to be reassessed in order to drastically alter the way improvement is viewed. It was argued that widespread cultural change is unlikely to occur at this time due to current leaders' resistance to change. A different generation of health care leaders may be needed to make the greatest strides. By making small, concrete steps, medical residents and students of health care could be trained to have different expectations of the culture of health care. However, others were not willing to sacrifice the current generation, stating that expectations must be changed now. Specifically, future leaders should be trained in an interdisciplinary manner and should be expected to engage other researchers such as behavioral, engineering, and organizational scientists. Partnerships should also be used to conceptualize how best to implement change.

OPPORTUNITIES FOR CHANGE

One particular call for knowledge focused on quantifying opportunities for change, particularly for errors in care. The total costs to society of errors in health care, from all perspectives, are not well understood. The goal should be to minimize errors while recognizing that they cannot all be eliminated. Work should be done, an attendee commented, to change the culture of health care to one that can achieve this goal.

Comments were made supporting the need for cost-effectiveness analyses and benefit–cost analyses for performing quality improvement interventions. The ability to articulate the business case to both private and public payers will also become very important. In addition to informing decision makers, these analyses could help improve funding for quality improvement research. To attain this information, however, financial data for quality improvement research must be regularly collected and analyzed.

One person argued that health care is full of incompletely characterized problems. One way of determining the opportunity for

[1]In this usage, S-shaped curve refers to the shape of the line when rate of spread versus time is graphed: rate of spread is initially low, quickly rises, has an inflection point, and levels out over time.

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improvement would be to compare the current problem (e.g., take sampling of providers' infection rates) to the theoretical limit (e.g., no infection rates). The economic value to society, including the patient's perspective, should be assessed. What is not "perfect" is the opportunity for change. Thinking in this manner could help provide discipline in characterizing problems and finding solutions.

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5

Spread and Implementation of Research Findings

This session of the workshop consisted of two parts: how research findings and innovations are transferred among implementers in health care and what lessons can be learned from other disciplines. Perspectives from other disciplines included systems engineering, organizational change and development, and the history of medicine.

HEALTH PLAN PERSPECTIVE

This session focused on what is known about spread and implementation from health plans. While other perspectives are important, such as those of small providers and nursing homes, the planning committee chose to focus on health plans due to their leadership in this area and unique organizational structures. Speakers were asked to answer the following questions:

1. How do you spread research findings or other quality improvement strategies within and outside of your organization?
2. How are the innovations you implement identified? What types of evidence (e.g., clinical evidence, evidence on the innovation's effectiveness, generalizability to your setting) are required before an innovation is chosen for implementation?
3. What methods are used to evaluate the success of implemented innovations?

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Kaiser Permanente

Paul Wallace of Kaiser Permanente provided an overview of how Kaiser spreads research findings and chooses interventions for implementation. (See Appendix C for submitted responses.) The challenge is in balancing the tension between providing evidence-based care while providing care seen as relevant and important by both clinicians and patients. Kaiser operates in eight regions, giving rise to local issues, and provides care to 8.6 million members in a variety of settings. With hundreds of clinics, thousands of modules, tens of thousands of clinicians, and hundreds of thousands of employees, it is a challenge to balance both organized and "random acts" of quality improvement at the local level while implementing large national plans.

Kaiser Permanente is formally organized at both the national and regional levels. Certain core values are shared nationally and others locally. One national core value is the mutually exclusive relationship between Permanente medical groups and Kaiser health plans. Another core value is that all of Kaiser's physicians work for the Permanente Medical Groups and operate under capitated payment agreements with the Kaiser health plans, allowing for creative methods to pay for care innovations. The Permanente Medical Groups are multispecialty medical groups where specialists work closely with primary care physicians on a regular basis. Another national feature is Kaiser's overall governance, which includes a national board of directors for the health plan and an overall strategy developed jointly between the medical groups and health plan. One part of its national strategy is quality—including clinical quality, service, safety, and risk management. The Care Management Institute (CMI) was developed as a central place to share ideas about population-based care across regions. The CMI also houses formal networks for implementation and measurement.

Although consistent values are held nationally, organizational culture is largely a regional phenomenon, Wallace said. Each region and even each local office practices within its own locally evolved and defined culture. Locally, Kaiser's organizational cultures can largely be defined by regional medical groups that work together interregionally, but are considered separate entities running under separate budgets. The work of these medical groups is local, meaning in practical terms that "credit" for improvement is largely "owned" at the local level, despite the fact that Kaiser is a national organization.

Theoretically, ideas can flow through an organization either from the bottom up or from the top down. At Kaiser ideas flow in

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both directions. In the bottom-to-top approach, some innovations begin in local clinics and/or research centers and spread to others within a region. National awards for quality recognize outstanding innovations and are presented to give innovators an opportunity to share ideas with others outside their local region. Some ideas can be approached from the top down, such as key priorities for improvement that are identified and promoted nationally. Using a case study, Wallace described how a unique innovation for cardiovascular risk protection spread in about 17 months. The literature showed that a few different pharmaceutical interventions each yielded incremental improvement in the occurrence of cardiovascular events. Using Archimedes, a modeling and simulation program developed by David Eddy, it was found that a new drug combination regimen was more effective in preventing major cardiovascular events in diabetics than the traditional approach of focusing primarily on diabetes glucose management. Using the results of the model, a financial case was made that prescribing generic aspirin, lisinopril, and lovastatin together could decrease cardiovascular death, myocardial infarctions, or stroke in high-risk patients, such as diabetics older than 50 years old, saving approximately $600 per person per year.

The regimen spread to other regions based largely on the evidence provided by the Archimedes model. Within 18 months, all Kaiser regions were actively involved in implementing the regimen. Each region tailored the regimen as needed, but the core innovation was implemented nationwide. Currently, it is also being spread outside of Kaiser to community clinics in California, which has anecdotally seemed easier than achieving spread within Kaiser. This spread has been largely because people immediately recognize its value, Wallace said.

From this experience and others, Wallace derived driving factors for innovation and successful spread. The first factor centers on credibility, earned through strong literature, previous successful implementation of the innovation, and a compelling business case. Spread also requires balancing the tensions of the intervention, reflecting true change but not being too disruptive or considered unorthodox. Paradoxically, a somewhat controversial intervention can stimulate discussion and lead to engagement. Another critical factor was that the intervention must be able to be modified at the local level. A fourth factor for spread was having available an established network that is experienced with spread of innovation and ensuring that the innovation will fit with the network's strategies, much like Plsek's attractors. Although it is not a certainty that the spread of this drug regimen could be replicated with other interventions, Wallace said,

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the most critical factors in this example potentially were the leveraging of multiregional formal networks and of people whose jobs were to outline and locally pursue implementation and associated performance measurement. The final contributor to spread of innovation was luck in terms of timing, alignment with developing priorities, and availability of funding.

Aetna

David Pryor of Aetna described Aetna's engagement in care management and quality improvement. (See Appendix C for submitted responses.) Aetna is a health benefits company serving 15 million members nationwide through large plan sponsors and employer groups. Aetna sees itself as a partner with its employees and members in improving the quality of care. Of particular interest are understanding best practices and leveraging technology to assist in the practice of evidence-based medicine. Aetna also focuses on consumer engagement, exemplified in its leadership with consumer-driven health plans.

Aetna's approach to quality improvement builds on the IOM's six aims for quality: care should be safe, effective, patient centered, timely, equitable, and efficient (IOM, 2001). Pryor noted that it was particularly important to balance efficiency with the other quality aims. Opportunities for quality improvement are identified in several ways. One method detects gaps in care by assessing data collected from surveys. For example, HEDIS scores are measured for care provided (e.g., preventive health screenings and chronic care treatment) through all of Aetna's regions. If performance is below standard in an area, it becomes an opportunity for quality improvement. Aetna made improving maternity care a priority when it realized HEDIS scores were sub-optimal in selected areas. As a result, Aetna's maternity care program became more comprehensive, offering a full range of maternity services for families contemplating or expecting children. In addition, Aetna has developed programs aimed at addressing quality and efficiency in neonatal intensive care unit care.

A second approach to quality improvement identifies gaps from external data analyses. This approach has been used in addressing health care disparities. Through its breast health initiative, Aetna developed an RCT to assess improvements in mammography screening rates among African American and Latina women. Conducting external scans of the environment is another method Aetna has used to identify disparities and opportunities for change.

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A third method used to identify opportunities derives from collaborations with internal and external constituencies. Aetna has increasingly gained leverage when working collaboratively with large employer groups to improve quality for employees and reduce costs. Aetna worked with Virginia Mason Hospital and Medical Center to improve treatments of low back pain by relying less on advanced imaging processes and instead has focused on tracking patients into physical therapy treatments sooner in the process. The improvement resulted in savings for employer groups and insurers, and Aetna worked with the hospital to minimize the adverse impact of reduced reimbursement from imaging studies.

Aetna also surveys the Medical Network Trend Operating Report, which focuses on costs, utilization, and the economic impact of practice patterns. This approach was used to improve monitoring of anesthesia during colonoscopies. It was found that anesthesiologists did not need to be present for certain routine procedures and that the proper adjustment to staffing could greatly decrease costs without negatively impacting patient safety during the procedure. Improving quality while also improving efficiency is a concept at the heart of Aetna's medical management philosophy and one does not have to be sacrificed for the other, Pryor said.

The role of technology to improve quality is also critical. Aetna uses a robust data warehouse called Active Health Management to compile many different types of data about each of its members. Data can be aggregated at all levels to help assess care delivery.

Pryor discussed three influencing factors of implementation. First, the impact on membership and size is a key consideration that drives Aetna's focus on improving chronic disease care. The second factor is customer buy-in and support, where Aetna, as an insurer, can monitor customer preferences and can determine how to pursue those preferences if they fit into the company's vision. The last factor for implementation is feasibility, which is especially important in Aetna's structure, where physicians are independent from the company.

To evaluate their quality improvement efforts, Aetna studies measures of performance and return on investment. Some programs have relatively easily measurable metrics (e.g., hemoglobin A_1c levels in diabetics), but others are much more difficult (e.g., return on investment and efficiency). The return on investment measure is an area receiving particular attention in the company because it is being asked for by many employers or plan sponsors, but it is not always a factor used to determine whether an intervention should be implemented.

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Information about quality improvements is shared both internally and externally to encourage spread of best practices. While many efforts begin with top management, some begin within local markets and spread to others. One method for internal sharing is Aetna's internal website, where new information is posted daily. Externally, Aetna participates in a variety of industry associations, such as America's Health Insurance Plans and the Disease Management Association of America. All stakeholders must be involved, including academia, the private sector, and employer groups. Partnerships are imperative to providing evidence-based, high-quality care.

PERSPECTIVES FROM OTHER DISCIPLINES

The forum invited speakers from engineering and organizational change and development to discuss the role research has had on spread in their disciplines. These speakers were asked to respond to the following questions:

1. In your area of research, how are findings and best practices spread? What lessons can be leveraged from your experiences?
2. What methods are used to evaluate the success of implemented innovations?
3. Due to the high levels of variability between patients and health care systems, how should this variability be considered in assessing implementation?

To better characterize health care, the perspective of a historian of medicine was also sought. Although the planning committee recognized the importance of other disciplines, the workshop was limited in the number of speakers.

Engineering

Improvement can be viewed as getting better at things already being done, said Bill Rouse of the Georgia Institute of Technology. From a systems perspective, mere improvements will not be sufficient to address the problems facing health care. Instead, the focus should be on innovation, the creation of change.

Rouse identified a number of sources for best practices. When identifying best practices, inventions must be differentiated from innovations. As creator of change, innovation is related to patterns in data, processes, and improvement, among others. Invention and

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innovation involve the discovery of patterns, as identified by data in a broad sense that work and are adopted widely. From a multidisciplinary perspective, it has been found that basic behavioral and social processes are fundamental to the adoption of discoveries for all people and disciplines. Innovation occurs either from the inside out or the outside in. Inside-out innovation refers to those changes driven from internal sources and tested in a market; in this type of innovation, patterns are created. This is the type of innovation largely discussed during the workshop. Outside-in innovations are those where patterns are exploited—practices across other sectors and industries are identified and brought into a new industry. From a systems perspective, a balance between inside-out and outside-in innovations should be sought.

Rouse bridged four lessons from other industries into health care. The first lesson was the notion of an innovation funnel (Figure 5-1), aimed at answering the question of how many ideas are required to get one fundamental change into the marketplace. Although the literature varies, Rouse gave the following example: A thousand ideas can lead to about a hundred projects, leading to launches on the order of tens of new products, one of which will fundamentally change the market. The challenge is to sift through the thousands of ideas to find the innovation.

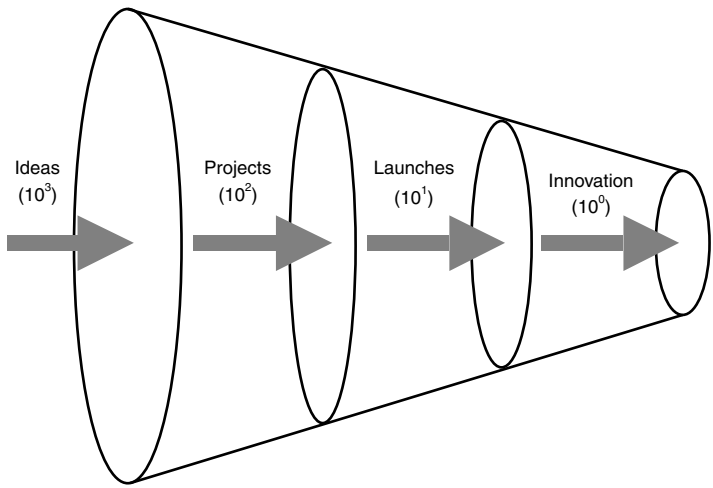

FIGURE 5-1 Innovation funnel.

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How 80–85 percent of American companies sift through ideas was Rouse's second lesson: having multistage investment strategies where investments are made in many small ideas. Evaluation of multistage strategies will be discussed later.

The third lesson, bridged from financial markets, leverages the use of options for investment. This lesson requires that dollar values be determined for a technology or idea. Like stock options, once a company decides to fully invest in an innovation, it would have the flexibility to use the idea immediately or at a later date.

The fourth lesson comes from a session with IBM, where it was recognized that health care is an incredibly complex system with nobody in charge, Rouse said. To address this issue, an online game was created called Health Advisor. In the game, 10,000 11-year-olds would manage a variety of patients in the health care system. The expectation is to find one or two good ideas out of 10,000.

Innovations can be evaluated using a number of approaches. First, innovations may be assessed in stages, using multistage criteria to consider the innovation. Multistage criteria include strategic fit, payoff, resources, application risk, and personnel. These criteria must be explicitly stated so that the innovators know how they are being measured. Balanced scorecards may also be used to evaluate innovations. A third method for evaluating innovations was by human-centered design, a process that considers and balances the concerns, values, and perceptions of all the stakeholders in the process. This occurs through a number of phases that include getting to know stakeholders and their needs as well as their reactions to new ideas.

Rouse identified a number of methods for considering variability. First was a continuation of the above-described human-centered design with understanding stakeholders as the focus. Another method for handling variability is the staging of investments to hedge risks. Rouse also proposed the use of options-based valuation to protect investments in innovations. The last method suggested was use of process controls to limit variations in subjects.

Organizational Change

Simple behavioral changes, such as folding your arms the other way, are awkward to make, said Newton Margulies of the University of California, Irvine. Change is difficult, resistant, and often feels wrong. Inducing major change in large organizations is much more difficult than simple behavioral changes because organizations themselves are problematic. Additionally, most organization designs

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are outdated and do not reflect current environments, requiring more comprehensive organizational change.

There is a process in which change occurs, beginning with collecting data, making a judgment or diagnosis, and deciding on the appropriate change intervention to use. Although the process is known, it is rarely implemented, causing change to be cumbersome and slow. Various definitions are often used for change and include planned change (a process and a technology aimed at improving the health and performance of an organization), organizational development (the continuous application of a single or several techniques focused on improvement), organizational transition (planned change from current state to future state where the future state is reasonably well defined), and organizational transformation (planned change from current state to future state where the future state is emerging and is not clearly defined). All these concepts are becoming increasingly common and better understood in organizational change.

Margulies presented two sets of categories for change, the first being reactive and proactive change. Reactive change is change stimulated by a force and focuses on the present (e.g., change in chief executive officer leads to changes throughout the organization). Proactive change is stimulated by strategic vision and focuses on the future. Another set of change categories presented was incremental and framebreaking change. Incremental change consists of making small improvements, whereas framebreaking change requires major shifts in the mission, value, and process of an organization, leading to a different culture. Combining these sets of categories creates a matrix with four phases of change (Figure 5-2).

Phase I is reactive, incremental change—something occurs and a small change is made—which is mostly done well. The type of change that tends to fail is reactive, framebreaking change (Phase IV). In Phase III, proactive framebreaking change, there is time to prepare and plan for transition for major shifts, but not so in Phase

	Reactive	Proactive
Incremental	I	II
Framebreaking	IV	III

FIGURE 5-2 Phases of change.

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IV. This matrix can also help an organization determine the amount of time and resources generally necessary for a particular type of change, Margulies said.

To ensure successful implementation of change, Margulies offered several tips. The first tip was that communication is a major factor for change. Communication includes not just disseminating what the change is, but the purpose, the plan, and end goal as well. Development of a plan for communication itself is encouraged. The second tip noted that there must be strong communication between senior management and change teams. Margulies also discussed the need to thoughtfully balance planning for change and urgency of implementation. A carefully thought-out plan for change is critical and often does not occur. The fourth tip highlighted the need for transition planning. The biggest failure in change implementation is the lack of careful transition planning, Margulies noted. The fifth tip stated that engaging participation from those affected by change is critical. The sixth tip was to carefully consider culture change. Development of a clear communication and commitment plan was the seventh tip. Finally, appropriate resources must be allocated and applied.

History of Medicine

History is the ultimate outcome, noted Guenter Risse. (See Appendix C for submitted response.) Historians are the students of change and are responsible for interpreting and articulating change, often through stories. Imperative to change is understanding context, Risse said. Stories are contingent on context and therefore must be translated before they can be applied. For lessons to be broadly generalized, commonalities must be found among organizations.

Risse introduced the notion that hospitals are houses of rituals. Often irrational institutional routines and inefficiencies can be viewed as barriers to care. These seemingly unnecessary routines are often remnants of long traditions that are deeply embedded in the culture of medicine. Culture moves slowly, but to be changed effectively, traditions or rituals must be acknowledged and considered. Rituals can also be used as framing devices to identify distinctive, deliberate actions to express and reaffirm values, beliefs, and relationships. The goal of rituals is to structure reality and provide cohesion to sequences of acts in life. Some rituals are shared, while others are not. They are constantly being created as ideas and environments change. One example of rituals is communication because it depends on very ordered, patterned sequences. Health

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care processes rely on communication. Elementary healing processes rely on cultural symbols that address emotional aspects of sickness such as restoring a sense of control and order by communicating with the divine. Diagnoses and treatments are no longer viewed as punishment by divine retribution for the sick or a form of social retaliation.

Health care has been transformed into a commodity. Care is currently viewed as a type of service where patients are labeled consumers and hospitals are considered corporate entities. Corporate culture encourages and rewards creativity, innovation, and risk taking. However, rituals of corporate life in hospitals are yet to be examined. Better understanding for these rituals would help contribute to the understanding of organizations and help yield better outcomes.

Health care is not just about cost cutting; it is about respecting patients and caregivers. Patients are often treated as ignorant, but it is no longer applicable to treat patients this way, especially with the increase of information available to patients on the Internet. Understanding the meaning of the ceremonies in health care can help serve as a reminder of the humanity of health care institutions, Risse said.

Open Discussion

Audience members were invited to ask questions. One question posed to Pryor and Wallace asked how grassroots participation is integrated into management to sustain change, given Aetna's limited control of its affiliated independent physicians as well as Kaiser's group and top-down constructs. At Aetna, engagement at the physician specialty group level is critical. A main leverage point for new policies is attaining buy-in from professional societies such as the American College of Gynecology and the American College of Physicians, Pryor said. Wallace supported Pryor's statements, adding that benefits must be framed in concrete terms when considering new policies. Often, the best way to frame opportunities is from the perspective of patients, Wallace said. There is a growing need to understand social networks within care environments to determine whether a physician's primary affiliation is with, for example, the American College of Surgeons or the hospital (e.g., "What tribe are you in?"). Being aware of these affiliations may hold implications for spread and implementation, Wallace noted.

The next question asked what the research and development budget should be in health care. Some provided specific plans for

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finding this money, noting the total amount is considerable once investments in technologies are included. The cost of improving quality must be considered in the context of financial realities, one speaker noted. Another speaker also recognized that the health care system is not value reimbursable, but is cost reimbursable, which provides little incentive for innovation. The bottom line was that evaluation should be a byproduct and an expected consequence of care. Marginal activities to conduct evaluations would be counterproductive in this sense. Although evaluation is not currently a byproduct of health care, it may not be far off, given the evolution of data systems.

Responding to a question about the role of private payers to recognize the costs of quality improvement, to manage innovation, and to ensure sustainability, one speaker identified innovative collaboration as key. One type of collaboration is the formation of partnerships with academic institutions to obtain data and subsequently perform studies on those data. Pay-for-performance initiatives were also mentioned as a method to provide incentives for quality improvement.

The last question asked during this session was about publication in peer-reviewed journals as the traditional vehicle for dissemination, recognizing that many nonacademic institutions do not publish articles. One speaker noted the difficulty in publishing articles if data are collected from multiple sites around the country because approval from multiple IRBs would need to be obtained. For the effort required to publish articles, given the questionable value added to nonacademic institutions, the marginal costs would likely be substantial. Peer-reviewed articles are successful vehicles for spread for those who write papers, but are not always useful to those from an operational context. Other methods participants noted for disseminating knowledge and ideas were the Institute for Healthcare Improvement's annual meeting and the general media.

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6

Breakout Groups

Workshop attendees were asked to split into two breakout groups: (1) research and (2) spread and implementation of research findings. The groups met for an hour before reconvening. Each group had a leader in charge of reporting the content of their discussions to the entire workshop. This chapter summarizes these reports.

SPREAD AND IMPLEMENTATION OF RESEARCH FINDINGS

Andrea Kabcenell of the Institute for Healthcare Improvement served as leader and reporter for the spread and implementation group, which discussed the following question: What do we need to know about strategies for change to foster spread and implementation? The group developed a three-part model, recognizing that information was needed in three general areas to foster spread of good ideas: the why (will), the what (ideas), and the how (execution).

A number of themes were addressed in discussing the will and motivation for spread. The discussion included leadership, which built off of the earlier notion of "What tribe are you in?" to figure out how to leverage people's affiliations to motivate change.

In discussing the ideas for spread, the conclusion was that the information gleaned from typical research studies was necessary but not sufficient. The common frustration was that current research

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is not as in depth as needed, Kabcenell said. Gaps in knowledge included how to get changes right and how to engage physicians. Making relevant knowledge accessible was identified as a systemic issue. In discussing the information marketplace, the group identified a number of ways to collect information, including the Internet, improvement networks, and social networks.

Execution of spread covered a range of issues, from high-level policy issues to front-line practitioners, with an emphasis on the need to capitalize on opportunities for collaboration. Environments can foster teamwork and tools such as technology, and transparency can enhance data sharing. The group also explored the idea of a renewable organization for improvement, where the expertise and power built for one project could become the basis for future projects. One particular call was to disseminate the knowledge that is already known. Much of what is known already is not widely known or readily available to a broad audience. Competition was also identified as a barrier to collaboration.

The importance of having linkages between the research and implementation communities was highlighted. Implementers could offer researchers the ability to test theories and ideas in real labs, while also providing expertise from an operational perspective. The need for research to have a user-oriented approach was also discussed. Additionally, allowing implementers to provide more input could be beneficial in research design and execution of change. Implementers could also be used a resource for funding.

The group discussed what information implementers wanted from researchers. In particular, core elements or essential ingredients for implementing change were desired, ranging from measures of organizational readiness to context, from the tools available for change to who needs to participate. It was noted that a standard way of communicating across organizations is imperative. Another type of information centered on troubleshooting to help determine why a tool or mechanism did not achieve its desired effects. Although cost data and strength of evidence are necessary, rigorous evaluations also are required to move forward. Reports on failures and successes should ideally be about equal—documentation of failure is as important as documentation of success, although few may want their failures documented. Information is also needed to predict both short-term and long-term returns on investment.

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RESEARCH

Marita Titler from the University of Iowa summarized the research group's discussion, which focused primarily on the challenges to be addressed to strengthen quality improvement research.

Fundamental problems with quality improvement center on the fact that the research focuses on a wide range of evaluations, from reviews of individual interventions to entire systems. The heavily disease-oriented evaluations pose additional barriers to performing good research because positive findings cannot be generalized from one disease to another. Part of the inability to compare between interventions for different diseases is the lack of a standard language to share ideas and compare findings.

Other problems in quality improvement research are the methods used. As mentioned throughout the workshop, the contexts in which interventions take place are not well studied or documented. Additionally, there is little guidance on how to balance tradeoffs, such as internal and external validity. It was also noted that multiple methods would be necessary to evaluate cultural change and transformational change. This would require strengthening of research methods, especially qualitative methods. Limited progress has been made in qualitative methods in part because guidelines for how to do so have not been developed and because of their limited acceptance in peer-reviewed journals. Most major journals have word limitations for articles, and qualitative research and comprehensive summaries of methods often exceed those limitations. It was suggested that specific components be written for a major journal and lengthier sections be published in other more focused journals.

The current state of quality improvement research was compared to community-based partnership research a few years ago and clinical research 25 years ago. Sciences evolve and patience needs to be exercised as quality improvement researchers learn from the development of those fields.

Collaboration is needed with researchers in other disciplines, including researchers studying human factors, engineering, and social science. Researchers also need to learn from social and behavioral theorists to better understand the mechanisms of organizational cultural relationships.

The session ended with a note to consider both the costs of implementing interventions and the costs of not understanding the opportunities of quality improvement projects.

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7

Strategic Opportunities

This panel was designed to provide reactions to the previous speakers from the perspectives of barriers to quality improvement research.

ETHICS

Jeffrey Cohen of HRP Associates, Inc., discussed the questions surrounding quality improvement research and the ethics of human subject protections. In most institutions, quality improvement research will face ethics review by IRBs, which make decisions about research by bringing together ethical principles and regulations. The basic principles governing human subject research and IRBs are respect for persons, beneficence, and justice. These principles, however, do not necessarily govern quality improvement research because it is not evident that much work has been done to determine what the ethical principles underlying quality improvement research are, Cohen said.

IRBs make decisions about what must be reviewed by considering the definition of regulations as inclusive of two parts: research and human subjects. Research was defined as "a systematic investigation designed to develop or contribute to generalizable knowledge," and a human subject as a "living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private

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information." Assessing whether quality improvement research is actually "research" may be a problem because the definition states that investigations must contribute to generalizable knowledge, Cohen said. Communication is necessary between IRBs and quality improvement researchers to discuss this issue. The second question is determining whether quality improvement research is human subject research. The definition uses the term "about whom," which begs the question of who subjects are in quality improvement research. In many instances it could be argued that the subjects are institutions and systems, while others target individual patients. Quality improvement researchers should clearly identify subjects in discussions with IRBs to determine whether IRB approval is necessary. A better framework explaining what quality improvement research is and what the research model is should also be clearly communicated to IRBs. Cohen agreed with Tierney's point that quality improvement researchers should become members of IRBs to help facilitate this dialogue.

IRBs have the flexibility to efficiently and effectively review nonbiomedical research. Some believe the regulations do not match social science research, but Cohen does not believe regulations to be problematic for social science or quality improvement research.

Having separate IRBs focus on just quality improvement is a highly contested issue as well as a problem in social and behavioral research. Although there is some merit to separating ethics review for biomedical research and other types of research, the amount of overlap in protocols makes it difficult to separate the research. Another barrier to separating into different IRBs is expertise because there is often not enough expertise to fill multiple IRBs.

IRBs must have sufficient knowledge and expertise in order to rule on quality improvement research. Although this creates a burden for IRBs, there is also a burden on quality improvement researchers to develop clear research frameworks and ethical standards as well as to educate IRBs, Cohen said.

RESEARCH TRAINING

Evidence-based medicine and evidence-based management need to work together to sustain improvement in quality of care, said Steve Shortell of the University of California, Berkeley. Evidence-based medicine can be defined as using the best available evidence in making treatment decisions, interventions, and technologies to improve care for patients. Evidence-based management draws on the social and behavioral sciences, human factors engineering, and

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health services research for managers to make the best decisions with a given allocation of resources to be used to, for example, make organizational changes and implement different strategies. The gross underuse of evidence by both clinical practitioners and managerial leaders can be partially addressed in how future leaders are educated and trained.

Because the health care system cannot afford to wait until the next generation to change, Shortell said, health care workers should take advantage of the many opportunities to work with clinical and managerial leaders. Some opportunities include designing short courses to educate leaders, encouraging team-based learning, and developing online distance learning. To make information gleaned from meta-analyses and synthetic review more accessible and to train people how to use that evidence appropriately, Shortell suggested the development of a National Center for Evidence-Based Health Care Management, following the examples of similar centers in Canada and the United Kingdom. This center would identify the best evidence about effective strategies found in the organizational behavior and social science literature and would be shared with clinical and managerial leaders in a meaningful manner. These leaders would, in the long run, be able to integrate evidence with efforts taking place in evidence-based medicine.

Researchers and leaders must be trained in process improvement skills, Shortell said. This includes becoming more interdisciplinary, perhaps asking engineers and psychologists to discuss human factors engineering approaches, change management, conflict management, and culture management.

Education of future leaders begins with targeting current students of medicine, nursing, pharmacy, public health, and health services management. These students should be trained in the abovementioned disciplines, but also should be exposed to evaluation research and study design. The role of accrediting bodies such as the Association of American Medical Colleges could be leveraged.

Training of researchers can be divided into two parts: clinical and social science. Likening quality improvement research to health services research, Shortell identified the need for students to study epidemiology, biostatistics, study design, ethics, and cost–benefit and cost-effectiveness analyses. Approximately 20 to 25 years ago, the Robert Wood Johnson Foundation Clinical Scholars Program trained physicians in health services research. At the time, the field had not been widely developed, but as a consequence of those scholars' continued support and interest in health services research, that field is much better defined today. Students should be trained to

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triangulate different methods, theories, and concepts. For those students in interdisciplinary doctorate programs, the emphasis is on social science backgrounds with some clinical background. Shortell believes these students should have not just a broad understanding of many subjects, but also in-depth training in one discipline, which is extremely useful when working with multidisciplinary teams. This additional training does not have to span a number of years and can be taught in intense focused sessions, and the skills would be reinforced on the job. The notion of learning organizations needs to be built on to fundamentally change practices.

Shortell offered some first steps about resource needs. For example, development of awards for investigators and postdoctoral students as well as career development in quality improvement research would encourage both current and future researchers. Additionally, fellowships in quality improvement research would also improve engagement. Highlighting a recommendation from a joint National Academy of Engineering and IOM report, Shortell suggested the development of approximately 10 centers for engineering and improving health care delivery. These centers would house interdisciplinary groups of engineers, health services researchers, social scientists, managers, and clinical and managerial leaders to work together in certain settings to work on these largely interdisciplinary issues. Development of these centers would be a great opportunity to train researchers, Shortell said. The United States produces very competent providers of health care who are equipped with 21st-century knowledge of biomedicine and technologies. Those providers are then turned over to a delivery system largely still in the 19th century. Quality improvement is one of the most apt tools to bridge that gap.

PUBLICATION

General

Major medical journals can have great impact with their broad circulation, media coverage, and website hits, said Cathy DeAngelis of the *Journal of the American Medical Association* (*JAMA*). *JAMA* is the most widely read medical journal in the world, with 365,000 print circulation and a million hits online every week. Because of this high visibility, *JAMA* is extremely selective in the articles it publishes.

Journals are rated by a measure called impact factor, which divides the number of citations from the journal over a 2-year period (the numerator) by the number of articles of original research and

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others (the denominator) calculated by Thompson ISI, DeAngelis explained. The denominator is not a clearly defined calculation, but it does not include letters, editorials, commentaries, or perspectives. To improve its impact factor, *JAMA*, like some other journals, could make adjustments to categories counted in the denominator or publish only basic science and RCT articles to increase citations. *JAMA* does not publish articles only to increase its impact factor, as exemplified by its issues dedicated to topics that result in few citations, such as its annual issues covering medical education.

Studies with high likelihood for publication have a number of characteristics. The most sought-after articles are those showing causality with significant impact on patient care, primarily RCTs. Large cohort studies, which do not show causality but can provide association, also can generally be published. Research on quality improvement that can be studied in randomized or prospective cohort studies focused on specific interventions or ensuring that individuals receive certain diagnostic tests. Rigorous trials on systems are far more difficult to conduct, DeAngelis said. To be of most use, studies must establish rules that improve care, not guidelines. The difficulty in establishing rules is that they must account for context, including the type of intervention required, the type of patient involved, and the methodology. General guidelines, while useful, are not often followed.

Methods sections are extremely important for diffusing knowledge and ability to be replicated. The average *JAMA* article is about 3,500 words, while articles with full explanations of methodology tend to be much larger. This space limitation deters from the journal's publication of qualitative research, and thus these articles are not often accepted for publication. In addition to its length, qualitative research is hypothesis generating, not hypothesis testing. High-citation papers tend to be those that are hypothesis testing. One alternative offered is to publish a more complete methodology in a different kind of journal and publish the results section in a journal like *JAMA*, referring readers to the methodology paper.

Meta-analyses and systematic reviews, if well done, can be published, DeAngelis said. Although these are hypothesis generating, they often help in the practice of medicine or health care. These types of studies are difficult to conduct, but worthwhile. The difficulty with meta-analyses and systematic reviews in quality improvement is that they tend to have only a few articles to analyze, which are often of poor quality and thus do not provide a strong base.

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Focus Journals

In some respects, a goal for quality improvement research should be to increase both the quantity and quality of research, said Mittman of the VA and the journal *Implementation Science*. Increasing the *quantity* requires more than just funding; it requires the research community to more wisely use its funding. Improvements in the health care delivery system's commitment to train researchers and facilitate collaboration with other researchers are also needed. Improving the *quality* of research is a multidimensional issue in which journals have a role, Mittman said.

Journals should view themselves as partners in supporting the progress of the field. Journals should not just passively be places for researchers to publish, but rather, journals should be more proactive in stimulating interest and in identifying key challenges facing research, Mittman said. Journals and their editorial boards share the burden of identifying the types of research questions and articles being pursued with individual researchers and funding agencies. In a more proactive way, these stakeholders can collectively help guide the field to address the right questions.

Mittman recognized the need to lay out a vision for documentation of future research. This includes ensuring full details of studies be published before studies begin, including the motivation, the literature review, design and methods, hypotheses, and conceptual frameworks. Of particular importance to quality improvement research is publication of accurate baseline data, which are good indicators of gaps in quality to be addressed. These components should be made accessible to all. Journals that are highly specialized, such as *Implementation Science*, have the responsibility to publish supporting analyses and details of studies. With the increasing popularity of online publication without page limits, documentation of all details is possible.

Better communication strategies are needed to prevent information overload. Different messages will be required for different audiences; thus, different types of information should be placed in different journals.

Cumulative knowledge is a fundamental goal of science. Research is often published in a stand-alone manner. An adequate amount of effort has not been taken to explain and understand the interrelations among past findings, current implications, and future needs. Journals should emphasize this goal and should help ensure that studies are documented in a way that facilitates knowledge accumulation.

Mittman also suggested the need for journals to increase their

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roles in stimulating and supporting interaction and debate about articles. Some efforts have begun in this direction, such as rapid response letters, but more could be done.

FUNDING

Agency for Healthcare Research and Quality

Funding for quality improvement has not been well funded federally, said Dougherty of AHRQ. Although funding has increased over time due to investments in patient safety and health information technology, AHRQ's budget of $318 million is used toward achieving its mission to improve quality and the safety, efficiency, and effectiveness of health care for all Americans. AHRQ has also modified its approaches to funding and reviewing quality improvement projects. Not satisfied with the results of awarded grants, AHRQ used cooperative agreements directly with implementers of quality improvement to accelerate change in 2002. Rather, these grants and contracts were designated for large national or regional organizations with the potential to be agents for change in professional behavior; academic institutions could not apply. However, by not requiring the kinds of rigorous evaluations that academic researchers would have used, summarizing evaluations of these cooperative agreements was made difficult.

In 2004, the administration and Congress focused AHRQ's improvement work on health information technologies, including electronic health records and regional health information exchanges. Given that electronic health records and regional health information exchanges were implemented in large settings with little opportunity for randomization, making meaningful evaluations a challenge. Health information technology was a focus again in 2005, with a slant toward patient safety.

This year (federal fiscal year 2007), the focus will be on improving ambulatory safety and quality, with a total of $22 million in grants, including cooperative agreements. AHRQ also issued special emphasis notices to encourage research on policy, systems, and organizational changes, particularly in low-resource settings. Small grants for implementation of emerging or existing research findings and related tools are also encouraged. Other funded areas relevant to improvement in the current fiscal year include the Accelerating Change and Transformation in Organizations and Networks program, the PBRNs, and health services research demonstration and dissemination grants.

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In 2008, the President's budget asked Congress to provide AHRQ with about $6 million in new research for ambulatory safety and quality and $1.7 million for new research in patient safety. Patient safety organizations will be funded to help form baseline data on patient safety. In addition, contracts related to value-driven health care will be funded for $3.7 million, Dougherty said. Also in 2007, AHRQ will launch the Healthcare Innovations Exchange, a web-based tool to disseminate information in a meaningful way.

In addition to providing grants and contracts, AHRQ conducts evidence syntheses through its Evidence-based Practice Centers. In particular, one EPC conducted condition-specific reviews about what was known about quality improvement in high-priority areas as identified by the Institute of Medicine (IOM), as discussed in Chapter 3 by Heidenreich.

From her own perspective and not that of AHRQ, Dougherty commented on the future importance of interdisciplinary team building to help make breakthroughs in quality improvement. She noted that good ideas lead to funding. Better funding for interdisciplinary team building has been an area of focus for some funders and should continue to be strengthened.

The California Endowment

The mission of The California Endowment (TCE) is to improve the health of Californians, said Ignatius Bau of TCE. In particular, TCE emphasizes the underserved in terms of racial and ethnic minorities and other uninsured and poor populations, many of whom bear the brunt of quality gaps. TCE also believes in a broad public health approach, stemming from the belief that health is influenced largely by social and environmental factors, not just visits to the doctor or hospital.

Quality improvement is thus a small piece of TCE's strategies. TCE's view is very broad and expansive in its focus on access to care. With respect to quality, TCE would focus on the two aims of the IOM's six aims of quality receiving the least attention: patient-centeredness and equity.

From the perspective of a foundation like TCE, Bau said, ideas with the potential to make lasting change are the most intriguing. Bau encouraged potential grantees to consider developing ideas within particular levels of the health care system—the individual provider, the health care team, the organization, and the system. Developing ideas in this context of a specific level will help grantees understand the challenges facing both research and implementation

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in sustaining change. Individual champions often seek funding for their change ideas in order to provide validation to their organizations. On the other hand, team leaders tend to ask for funding when a new structure is taking place, such as during times of reorganization or new leadership. At the organizational level, adverse events and bad publicity are often the motivators to improve quality. At the system level, change can often be leveraged through legislation, regulation, accreditation, or financing. Using these examples, Bau observed that sustainable changes in quality improvement are generally much more reactive to opportunity or crisis than proactive.

Stakeholders often neglected in planning change are consumers and purchasers. In talks with unions and businesses, Bau said their focuses are often on access to care and cost, without regard for quality. Creating a demand for quality through purchasers, including smaller businesses, could be a promising way to advance quality improvement. Patients should be more involved in this, especially in moving beyond measures of patient satisfaction (e.g., being treated with respect and having long wait times) to really being able to judge whether care was of high quality. Patients should be empowered with enough information to create expectations for their care without having to know the technical details of medicine.

If health care delivery and research were more patient centered, the system could begin to break down the barriers to providing coordinated care. Quality improvement should not be based on condition, disease, or procedure, but on people interacting with the health care system.

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8

Opportunities for Change

Summarizing the workshop discussions, Rouse organized the workshop into three themes: the problem, research approaches, and people.

THE PROBLEM

During the workshop, the problem facing quality improvement was often characterized as a multifaceted problem. Components of the problem were said to exist on many levels, ranging from process improvements and process innovations to reductions in costs and errors. Connecting these components are the ways in which information is gathered and conclusions are reached. Commonly, information sharing occurs though stories, online information, evidence, and statistics. These components and connections collectively define the areas where problems occur with health care quality improvement research. For example, at the individual intervention level, problems with process improvements centered on their ability to generate only modest effects (around 5 percent) and variability (the high variability of organizations, variability of time, and variability of locations). At the organizational level, challenges in quality improvement research include management of processes, management of the transition between research findings and practice, management of innovation, and management of organizational change.

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On a systems level, the issues of cost and value and the incentives for improvement and change were also of concern.

RESEARCH APPROACHES

The workshop identified a number of research approaches used to address the problem. Rouse recognized the current cultural conflict in the field related to conducting quality improvement evaluations as medical research when much of the work is actually organizational research. These types of research are conducted differently and often have different goals, thereby creating a dilemma for researchers. Other research approaches that were discussed include interdisciplinary collaboration and the approaches required to properly address ethical questions surrounding quality improvement research. These approaches employed a variety of interventions at different levels, such as provider reminders and methods to manage risk. It was often mentioned that to study change, secular trends needed to be separated from trends actually caused by an intervention. To disseminate approaches and findings, the role of journals was discussed as critical.

PEOPLE

Bringing the approaches, the tools, and the problems together are the people, who range from providers and purchasers to patients and researchers. The central question, Rouse said, is how to deal with professionals and their disciplines in terms of dealing with change. Effecting change requires people, but engaging people is itself a difficult task. Change requires encouragement of coordination, identification of attractors, understanding of patterns of behavior, and recognition of routines, rituals, and beliefs of all people involved. In other words, everyone is a participant in the process of addressing the problem, Rouse said.

PUTTING IT TOGETHER

The health care quality improvement ecosystem can thus be organized around the three themes—problem, approach, and people (Figure 8-1). The problem and approaches are connected by information gleaned from the problem and the interventions at all levels. In addressing the problem, people face the paradox of being agents of change as well as being the focus of change. People are connected to the approach because implementation of identified approaches

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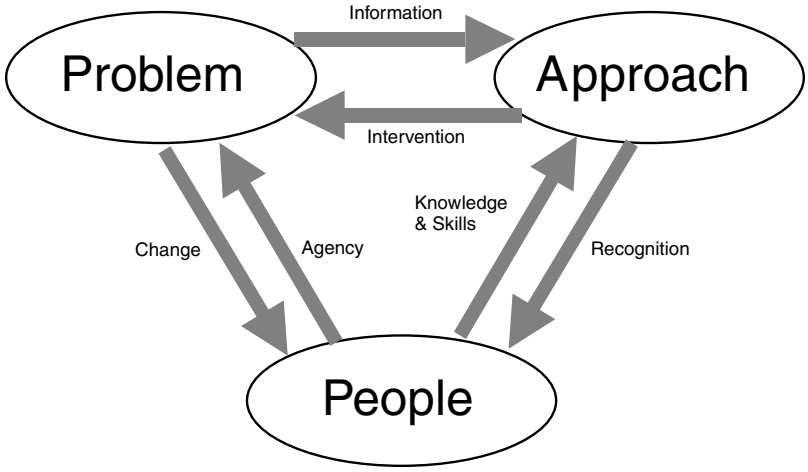

FIGURE 8-1 The quality improvement ecosystem.

is driven by their knowledge and skills. In the opposite direction, people need to receive recognition of their work at an individual level, organization level, or subdiscipline level.

A new model should be developed to study the delivery of health services in the 21st century. As opposed to experimental designs and analyses of variance to determine best models, process models could be developed to simulate different scenarios, Rouse said. Simulations are often used in industry; for example, IBM used a model to decrease the time to market for some of its products by 50 percent. Although simulations are difficult to validate, their potential implications are huge, and validation is not always necessary, particularly if the goal is insights rather than predictions. Large-scale changes are very difficult to achieve based purely on empirical data, Rouse said. It was noted, however, that it is difficult for simulations to adequately capture human interactions and the effects of those interactions.

The nature of the current health care system constrains improvements, Rouse concluded. Simply improving all current efforts will not produce desired changes. Using an example from government, it was believed that if researchers worked harder, better outcomes would result. Simulations showed this not to be true—in fact, the way in which the government operates actually constrained the yield from the system. Substantial change requires dramatic shifts in culture and innovation; however, innovation is difficult because it is both afforded and hindered by people.

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CHANGING THE SYSTEM

In addressing the question of what would really drive fundamental change in the overall system, Rouse suggested a lesson from the university system, where students are "free electrons" and catalyze enthusiasm for new areas of study, attracting faculty to focus on those areas. In the health care system, the catalyst is unclear, but very well could be patients as consumers of care.

Building off Rouse's points, Wallace discussed consumers as the way to identify change and as the source of leadership for change. For example, the ability for patients to access large parts of their medical charts and to securely e-mail their physicians directly was not an innovation stimulated by providers, but by patients. The success of this was largely due to the innovation being aligned with patient interests. As an example, Kaiser used directed consumer advertising to notify consumers of the availability of a new patient–physician secure messaging service. Another example of how consumers have stimulated change is the Internet itself. Beginning about a decade ago, patients began bringing in piles of research from the Internet about their conditions, changing the physician role from being an oracle to someone who helped patients understand what the information means to them. The opportunities for transparency and access to information to change the system are great. Whether patients will learn how to use this information for their own benefit remains to be seen.

Part of leveraging patients to change the system requires understanding patient preferences and the tradeoffs patients make. For example, the rise of retail-based clinics could be interpreted as patients' willingness to give up the idea of continuity of care with a single physician because they would rather have care be more tailored to their schedules (e.g., open late and in more convenient locations).

Patients can be used as implementers to facilitate spread for those ideas truly in patients' interests. This capacity needs to be leveraged where appropriate, Wallace said, such as disease management. On the other side of the continuum, provider systems must also become more self-aware and act on opportunities outside of consumers' view. Different solutions will be necessary for various parts of the health care system, but the ability to both engage and leverage the consumer has been underused. The design of the health care system, research designs, and program designs all must recognize the need to put the patient at the center of health care and allow patients to become participants in and drivers of change.

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9

General Reactions

The following text summarizes general reactions offered by members of both the forum and the audience during the last session of the workshop.

INFORMATION CAPACITY

Paul Epner of Abbott Laboratories proposed the idea of making information about quality improvements ubiquitous. The capacities of the research system to manage information remain unknown. The system should encourage free exchange of ideas to improve creativity and augment the amount of research being conducted. O'Neill noted that the greatest skill shortage is leadership. Good leaders successfully pick and choose among tools. Epner added that in a more accessible system, people would be able to better identify tools from all that have been attempted.

TRAINING

Diane Rittenhouse of UCSF said that developing skills related to health policy and health services research to be taught to medical students requires a lot of effort. Medical students often are not knowledgeable about quality, cost, access, and variations in care, among other issues. Part of the problem is that there are no models for behaving or teaching in this way. The culture of medicine

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and medical education must change to support widespread reforms in how medicine is practiced. The patients will benefit from these changes.

BRIDGING THEORY AND PRACTICE

Dougherty commented on potential opportunities to blend the basic science (theoretical side) and applied science (practical side) of quality improvement research. The testing of theories about context and the nature of implementation in real-world settings can help build the basic science, Dougherty said.

Shortell proposed a framework for considering context. The framework focuses on the alignment of four areas: an organization's strategy, its culture, its technical components, and its structure. First, an intervention must fit in an organization's overall strategy and be considered a strategic priority to be sustained. Second, support for the intervention must be supported by the organizational culture; otherwise, people will not be able to successfully spread the change throughout the organization. Third, technical components to support the intervention must be in place so that information can be gleaned to assess the change. Fourth, the organization's structure must be able to support both formal and informal ways of learning to share information. Otherwise, improvements will be suboptimized, with improvements in one division or team, but not throughout the organization. The challenge for systemwide quality improvement is to align all four areas to achieve sustained change.

SYSTEMS CHANGE

Responding to a comment about the risk of attempting quality improvement at the system level when the basic science of quality improvement is not well understood, O'Neill said there are some truths to all organizations, one of which is binary communication. Binary communication allows for only yes or no answers, not maybe, and helps judge a system's level of organization. Health and medical care has not done a good job of encouraging binary communication, O'Neill said. Better binary communication could decrease chaos in the system and would thus be able to identify leverage points for change.

Characteristics of great organizations hold three virtues, O'Neill proposed. First, every person in the organization should be able to say that he is treated with dignity and respect. If a person is not as valuable or is less valuable than others, he should not be there.

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Second, every person should be able to say that he has been given everything needed to succeed in terms of training, education, tools, and information. Third, every person should be able to say that someone recognized his efforts. Great organizations are difficult to find, but if they could be identified, huge gains in the value of health and medical care could potentially be captured.

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Appendix A

Workshop Agenda

CONDUCT OF HEALTH CARE QUALITY IMPROVEMENT AND IMPLEMENTATION RESEARCH
Arnold and Mabel Beckman Center
100 Academy Drive
Irvine, CA 92612
May 24–25, 2007

THURSDAY, MAY 24, 2007—Auditorium

8:30 am Welcome
Major persistent quality problems
- Value perspective—Paul O'Neill, Forum co-chair
- Patient perspective—Denise Dougherty, Agency for Healthcare Research and Quality (AHRQ)

9:00 am Major problems in spreading health care quality
- Paul Plsek, Directed Creativity

9:45 am Break

10:00 am Approaches to researching health care quality improvement: State of the science
- Kaveh Shojania, University of Ottawa
- Paul Heidenreich, Stanford University
- Jeremy Grimshaw, Ottawa Health Research Institute
- Trish Greenhalgh, University College London
- Brian Mittman, Veterans Administration
- William Tierney, Indiana University

Discussion
—Moderator: Marshall Chin, University of Chicago

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12:30 pm What we know and don't know about effective quality improvement (QI) strategies: Developing agendas for research/evaluation and spread
- Identify three high-priority, effective QI strategies as basis for developing a spread agenda
- Identify three high-priority, unanswered questions about QI strategies as basis for developing a research/evaluation agenda

1:30 pm Spread and implementation of quality improvement research findings
- Spread and implementation of research findings
  - Paul Wallace, Kaiser Permanente
  - David Pryor, Aetna
- Research
  - William Rouse, Georgia Institute of Technology
  - Newton Margulies, University of California, Irvine
- Other observers
  - Guenter Risse, University of Washington

3:15 pm Break

3:30 pm Breakout groups (discuss what we need to know)
- Spread and implementation of research findings
  - Strategies for change in various settings
  - Accounting for context

—Moderator: Andrea Kabcenell, Institute for Healthcare Improvement
- Research
  - How to get new methods accepted
  - Strengthen research methods

—Moderator: Marita Titler, University of Iowa

4:45 pm Reconvene with larger group
- Report answers
- Discussion

5:30 pm Adjourn

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FRIDAY, MAY 25, 2007—Auditorium

7:45 am Revisit themes from Day 1
- Tom Boat, Forum co-chair

8:00 am Reactions panel: Strategic opportunities
- Ethics
  - Jeffrey Cohen, HRP Associates, Inc.
- Research training
  - Steve Shortell, University of California, Berkeley
- Publication community
  - Cathy DeAngelis, *Journal of the American Medical Association*
  - Brian Mittman, *Implementation Science*
- Funding
  - Denise Dougherty, AHRQ
  - Ignatius Bau, The California Endowment

9:30 am Moving forward: Opportunities for change
- William Rouse, Georgia Institute of Technology
- Paul Wallace, Kaiser Permanente

Discussion

10:30 am General reactions

11:00 am Adjourn

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Appendix B

Workshop Participants

Cleopatra Beaton
VA Greater Los Angeles Healthcare System

Denise Cardo*
Centers for Disease Control and Prevention

Joni Cohen
VA Greater Los Angeles Healthcare System

Teresita Corvera
VA Greater Los Angeles Healthcare System

Nancy Donaldson
University of California San Francisco School of Nursing

Denise Dougherty*
Agency for Healthcare Research and Quality

Paul Epner
Abbott Laboratories

Melissa Farmer
VA Greater Los Angeles Healthcare System

Diane Fitzpatrick
University of California Los Angeles

Gus Fowler
Medata

Robbie Foy
VA Greater Los Angeles Healthcare System

Kathryn Fristensky
Monarch Healthcare

Ying-Ying Goh
University of California, Los Angeles

*Representative for Ex-Officio Members

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Sally Kraft
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Karl Lorenz
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Linda McKibben
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Patricia Parkerton
University of California, Los Angeles

Franklin Pitt
Los Angeles County Fire Department

Siddharta Reddy
American Board of Internal Medicine

Cori Reifman
California Office of the Patient Advocate

Diane Rittenhouse
University of California, San Francisco

Susan Rossi*
National Institutes of Health

Scott Shiffman
Bristol Park Medical Group

Karen Shore
Center for Health Improvement

Lisa Shugarman
RAND

Maureen Smith
University of Wisconsin—Madison

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Allison Snow
Lumetra

Bruce Spurlock
Beacon—The Bay Area Patient Safety Collaborative

Patricia Teske
Beacon—The Bay Area Patient Safety Collaborative

Sharon Valente
Department of Veterans Affairs

Margaret Wang
University of California, Los Angeles—RAND

Lisa Zubkoff
VA Greater Los Angeles Healthcare System

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Appendix C

Submitted Responses

Speakers in the "State of the Science of Quality Improvement Research" and "Spread and Implementation of Research Findings" sessions were asked to respond to specific questions. Some speakers opted to submit written responses to those questions in addition to their comments during the workshop. The planning committee also invited Richard Grol, a researcher who could not attend the workshop, to submit written answers. This appendix is devoted to speaker responses.

STATE OF THE SCIENCE OF QUALITY IMPROVEMENT RESEARCH

Trish Greenhalgh

1. With respect to quality improvement, what kinds of research/evaluation projects have you undertaken/funded/reviewed? In which contexts (e.g., settings, types of patients)? With whom do you work to both study and implement interventions? For what audience?

I am an academic at University College London. In my talk I will describe two projects (out of a much wider portfolio) that illustrate the kind of work I do in quality improvement (QI). These projects are (1) a study of primary care interpreting services in a multiethnic area of London, and (2) a recently commenced study of Internet-based electronic patient records across the United Kingdom.

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2. How do you/does your organization approach quality improvement research/evaluation? What research designs/methods are employed? What types of measures are needed for evaluation? Are the needed measures available? Is the infrastructure (e.g., information technology) able to support optimal research designs?

My take-home message is that QI research is currently undertheorized and would benefit from the application of a much wider literature—such as from mainstream organization and management research. There has been far too great a focus on "what works" and too little emphasis on "why might X work (or not work)."

3. What quality improvement strategies have you identified as effective as a result of your research?

See response to previous question. If you asked instead, "What key theoretical approaches have you found that illuminate the process of quality improvement?" I would say there are many powerful theories out there in the literature, and there's nothing as practical as a good theory. In my talk, and just as an example of the rich pickings available, I will briefly introduce the work of Martha Feldman on organizational routines, which I think would add huge value to current work in health care on "implementation."

4. Do you think the type of evidence required for evaluating quality improvement interventions is fundamentally different from that required for interventions in clinical medicine?

a. If you think the type of evidence required for quality improvement differs from that in the rest of medicine, is it because you think quality improvement interventions intrinsically require less testing or that the need for action trumps the need for evidence?

b. Does this answer depend on variations in context (e.g., across patients, clinical microsystems, health plans, regions)? Other contextual factors? Which aspects of context, if any, do you measure as part of quality improvement research?

I'm not sure I'd frame the question this way. There's a fundamental difference (but also some commonalities) between research and evaluation. I recommend Michael Quinn Paton's book on *Utilization Focussed Evaluation*. I think QI work has many parallels with evaluation work. Some ideas:

- In general (but not universally), research is systematic inquiry directed at producing generalizable new knowledge. It is explicitly conclusion oriented (we look for the "findings" of research, and for its "bottom line").

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- Evaluation (and much QI work) is decision oriented and (hence) utilization oriented. Its goal is to inform decisions, clarify options, identify areas for improvement, and support action. Creation of generalizable knowledge may occur as a "byproduct" of evaluation (and of QI), but it is not its primary output.
- In evaluation (and in much QI work), the sociopolitical context of the project or program is explicitly factored in, whereas in most research, it is controlled for or otherwise "factored out."
- In evaluation, as in research, measurement is important but in evaluation, the decision about what to measure requires context-specific value judgments about what is important (what has merit, what we care about). Evaluation concerns itself centrally and systematically with identifying what is important to the actors and stakeholders, and in developing approaches to measurement that are designed to produce the data needed for particular judgments by particular actors and stakeholders in particular contexts. Scriven has captured this key feature of evaluation as follows: "the key sense of the term 'evaluation' refers to the process of determining the merit, worth, or value of something, or the product of that process. The evaluation process normally involves some identification of relevant standards of merit, worth or value; some investigation of the performance of evaluands on these standards; and some integration or synthesis of the results" (Scriven, 1991).

These differences notwithstanding, research and evaluation also have much in common. In particular:

- Both research and evaluation benefit from theory-driven approaches that can guide the collection and analysis of data. Just because evaluation is not primarily oriented toward producing generalizable findings does not make it a theory-free zone.
- Both research and evaluation require definition of data sources, meticulous collection and analysis of data (using appropriate statistical tests or qualitative techniques), and synthesis and interpretation of findings.
- Both research and evaluation may be approached from an "objective" epistemology (which assumes that there is a reality "out there" that can be studied more or less independently of the observer) or a "subjective" one (which holds that there is no "view from nowhere" and that the researcher's identity, background, interests, affiliation, feelings, and other "baggage" not only unavoidably influence the findings, but may themselves be viewed as data).
- Both research and evaluation may use quantitative meth-

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ods, qualitative methods, or a combination of both. Both may also employ participative approaches such as action research.

- Both research and evaluation may employ a variety of approaches to engage stakeholders, gain access to data sources, and involve staff and service users.
- Both research and evaluation require informed and ongoing consent from participants.

5. Do you have suggestions for appropriately matching research approaches to research questions?

I think the fundamental bridge to cross here is to understand the difference between research (oriented to generalizable conclusions) and evaluative approaches (oriented to context-specific decisions). See above. Where QI researchers get tied in knots, I think, is in the well-intentioned but fundamentally misplaced drive for "generalizable truths about what works." There are few truths, and even those that exist are always contingent and ephemeral.

6. What additional research is needed to help policy makers/practitioners improve quality of care?

I'd put my money on the study of policy making itself.

Kaveh G. Shojania

1a. With respect to quality improvement, what kinds of research/evaluation projects have you undertaken/funded/reviewed?

The bulk of my work has involved conducting literature syntheses to compile and critically assess the evidence for the effectiveness of interventions to improve health care quality and safety. For instance, while at the University of California, San Francisco, I led the efforts of 40 researchers from 10 academic institutions to produce, for the Agency for Healthcare Research and Quality (AHRQ), a compendium of systematic reviews of the evidence supporting more than 80 specific interventions aimed at improving patient safety (Shojania et al., 2001). This report gathered and assessed the evidence for interventions that ranged from very clinical safety practices (preventing common infectious and noninfectious complications of hospitalization, as well as uncommon but egregious ones, such as wrong-site surgery) to information technology solutions such as computerized provider order entry (CPOE) and bar coding through to more "safety science" strategies such as human factors engineering and root cause analysis. More than 125,000 copies of the full report have been downloaded or obtained in hard copy since its

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release in 2001, and a pair of commentaries on the report appeared in the *Journal of the American Medical Association* (Leape et al., 2002; Shojania, 2002).

I have conducted similar syntheses of the evidence in the field of quality improvement, assessing the evidence for interventions designed to improve care across a range of conditions and settings, as part of a series of evidence reports for AHRQ (Shojania et al., 2004). Most noteworthy was the evidence synthesis for improving outpatient care for patients with type 2 diabetes (Shojania et al., 2006a). Using data from 66 clinical trials, we showed that the single most effective type of quality improvement intervention consisted of case management in which nurses or pharmacists played an active role in coordinating patients' care and were allowed to make medication changes without having to wait for approval from physicians. The negative results of this analysis were also very important, as they emphasized the extent to which most quality improvement interventions conferred quite small to modest gains in glycemic control, even if they showed more substantial improvements in processes of care.

I present some of the details of the above research rather than just describing what kinds of projects I have been involved with because many do not regard evidence synthesis as a type of research in itself. However, synthesizing the literature can—in addition to providing a valuable resource for practitioners, policy makers, and other researchers—yield results that were not previously clear from primary studies, as with the example of case management for diabetes. Although case management has received considerable attention, previous studies and writing on the subject had not highlighted the fact that even very labor- and resource-intensive case management interventions tend to have small effects unless they include this key ingredient of some authority for case managers to make management changes, rather than just sending recommendations to physicians.

Though I am still engaged in evidence synthesis work related to patient safety and health care quality, I have more recently become involved in leading an extensive qualitative research project in which we are interviewing senior administrators, physicians, nurses, pharmacists, patient safety officers, and information technologists at hospitals across Canada in order to identify barriers and facilitators in efforts to implement three widely recommended patient safety interventions. I have also participated in several studies led by my colleague in Ottawa, Dr. Alan Forster, to improve methods for detecting safety problems using a variety of techniques, ranging

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from prospective, active surveillance by trained observers of care (Forster et al., 2006) to automatic detection of likely adverse events based on natural language search engines applied to discharge summaries and other text-based aspects of the medical record (Forster et al., 2005). Lastly, in follow-up to a previous evidence synthesis that focused on clinically significant diagnostic errors detected at autopsy (Shojania et al., 2003), I am piloting a project to detect important diagnostic discrepancies among patients who undergo surgery or biopsies, rather than studying only those patients who have died and undergone autopsy.

1b. In which contexts (e.g., settings, types of patients)? With whom do you work to both study and implement interventions? For what audience?

Most of my work has focused on the hospital setting, as my clinical expertise primarily involves acute care, hospital-based medicine. In the past, I typically worked with other researchers and physician clinicians, but now work with several senior hospital administrators and more frequently collaborate with nurses and pharmacists. Funded research for patient safety and quality improvement in Canada tends to come with requirements for "matching funds" (much of which typically come from the investigator's health care organization), so my research has necessarily involved closer ties with my hospital's administration. However, the Ottawa Hospital has also taken a special interest in patient research, funding its own Center for Patient Safety with a budget of approximately $100,000 per year. So, several senior administrators are more open to collaboration on research projects than is probably the case at most hospitals.

2. How do you/does your organization approach quality improvement research/evaluation? What research designs/methods are employed? What types of measures are needed for evaluation? Are the needed measures available? Is the infrastructure (e.g., information technology) able to support optimal research designs?

One of the reasons I have not participated in research that directly studies my hospital is precisely the lack of readily available data and inadequate information technology (IT) infrastructure. My colleague at the Ottawa Hospital, Dr. Forster, has made great strides in building a so-called data warehouse, which will greatly facilitate efforts to characterize safety and quality problems in the hospital, and possibly even provide reasonable outcomes for some intervention projects.

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We are implementing a CPOE system at our hospital over the next few years, which will also facilitate conducting research in quality improvement and patient safety. In the meantime, however, most hospital resources that could have gone into specific safety or quality research projects are consumed by the development and implementation process for CPOE. Thus, while I have a large externally funded grant to study CPOE implementation across Canada, I am mostly staying away from in-depth research in my own hospital until we actually have a CPOE system successfully in place, which may not happen for 5 years or more.

3. What quality improvement strategies have you identified as effective as a result of your research?

The short answer is that no strategy works particularly well, and even the ones that work modestly well do not necessarily generalize to multiple quality targets or across clinically distinct settings (Shojania and Grimshaw, 2005). This should not be misconstrued as saying that nothing works. The key is to recognize that, while many people expect dramatic interventions to more or less solve quality problems, QI interventions resemble interventions in the rest of medicine—they tend to work modestly, not confer dramatic breakthroughs, and they tend to work with specific types of patients and/or in some settings better than others. So, just as no "one size fits all" pill will cure all ailments in clinical medicine nor any general lessons about "what therapies work" guide clinicians across the whole of medicine, there is no general lesson about what works in all of quality improvement. The specific quality problem matters, as do features of the patients, providers, and organizations involved, just as the specific disease and patient population matter in clinical medicine.

Some would argue that there are certain useful rules of thumb, such as multifaceted QI interventions work better than single-faceted ones, or "active" strategies work better than passive ones, but even these have proved not so clear-cut on close examination. For example, in our review of diabetes QI interventions (Shojania et al., 2006a), multifaceted interventions worked no better than single-faceted ones, a result replicated in a similar review of QI strategies for hypertension care (Walsh et al., 2006).

4. Do you think the type of evidence required for evaluating quality improvement interventions is fundamentally different from that required for interventions in clinical medicine?

An emphatic "No"! Arguments by those who would answer in

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the affirmative comes in three main forms, which I briefly summarize and respond to below.[1]

- The need to improve is so urgent that action trumps evidence.

Many regard the need to improve care as so urgent that, even if they feel QI is not fundamentally different from the rest of medicine, they feel we cannot afford to submit candidate interventions to the same type of evaluative rigor carried out in the rest of clinical research. It is surprising how commonly one hears this argument, since clinical research has always had as its goal the saving of lives. Researchers in cardiovascular medicine, oncology, HIV/AIDS, and many other diseases can claim numbers of lives lost each year to these diseases that match (if not exceed) "quality problems." Why would we exempt research in QI from scientific standards that we routinely apply to the leading causes of morbidity and mortality?

- Some QI interventions are so obviously beneficial that evidence is not necessary.

First, very few interventions truly have such self-evident benefit, but even if they did, and even granting the perceived benefit as real, there will always be a need for evidence about implementing interventions. For instance, handwashing for providers is generally regarded as a simple, obviously beneficial practice, yet interventions designed to increase handwashing are anything but straightforward and typically produced modest (at best) results.

A patient safety example involves the removal of concentrated potassium chloride (KCl) from clinical areas, which represents an "obviously beneficial" intervention to prevent fatal, iatrogenic hyperkalemia. Instead of relying on the vigilance of providers not to confuse concentrated KCl with other medications that have similar containers, simply remove it from clinical areas and make it available only in the pharmacy. This intervention represents a so-called "forcing function" because it supposedly prevents the wrong thing from occurring. In practice, however, because the error involved is so rare that the vast majority of providers have never seen it, they simply view this intervention as an annoyance, leading to a high potential for "workarounds." For example, after concentrated KCl was removed from the general floors of one hospital, ward personnel could not obtain potassium solutions from the pharmacy quickly

[1]My response to this question paraphrases material from a commentary written with Drs. Andrew Auerbach and C. Seth Landefeld, both at University of California, San Francisco (Auerbach et al., 2007).

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enough to meet their patients' needs. Some of them began to hoard intravenous potassium on their floors. Pharmacists were forced to chase after these hidden stashes, and intensive care units (which were allowed to continue to stock KCl) quickly became de facto satellite pharmacies, informally distributing concentrated KCl to ward personnel (Shojania, 2002). Thus, the simple and obviously beneficial "forcing function" not only failed to force the desired result, it led to an even more hazardous situation than before, since front-line personnel were now handling and administering concentrated KCl in an uncontrolled and potentially chaotic fashion.

Even when an intervention is as beneficial as it appears, evaluation will be required to ensure that implementation has occurred as expected and achieved the desired results.

- Quality improvement interventions do not have side effects, so they do not require the same level of testing applied to drugs and other clinical therapies

There are two ways in which this view proves false. First, many quality improvement interventions, by their nature, involve delivering more care to patients (e.g., more patients receive treatment for their hypertension or diabetes), so an increase in complications of care (not to mention costs) is definitely possible.

For example, only 12 of 66 trials of strategies to improve diabetes care reported rates of hypoglycemia (Shojania et al., 2006a). However, 7 of those 12 studies reported more frequent hypoglycemia in the group receiving the quality improvement intervention.

Hypoglycemia represents an easily anticipated consequence of efforts to intensify diabetes care, but adverse consequences of many other improvement efforts have been less predictable, including errors introduced by computerized provider order entry (Koppel et al., 2005; Campbell et al., 2006; Ash et al., 2007), bar coding (Patterson et al., 2002), and infection control isolation protocols (Stelfox et al., 2003). Side effects may seem inherently less likely with quality improvement interventions than with drugs and devices. However, most quality improvement interventions involve changes to the organization of complex systems, where the law of unintended consequences—long recognized as a side effect of complex change—tends to apply. The potassium chloride example above provides just such an example. Another recent example is the reduction in work hours for postgraduate medical trainees. The intended goal is to reduce errors due to fatigue. However, reducing work hours inevitably involves creating new opportunities for errors due to increased handoffs between providers (not to mention potential

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educational impacts and impacts on work for supervisors) (Shojania et al., 2006b).

In addition to adverse unintended consequences with direct potential for harm, quality improvement initiatives can consume substantial resources. The time and money spent implementing costly and complex interventions such as work-hour reductions or, for instance, medication reconciliation could have been spent on other interventions, including moderately costly, but definitely effective interventions, such as hiring more nurses (Aiken et al., 2002; Needleman et al., 2002) and pharmacists (Leape et al., 1999; Kucukarslan et al., 2003; Kaboli et al., 2006).

- Quality improvement needs to draw on fields outside traditional clinical research, such as psychology and organizational theory, and needs to pursue other methodologies, such as qualitative research.

This is true. Importantly, however, psychology, organizational theory, and results from qualitative research represent the basic sciences of QI, not the methods for evaluating candidate interventions. Thus, the paradigm that I and others (Brennan et al., 2005) think needs to merge is one in which QI and patient safety have the same overall approach to moving from basic research through to initial trials through to large, well-designed Phase III trials, as in the rest of clinical medicine. However, the basic sciences in QI happen to be psychology, organizational theory, and human factors research, not molecular biology and physiology.

Research in these basic sciences of QI may involve using qualitative research techniques or mixed-methods research techniques. However, in order to evaluate the effectiveness of interventions designed on the basis of such research, we need a framework more or less the same as we do elsewhere in medicine. That said, not all evaluations need to involve randomized controlled trials (RCTs). The figure below (Figure C-1) provides a framework for thinking about the decision of how to evaluate a candidate QI intervention, especially one that would be recommended for implementation at more than one site.

But clinicians have often used therapies without good evidence; why should this be any different?

This is an interesting point. In fact, the rise of evidence-based medicine in some ways represented a response to the fact that physicians have often applied therapies and other processes of care that had little evidence and even varied widely in their tendencies to do so, often with striking geographic variations, as first shown by Wennberg and colleagues (Wennberg and Gittelsohn, 1973;

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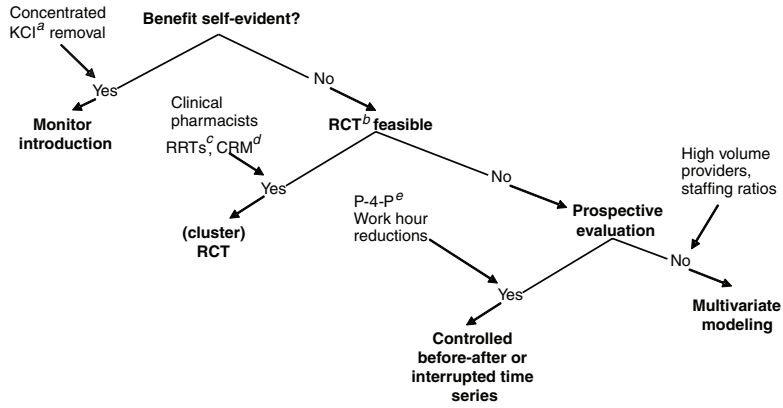

FIGURE C-1 Framework for evaluating the needs for evidence for candidate quality improvement interventions.
[a]KCl = potassium chloride.
[b]RCT = randomized controlled trial.
[c]RRT = rapid response teams.
[d]CRM = crew resource management (a type of teamwork training).
[e]P-4-P = pay for performance.

Wennberg and Gittelsohn, 1982). However, such variation and the use of unestablished processes of care has generally been regarded as a problem. When the stakes are high (potential harm to patients, consumption of substantial health care costs), large trials or other efforts to assess effectiveness have typically ensued. When conclusive evidence about a practice has not emerged, we tend not to regard the practice as "established" or "standard of care."

Thus, in the case of QI, individual hospitals may pursue promising strategies on the basis of scant evidence, including results of early "basic research," anecdotal reports of success, or face validity. However, just as clinical practices based on such limited evidence would never become broad standards of care, much less mandatory for accreditation or reimbursement, so with quality improvement: Widely disseminating a given QI strategy would require evidence in much the same way we would require in the rest of clinical medicine.

4a. If you think the type of evidence required for quality improvement differs from that in the rest of medicine, is it because you think

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quality improvement interventions intrinsically require less testing or that the need for action trumps the need for evidence?

4b. Does this answer depend on variations in context (e.g., across patients, clinical microsystems, health plans, regions)? Other contextual factors? Which aspects of context, if any, do you measure as part of quality improvement research?

I have more or less answered this question in my responses above.

5. Do you have suggestions for appropriately matching research approaches to research questions?

I think the framework I have outlined (in Figure C-1) helps with this. Traditional cost-effectiveness considerations will also help. Most QI interventions achieve small to modest effects, and they require resources to achieve what impacts they do have. As with any clinical therapy, therefore, there is a cost–benefit decision to be made (Mason et al., 2001). For instance, in order for a solution to the problem of resident work hours to be cost-effective, it would need to improve care more than any published safety intervention (Nuckols and Escarce, 2005).

6. What additional research is needed to help policy makers/practitioners improve quality of care?

There is no single answer to this—the simple answer is that "more research is needed." This may sound like a standard line from a researcher, but I think it's crucial that we adjust our expectations for the field. We've been fighting the War on Cancer for more than 30 years now. This has required hundreds of billions of dollars to produce small, but steady and incremental gains. Expecting dramatic advances in QI on the basis of 5–10 years of research funded at a fraction of the cost and with far less sophistication and rigor will serve no one's interests.

Richard Grol

1. With respect to quality improvement, what kinds of research/evaluation projects have you undertaken/funded/reviewed? In which contexts (e.g., settings, types of patients)? With whom do you work to both study and implement interventions? For what audience?

I believe that our research center (Centre for Quality of Care Science) is one of the largest centers in the world focusing specifically on quality improvement research and development. More than 40 Ph.D. theses have been finished in the past 10 years. Currently more

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than 60 Ph.D. projects focus on quality assessment and improvement in different settings: acute hospitals, primary care, missing care, allied health, emergency care, after-hours care. The studies address different aspects of quality and safety improvement and the implementation of change, c.q. clinical guideline development and implementation, development and validation of (performance) indicators to measure change and improvement, analysis of barriers and incentives related to improvement of quality and safety, effectiveness of quality improvement strategies, evaluations to understand success and failures in improving quality and safety, etc. A wide range of topics are covered, such as cancer care, management of diabetes and cardiovascular diseases, neurodegenerative disorders (dementia, Parkinson's), asthma and chronic obstructive pulmonary disorder (COPD), fertility disorders, health lifestyles (stop smoking, adherence to medication advice, exercises, alcohol use, etc.), safety issues (infections in hospitals, hand hygiene, pressure ulcers, triage safety, safety in primary care), organizational issues (integrated with chronic diseases, skill mix changes, etc.), and implementation programs (e.g., Breakthrough Series, accreditation, pay-for-performance models, consumer information).

For these projects (national and international) we collaborate closely with policy makers (e.g., departments of health), professional bodies of clinical professionals, health care plans/insurers, patient organizations, and specific QI institutes (similar to the Institute for Healthcare Improvement (IHI)).

2. How do you/does your organization approach quality improvement research/evaluation? What research designs/methods are employed? What types of measures are needed for evaluation? Are the needed measures available? Is the infrastructure (e.g., information technology) able to support optimal research designs?

A wide variety of research methodologies are applied. A few years ago we composed a series of articles for *British Medical Journal (BMJ)* and *Quality and Safety in Health Care* for that purpose (Grol et al., 2002).

We composed a book of that set of papers, which was published by *BMJ* books in 2004 (now Blackwell Publishing). We use this book for educational purposes for our researchers and Ph.D. students.

Another book that is now widely used for both practitioners and researchers of quality improvement is *Improving Patient Care: Implementation of Change in Clinical Practice* (Grol et al., 2005). This comprehensive book on QI covers theory, evidence, and research methods on QI in health care and is now used in many countries

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(Netherlands, Canada, Australia, and the United Kingdom) in education on quality improvement (research). We aim to build all our research projects and Ph.D. theses on the theories and models presented in that book.

A variety of health services research (HSR) methods are used in the average QI project, such as systematic reviews, variation and determinant studies, analysis of routine data, clinimetrics and psychometrics (in the development and validation of indicators and instruments to measure quality and change), (cluster) randomized trials controlled before and after studies, observational methods (e.g., surveys, audits), qualitative methods (interviews, focus groups, observations), process evaluations of change processes, and economic evaluations.

The average Ph.D. thesis contains around 6–7 papers published in or submitted to international scientific journals, with different methods used, often ordered as:

- Systematic review summarizing the state of knowledge in the field.
- Development and validation of measures, indicators, and instruments to measure quality and change.
- Assessment audit of actual care or services provided; analysis of determinants of variation.
- Barrier analysis (obstacles/incentives to change).
- QI study on effects of a specific strategy or change program (different designs).
- Process evaluations to understand causes for success and failure in the process of change.
- Economic evaluation of the costs involved in improving quality and safety.

We have a variety of continuous data collection infrastructures that can help us to undertake specific studies (e.g., on determinants of variation in care provision). Overall, we have very good infrastructures for this type of research both in terms of expertise (e.g., epidemiology, social sciences, education sciences, economic evaluation, management sciences), support staff (e.g., statisticians, research assistants), and information and communication technology (ICT).

We have experienced that you need critical mass and different types of expertise to perform QI research. More than 15 senior researchers are now involved in our program to supervise projects and Ph.D. students. Since most of the seniors have been trained as

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Ph.D. students in our own center, they have the appropriate expertise for this type of research.

3. What quality improvement strategies have you identified as effective as a result of your research?

We would like to refer to our comprehensive handbook on QI. This shows that different strategies can be effective in different settings under specific conditions, such as small-group interactive education (local collaborative) works well for isolated care providers in primary care; outreach visits and adding a nurse to the primary care are effective in prevention in primary care; and computerized decision support, restructuring care processes, and multidisciplinary collaboration are often needed to start change in acute hospitals.

What we found in most of our projects was:

- Organizational and structural measures often need to be taken and in place before change of professional decision making is possible.
- Whether change interventions are successful depends largely on the general culture and attitude to change in a hospital, a ward, a practice, and professionals.

We need to do more research on these issues and on strategies to improve these aspects.

4. Do you think the type of evidence required for evaluating quality improvement interventions is fundamentally different from that required for interventions in clinical medicine?

a. If you think the type of evidence required for quality improvement differs from that in the rest of medicine, is it because you think quality improvement interventions intrinsically require less testing or that the need for action trumps the need for evidence?

b. Does this answer depend on variations in context (e.g., across patients, clinical microsystems, health plans, regions)? Other contextual factors? Which aspects of context, if any, do you measure as part of quality improvement research?

Quality improvement research is a specific field within HSR, and the type of evidence needed for good HSR is also needed for good QI research. In order to convince policy makers and practitioners, we need rigorous research methodologies. Rigorous research is not automatically similar to RCTs. What the best research design or method is depends on the research question. Currently there

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are many research questions related to understanding successes and failures in quality improvement. Different theories need to be explored.

A variety of research methods, both qualitative and quantitative, can be helpful. In medicine there is a strong tradition to use methodologies from clinical epidemiology. To address complex issues related to change patient care successfully, approaches from other disciplines (e.g., sociology, psychology, anthropology, economics, management, education) may be crucial.

5. Do you have suggestions for appropriately matching research approaches to research questions?

Different steps in a quality improvement process (see our handbook *Improving Patient Care*) result in different research questions that demand different research methods (e.g., development and validation of measures to study actual quality or change in performance demand methods derived from psychometrics and clinimetrics: testing the value of a change program may demand a cluster RCT or controlled study).

6. What additional research is needed to help policy makers/practitioners improve quality of care?

See forthcoming paper on building capacity of QI researchers.

SPREAD AND IMPLEMENTATION OF RESEARCH FINDINGS

Paul Wallace

Organizational Background

The Kaiser Permanente Medical Care Program is a collaboration of three distinct legal business entities: the Kaiser Foundation Health Plan (KFHP), Kaiser Foundation Hospitals (KFH), and the Permanente Medical Groups (PMGs). The Permanente Federation is a national organization representing the collective interests of the PMGs. KFHP includes the insurance and financing activities; KFH owns large portions of the physical assets of the delivery system, including hospitals and clinics; and the PMGs are responsible for care delivery and overall medical management. KFHP and KFH are referred to collectively as Kaiser Foundation Health Plan and Hospitals (KFHP-H).

Key values of the KFHP-H and PMG partnership that are integral to the spread of innovations include:

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- Operations in multiple geographic regions as instances of a fully integrated delivery system.
- Health Plan and Permanente Medical Group contractual mutual exclusivity.
- Prepayment (global capitation).

Care Delivery and Strategy

The eight regionally based PMGs are organized, operated, and governed as autonomous, multispecialty group practices. Nationally, more than 12,000 physician providers participate in the PMG partnerships or professional corporations. The PMGs and Kaiser Health Plan and Hospitals collectively employ an additional 150,000 personnel. Each PMG has a medical services agreement with KFHP-H with delegated full responsibility for arranging and providing necessary medical care for members in their geographic region.

The PMGs and the Permanente Federation partner as equals with KFHP-H to govern the entire organization, develop strategy, and promote key initiatives.

Quality Oversight

Kaiser Permanente (KP) actively participates in national U.S. quality programs, including public accountability through the National Committee for Quality Assurance (NCQA), the National Quality Forum, and others.

The Federation, PMGs, and KFHP-H organizations include quality structures with shared accountability at both the regional and national levels to the highest levels of KP organizational governance. Overall quality or "Big Q" is viewed as a crosscutting and inclusive activity that includes clinical quality, safety, service, resource stewardship (utilization management), and risk management. An interregional KP National Quality Committee, including national and regional senior medical group and health plan and hospital leaders with accountability for quality (Big Q), meets regularly to review the ongoing program quality agenda and portfolio and to endorse and charter major national initiatives. For initiatives of the highest identified priority, additional endorsement will be sought from the Kaiser Permanente Program Group (KPPG), the penultimate organizational, operational governance group that includes the most senior Health Plan and Medical Group Leadership. A recent example of KPPG endorsement is a national effort to implement palliative care programs. An additional internal process, the Medical Director's

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Quality Review, annually reviews key aspects of each region's quality performance.

KP has created several national/interregional entities to oversee and support aspects of overall program quality. Examples include:

- The Care Management Institute (CMI), with a focus on evidence-based medicine and population-based care programs, especially for the chronically ill. CMI supports defined networks of regionally based individuals involved in implementation and program evaluation and analysis. CMI is overseen by a Care Management Committee that itself is accountable to the KP National Quality Committee.
- The KP Aging Network to oversee and promote care improvement and innovation for the more senior KP members.
- The Care Experience Council, charged to identify and promote opportunities to improve overall service delivery and the Care Experience.
- The National Product Council, to advise and promote use of evidence-based technologies and oversee appropriate stewardship of organizational resources in purchasing and procurement decisions.

Additional coordinated interregional efforts include pharmacy, transplants, new clinical technologies, diversity, and research. Finally, substantial coordinated resources are committed at the national and regional levels to support innovation and practice transfer in the use of the electronic medical record, KP HealthConnect.

Similar organizational structures and support capabilities are also often developed and sustained at the regional level, especially in the larger KP regions such as Northern and Southern California. Furthermore, in larger regions an additional layer of quality oversight and promotion will reside at the subregional (medical center) level. This document focuses primarily on interregional transfer and spread.

Formal Organizational Award Programs to Recognize and Promote Locally Developed Innovation

KP supports two major quality-related award and recognition programs to identify the most promising innovations evolving at the regional and subregional (medical center and clinic) level and to actively promote spread of those programs:

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- The James A. Vohs Award for Quality is presented annually for the project(s) that best represents an effort to improve quality through documented institutionalized changes in direct patient care, with potential for transfer to other locations. Recent examples include initiatives for hypertension control, breast cancer screening, and management of chronic pain.
- The annual David M. Lawrence, MD, Patient Safety Award recognizes projects that advance the quality of care by improving the safety of care. The award's goals are to (1) create a culture of safety, (2) develop and standardize successful patient safety measures in KP facilities, and (3) define and implement an innovative and transferable regional intervention in patient safety. Recent recipients include initiatives for rapid response teams, perinatal safety, and executive walk-arounds.

With both the Vohs and Lawrence awards, a major selection criterion is the potential for spread. Resources in the form of support for the award-winning team to travel and help promote their innovation in other regions are included in the awards.

1. How do you spread research findings or other quality improvement strategies within and outside of your organization?

Opportunities for spread can be modeled as two dominant channels:

- Arising at the most local aspects of the delivery system ("bottom up"); and
- From efforts of national quality-related groups adopting, importing, or developing de novo potential interventions ("top down").

While most examples of spread will require a mix of both bottom-up and top-down efforts, the two models have complementary features.

"Bottom up":

Operational investigations in the clinical setting, including busy physician practices, are common. For example, a clinic in the Northwest region was awarded a Robert Wood Johnson Foundation grant to study self-management among diabetic members, and the KP National Chronic Pain Workgroup has explicit goals for supporting regional plan-do-study-act projects in medication management,

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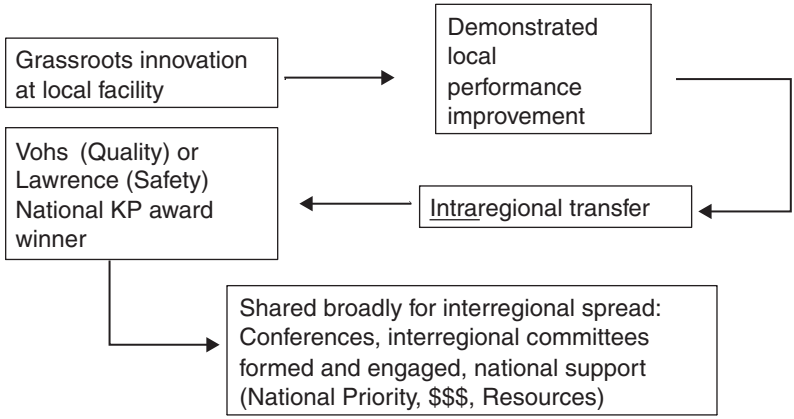

FIGURE C-2 Channel A: bottom up.

utilization issues, and clinician-to-clinician communication. Spread of similar innovations occurs as in Figure C-2.

"Top down":

National KP internal organizations such as the Care Management Institute and the Care Experience Council devote resources to ongoing "environmental scanning" within and external to KP to identify evolving and promising innovations for potential expanded implementation. Many of the areas of eventual focus have had their roots in the health services research activities of the regionally based KP Research Centers. The KP organization also has formal collaborations with multiple external improvement organizations, including the Institute for Healthcare Improvement, the Foundation for Informed Medical Decision Making (Boston), and Medicaid-centered improvement work and collaboratives supported by the Center for Health Care Strategies (Princeton, NJ). Identified innovations can be spread as in Figure C-3.

Additional implementation supports are leveraged for both channels and include the following examples:

- National meetings with either:
  - A crosscutting agenda, such as the Annual National Quality Conference attended by several hundred KP employees. The conference features all of the aspects of Big Q and highlights a few promising opportunities for adoption and spread.

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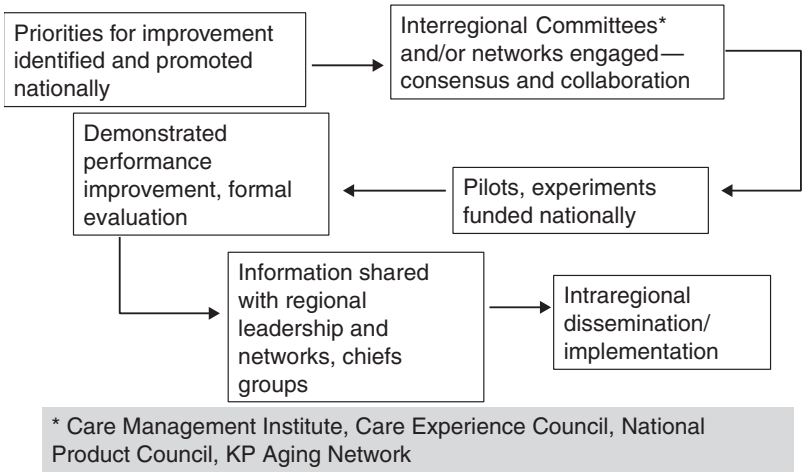

FIGURE C-3 Channel B: top down.

- An innovation-focused agenda, such as convening those working on palliative care program implementation.

- Initiative-specific webinars, workshops, and in-person trainings.
- Networks, formal (e.g., the CMI Implementation Network) and informal or created to support a specific initiative (e.g., a palliative care network).
- *The Permanente Journal,* a KP National peer-reviewed quarterly journal sponsored by the Permanente Federation to communicate and promote aspects of practice within KP.

2a. How are the innovations you implement identified?

As noted above, quality-based innovations selected for broad organizational spread will generally be either the product of ongoing environmental scanning, assessment, and prioritization by a national or regionally based quality oversight and promotion group (e.g., the Care Experience Council or CMI) or reflect a "bottom-up" local effort that has achieved regional implementation, endorsement, and advocacy. Overall quality portfolio balance is supported and overseen by the national quality oversight structures and processes, including the KP National Quality Committee. The selection processes for the Lawrence and Vohs awards have similar interregional representation by senior leadership with accountability for quality performance.

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2b. What types of evidence (e.g., clinical evidence, evidence on the innovation's effectiveness, generalizability to your setting) are required before an innovation is chosen for implementation?

While each initiative will reflect a complex calculus of benefit balanced with cost and resource demand, key attributes that will foster support for broad adoption include:

- Scientific credibility, including a strong evidence base generally qualifying for, if not yet having achieved, publication in a peer-reviewed journal:
  - Particular favorability will be given to work originally or primarily "done here" within KP either at the KP Research Centers and/or in a KP operational setting.
- Operational credibility:
  - A strong business case reflecting return in the form of overall enhanced value for a significant portion of the KP membership, generally within a less than 2- to 3-year time frame.
  - Internal initiative leadership combining both subject expertise and ideally, familiarity and facility with overall national and regional operations.
  - Agreement on the team structure and roles and responsibilities.
  - A draft workplan.
  - A draft measurement plan that can ideally be achieved with existing capabilities and resources.
- Demonstrated successful piloting followed by prior wide *intra*regional adoption and/or spread beyond the piloting site.
- Identified executive sponsors at the regional and national levels willing to commit appropriate resources.
- Consideration given to the degree to which an initiative complements and extends current efforts and capabilities, including leveraging existing network relationships that can be adapted to support spread versus the need to develop and sustain a new network.

An area of persistent internal controversy is the allowance and/or facilitation of local modification of an endorsed practice. Advocates of precise replication link full benefit realization with consistent and complete replication of the primary implementation of an intervention, while supporters of local modification cite improved local buy-in and accommodation of operational differences.

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3. What methods are used to evaluate the success of implemented innovations?

Innovations and initiatives identified for broad spread will have a proactively agreed-upon evaluation plan, including spread milestones developed in conjunction with and shared regularly with the initiative's executive sponsors at the national and regional levels. The KP National Quality Committee, and KPPG when involved, will provide regular oversight and monitoring from a national perspective. Similar accountabilities will be established within each operational site—either at a regional or sub-regional/medical center level.

The responsible national oversight group will ensure that networking resources such as an online community are formed to permit participants to share ideas, challenges, and solutions, in addition to letting people post key documents, tools, recent research, or articles or learn about upcoming webinars. While each innovation will to some degree be unique, key elements for evaluation will include:

- Progress in local settings on forming the infrastructure for implementation, including appropriate local care delivery and analytic personnel resource assignment, and when necessary, funding and successful recruitment of new professional roles.
- The establishment of local workplans and goals.
- The creation and deployment of training events and resources such as online training modules.
- Active communication about the initiative within the local setting to key stakeholders.
- Development and production of an initiative-specific measurement dashboard to show progress via agreed-upon outcomes and process metrics.
- Efforts, including successes and challenges, encountered in leveraging KP HealthConnect and other health information technologies to support the initiative.

In addition to initiative-specific evaluation, the portfolio of innovation and diffusion is periodically reviewed in total or in part at multiple levels of the organization, including KPPG, the KP National Quality Committee, entities like CMI and the Care Experience Council, and within regional governance and oversight structures. Crosscutting organizational goals for overall spread have been implemented, such as a recent accountability for CMI to support and document annually the spread between regions of at least 10 innovations related to chronic care management.

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David Pryor

1. How do you spread research findings or other quality improvement strategies within and outside of your organization?

INTERNAL

- By Intranet: We maintain a dedicated Intranet site that highlights all of our QI programs. This site provides information on program design as well as outcomes and provides resources for our internal partners.
- We also present the results of our QI programs to our aligned business leads throughout the company through regularly scheduled meetings. In addition, we have committees, such as our Internal Advisory Committee on Racial and Ethnic Equality that meet to discuss QI initiatives in this specific area of interest.
- Internal communication: We selectively use newsletters and e-mails to highlight QI programs. Our *Clinical Connection* newsletter is produced quarterly and is transmitted to the entire health care delivery team.

EXTERNAL

- Association meetings: Aetna presents on the outcomes of our QI programs at industry conferences and events such as the National Committee for Quality Assurance (NCQA), the Disease Management Association of America, and America's Health Insurance Plans Awards.
- News media: We use print and online media to share the results of our QI programs.
- Presentations to external customers such as the Aetna Client Advisory Group and Consultant Forums.
- Materials mailed to members.
- Physician tool kits supplied to Aetna network physicians.
- Presentations to our Racial and Ethnic External Advisory Committee and solicitation of feedback and guidance as this committee is made up of subject matter experts in implementing interventions that address racial and ethnic disparities in health care.

2a. How are the innovations you implement identified?

- Gaps identified from internal data analysis (e.g., HEDIS results, NCQA, provider surveys).
- Gaps identified from external data analysis (e.g., disparities in breast cancer screening, health literacy).

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- Suggestions from internal and external constituents.
- Surveillance of Medical Network Trend Operating Report (MENTOR).

2b. What types of evidence (e.g., clinical evidence, evidence on the innovation's effectiveness, generalizability to your setting) are required before an innovation is chosen for implementation?

- Membership impact and size.
- Buy-in and support from customers (e.g., Aetna Client Advisory Group (ACAG), National Sales Consultants).
- Feasibility of implementation.

3. What methods are used to evaluate the success of implemented innovations?

- Clinical/quality improvement.
- Improvement in satisfaction.
- Cost improvement—return on investment.
- Efficiency.

THE ROLE OF HISTORY

Guenter B. Risse

The theories and practices designed to improve quality of care demand changes in the conduct of health systems and their institutions. Most of the proposed changes represent alterations, adjustments, translations, even transformations, and replacements of current activities and technologies. This quest for improvement implies that current outcomes are unsatisfactory, occasionally harmful. Such assessments derive from retrospective studies gauging the outcome of previous decisions and procedures. Thus, it can be argued that the basis for health care quality improvement is historical: understanding the processes of change, how it occurs, and how it can be prompted.

History is the ultimate outcome study. As a basic social science, its methodology is central in collecting, organizing, and interpreting past events. In the area of health care, historical perspectives provide valuable insights into the construction and communication of medical knowledge with its empowering qualities for professionalization and education.

Understanding the nexus between professional action and identity in contingent, changing institutional settings can only be understood by examining the roots of medical development and behavior.

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Here the historical study of ritualism in health care constitutes a useful framing device to uncover particular values, belief systems, and relationships that are currently characterized as barriers to greater institutional efficiency and quality of care (Risse, unpublished).

In the United States, we are confronted with a highly decentralized, private health care system shaped more than a century ago. Since each institution functions within its own ecological niche determined by sponsorship and geography, cultural matrix and organizational schemes, professional relationships and technological capacities, case studies constitute a valuable source for understanding institutional identity as well as some of the paths and barriers to transformation and improvement (Risse, 1999). Employing a historical-ethnographic approach may capture some of the complexity inherent in quality improvement, promising valuable insights instead of full-fledged blueprints. The often-cited example of changes at the Allegheny General Hospital could be the target of such a probe. Historians, anthropologists, sociologists, and behavioral scientists should be recruited to interview all protagonists (health care personnel and patients), examine pertinent written and electronic records, determine organizational flow charts, and unpack and analyze decision making and its consequences. The final story will bring into consciousness a textured, organized narrative that may well provide valuable lessons for understanding the contours of change and the often-admirable ability of human beings to negotiate and adapt to it. In other occasions, historians and other social scientists became embedded in health care institutions, witnessing events and composing valuable diaries of their experiences (Fox, 1959).

Finally and perhaps most importantly, history is also a discipline within the humanities. It functions as our collective identity, revealing human nature and evolution. The 1970s transformed medicine into a "health care delivery service," solidly placed in the business world, something to be competitively offered and sold like other commodities. Linked through insurance contracts, physicians became known as "providers" and patients were transformed into "recipients" or "consumers," creating the current era of "retail health care." While health care delivery systems have benefited enormously from their inclusion into corporate structures and provision of managerial expertise, I disagree with the notion that health care now constitutes merely "repair work," provided within a customer–supplier relationship. The prevalent materialism in biomedicine neglects the human spirit. Since the dawn of humankind, health care has operated within a highly emotionally charged

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context, with matters of life, pain and disability, identity, and social status all at stake. Negotiating today's medical marketplace can be daunting. Suffering individuals, by the very nature of patienthood, will always remain in a vulnerable, emotional, and dependent condition. Mending bodies without reference to the mind creates a false dichotomy and forces patients to make hard choices. In the future, patients will still require both well-managed and technically proficient health care systems as well as empathetic human contacts. Both are necessary for building relationships that will terminate their emotional isolation while generating understanding, reassurance, and hope. Many find their true healing elsewhere, away from medical management. Seen from a historical perspective, the very notion of health care quality improvement must address the human condition. Better outcomes and true patient satisfaction depend on it. Whether our competitive commercial society and corporate, business-oriented medicine can comply with such essential human needs remains an open question.

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