Quality Improvement, Clinical Research, and Quality Improvement Research—Opportunities for Integration

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• Quality improvement • Quality improvement research
• Implementation sciences • QI

Society's investments in biomedical research have produced an explosion of new discoveries, and it is widely anticipated that advances will be translated into much more effective medical care and better health outcomes for patients. Yet the medical community is still slow to implement most new discoveries or to ensure reliable delivery of known effective treatments.[1,2] Studies have demonstrated significant variation in health outcomes across providers and communities in the use of appropriate care and in the safety and quality of care.[3–6] For example, investigators at the RAND Corporation showed that adults in the United States receive only 50% to 60% of recommended acute, chronic, and preventive health care.[3,4] Using the same methodology, they found that children receive only 47% of recommended care.[7]

The National Institutes of Health Roadmap initiative recognizes the need for much greater emphasis on research that spans the trajectory from discoveries in the laboratory, though the evaluation of new therapies at the bedside, to their application in routine medical practice.[8] The conversion of discoveries in the laboratory into

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widespread clinical care has been called translational research. Although initially conceived as the research necessary to move from discovery in the laboratory to the validation of laboratory findings at the bedside, translational research also embodies studies that go beyond the testing of what care works to the changes required to get effective treatments into widespread clinical practice.[9]

Health services research examines how people get access to health care, how much care costs, and what happens to patients as a result of this care. The goals of health services research are to identify the most effective ways to organize, manage, finance, and deliver high-quality care, to reduce medical errors, and to improve patient safety.[10] Among the most important contributions of health services research have been the identification and description of gaps in care. But describing gaps is different than closing gaps. Fixing the problems in health care delivery will require more intervention-oriented activities aimed at helping redesign the health care delivery system. The need to understand how to change clinical practice to incorporate new knowledge increases the relevance of quality improvement (QI) methods.

Other articles within this issue provide an overview of QI methods and measurement approaches. In this article, some of the opportunities for and challenges of integrating QI and more traditional forms of clinical research to achieve broad improvements in medical care are described. The authors suggest that such integration would include more active experimentation in the health care delivery system and that the application of QI methods offers a rational, effective, and reasonably fast method to support the learning required to adapt new knowledge to specific practice environments and to create and test innovations needed to improve systems of care delivery.

WHAT IS QUALITY IMPROVEMENT?

A July 2006 special report by The Hastings Center[11] defined QI in health care as systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. While QI uses a wide variety of methods, they all involve deliberate actions to improve care, guided by data reflecting the effects. Depending on the activity, QI can look like a type of practical problem solving, an evidence-based management style, or the application of a theory-driven science of how to bring about system change. Introducing QI methods often means encouraging people in the clinical care setting to use their daily experience to identify promising ways to improve care, implement changes on a small scale, collect data on the effects of those changes, and assess the results. The goal is to find interventions that work well, implement them more broadly, and thereby improve clinical practice.

The report goes on to suggest that QI is more than the implementation of discrete projects and includes an ongoing process of ''self-conscious change, undertaken as a natural consequence of health care providers' ethical responsibility to serve the interests of their patients.''[11] This makes QI different from research, which is aimed at addressing a specific question and takes place over a discrete period. The report also makes a distinction between QI and clinical and managerial innovation and adaptation that may take place as part of the normal work of leaders, managers, and workers, without the use of data or formal application of tests of changes.

Box 1 lists a number of additional characteristics of QI in health care. QI methods can be applied to (1) fixing problems in care delivery to become more effective, safe, or efficient; (2) improving processes, products, and services; and (3) designing new processes, products, services, and systems.[12] To date, most QI activity in health care has focused on the first two types of applications. For example, a multidisciplinary

Box 1
Characteristics of health care quality improvement

Contextual factors (background variables or confounders in research) are a major focus.

The initial intervention (changes to the system) is adapted and modified as study progresses.

Involves measuring over time (improvement is temporal).

Includes graphic analysis using statistical process control methods and presentation.

There is involvement of local expertise in conducting the project.

Includes multiple experimental cycles for quick feedback and learning.

Employs multifactor experiments to learn from complex systems that have nonlinear and dynamic cause-and-effect relationships.

Building reliability of the interventions can be a major part of the effort.

Sustainability is a consideration, often from the beginning of the project.

team at Cincinnati Children's Hospital Medical Center (CCHMC) implemented an evidence-based pediatric-specific bundle of care strategies in the pediatric ICU to reduce rates of ventilator-associated pneumonia (VAP).[13] The bundle consisted of a number of elements designed to prevent bacterial colonization of the oropharynx, stomach, and sinuses and prevent aspiration of contaminated secretions. Following implementation of the bundle, the VAP rate was reduced from 5.6 infections per 1000 ventilator days at baseline to 0.3 infections per 1000 ventilator days.

WHAT IS THE SCIENCE OF QUALITY IMPROVEMENT?

Deming[14] described the science of improvement as a body of knowledge that he called a "system of profound knowledge: the interplay of the theories of systems, variation, knowledge, and psychology." Deming believed that it was not necessary to be an expert in all of these areas to participate in QI, but that leaders of QI should understand the basic theories, how the different areas interrelate, and why they are important for any improvement effort. He considered the concept of profound knowledge a lens through which to view organizations and believed that, when combined with appropriate subject matter knowledge, the use of this lens could result in innovative approaches to improving health care processes and systems.

From a scientific standpoint, QI methods emphasize (1) the value of standardization as a means of learning and improving outcomes, (2) a forward-looking analytic framework designed to enable learning from each sequential data point, (3) explicit characterization of prior knowledge, and (4) testing theories about organizational processes and systems through experimentation and replication to produce a detailed understanding of factors affecting system performance. Seeking to understand multiple complex system interactions, rather than controlling or eliminating them, distinguishes QI interventions from therapeutic trials.

The application of QI is particularly useful in understanding the nonlinear, multitiered nature of relationships between processes and outcomes in complex organizational systems. This systems perspective implies that changes in the processes of care may take place at one or more levels within or outside a health care organization. For example, the user's manual[15] for the Institute of Medicine's report on "Crossing the Quality Chasm"[16] proposed a systems framework that identifies the potential influence of multiple layers of the health care system on the outcomes of health care for

patients and families. Changes aimed at improving care can be made at the levels of patients and communities; the small work units (microsystems) that provide the care that patients experience; the functioning of larger organizations such as hospitals or health systems that house or otherwise support the microsystems (macrosystems); and the environment (eg, policy, payment, and regulation) that shapes the behavior, interests, and opportunities of organizations. Appreciation of the multitiered nature of organizational systems is useful when guiding the design of interventions or changes. The potential for significant nonlinear effects within complex systems is great, making prediction more difficult. The difficulty of prediction in complex systems increases the importance of experimentation and replication as a basis of learning and theory development.

Reducing unintended variation through standardization is an important strategy in QI. Care standardization itself may significantly improve the quality of care and outcomes by eliminating errors. Indeed, much of the recent emphasis of QI in medicine has concentrated on the benefits that can be achieved by standardizing care. Changes produced by QI efforts typically take place over time. Changes are tested first on a small scale before implementing them widely, on the basis of data being collected as part of the improvement process itself. Thus, the application of QI makes extensive use of interrupted time series or repeated measures designs because of the significant time-related effects. Statistical process control methods,[17] which have been widely used in many industries for nearly 75 years, provide the analytic basis for studying the impact of interventions while they are ongoing so that they can be refined depending on emerging information.

A project to improve influenza vaccination rates for high-risk children and adolescents is an example of the use of QI methods described here. Diffusion of innovation theory[18] was used to scale up to a much larger population a series of evidence-based immunization strategies that resulted in an increase in the proportion of high-risk patients who received the influenza vaccination at seven clinics within the CCHMC.[19] Participating practices included five Ohio regional cystic fibrosis centers, the original seven CCHMC clinics, four additional CCHMC clinics treating high-risk children, and 164 physicians in 39 community-based pediatric practices in the greater-Cincinnati area.[20] The team at each participating site was presented with a tool kit containing supporting literature, sample goals, and communication strategies. The improvement strategies presented to each site were grounded in the previous initiative and modified on the basis of what was learned from that project. The strategies included (1) increased communication through reminder postcards sent to all families, (2) improved access through influenza shot clinics, (3) a standard influenza order set, (4) a Web-based registry and tracking system to identify and follow at-risk patients, (5) in-clinic reminders to patients and health care providers, (6) preplanning with suppliers to obtain vaccine, (7) posting weekly vaccination rates, (8) recall phone calls, and (9) a designated leader at each site. Each site was encouraged to adapt and customize the improvement strategies to meet its specific culture and needs. The intervention targeted 18,866 high-risk children, and 49.7% received the influenza vaccination. The community-based practices that actively participated in the scale-up effort reported using significantly more intervention strategies and achieved higher immunization rates than nonparticipating practices.

WHAT IS QUALITY IMPROVEMENT RESEARCH?

Although QI involves the structured application of the scientific method, it is not research per se for the reasons outlined previously. The authors define QI research

as the *design, development, and evaluation* of complex interventions to produce *generalizable* new knowledge related to creating and sustaining improvement in health care delivery in real world settings. This definition emphasizes the importance of producing generalizable knowledge as a feature of QI research.

QI research involves two types of studies: studies of interventions that apply QI methods to redesign care delivery and evaluate the effectiveness of the intervention, and studies focused on evaluating the efficacy of QI methods themselves.[11] The authors' work on improving preventive services delivery in primary care practices is an example of research that incorporates the application of QI. In this randomized trial, the authors evaluated the effectiveness of a QI-based continuing medical education intervention on rates of preventive services delivery in pediatric and family practices.[21] Research evaluating QI might include, for example, a study of different techniques to apply QI methods to affect change, or a study of the impact of various contextual factors such as leadership, incentives, teamwork, and QI knowledge on the effectiveness of QI.

INTEGRATING QUALITY IMPROVEMENT AND RESEARCH

To date, the application of QI in medicine has emphasized reducing errors and achieving more consistent and reliable care delivery. This emphasis has resulted in numerous studies of the process of care delivery. It is not enough to simply change the process and assume that improvements in outcomes will accrue unless those process changes have previously been shown to also improve outcomes. As public demand to redesign the health care delivery system grows, there is an increasing need to create entirely new systems of care delivery and to put new discoveries into practice more rapidly. Therefore, the use of QI methods could be an important part of ongoing health care research.

In the authors' view, greater use of QI methods offers the potential to contribute to the design, conduct, and analysis of health care research. Incorporating these methods may facilitate the design and development of new interventions, may enable greater use of studies of variation to understand organizational behavior and to identify innovations, and may support experimentation in the health care delivery system to better understand the importance of changes to care delivery in specific settings.

Campbell and colleagues[22] described the design and testing of complex interventions in care delivery as proceeding through a number of stages, including developing the theoretic and system models to be tested, defining intervention components, assessing the feasibility of interventions on care delivery, using formal experiments to test the intervention, and performing ongoing study of the intervention as it is disseminated into practice. **Box 2** outlines these phases of research implementation that are based on the framework developed by Campbell and colleagues[22] and describes the contributions of QI.

To illustrate how QI methods might support each of these stages, the authors use the example of designing and testing a care process to improve the management of children who have pain secondary to extremity injury in the emergency department (ED). Pain is the most common reason for seeking care in the ED, making up 48% to 72% of the presenting complaints of all patients.[23] Yet, despite its high prevalence, pain has been poorly managed in ED settings.[24,25] Pain management is particularly poor for children, who are approximately 33% to 50% less likely than adults to receive medication to relieve pain.[24,26]

Numerous QI tools and methods are applicable to the studies required to create a theoretic model and to define intervention components. For example, the Model

Box 2
Phases of research implementation and the contributions of quality improvement

Developing the theoretic and system models to be tested

Understanding the needs of the consumer (Kano survey method)

Process for intervention planning (Model for Improvement)

Relating changes to outcomes (key driver model)

Defining intervention components

Creativity methods and change concepts

Process and system mapping

Use of statistical process control to identify and learn from special causes

Assessing the feasibility interventions on care delivery

Quasi-experimental designs

Statistical process control charts

Using formal experiments to test the intervention

Multifactor experiments

Use of blocking to incorporate background variables in test design

Performing ongoing study of the intervention as it is disseminated into practice

Collaborative improvement methods

for Improvement[12] provides a framework to support the process of specifying outcomes goals and relating changes in the process of care to desired outcomes. Structured methods to incorporate patient perspectives in defining important outcomes of care delivery can take advantage of tools such as the Kano method or conjoint analysis, both of which are formal methods of eliciting the preferences and perspectives of patients.[12] Identifying and documenting current care processes using process mapping can uncover unexpected opportunities for reorganizing care delivery. The application of statistical process control methods can facilitate the study variations in care delivery within a single ED to uncover reasons for inadequate pain management.

The use of industrial benchmarking techniques to study how different EDs handle pain management provides a means to extend studies of variation to learn from the performance of outliers. Statistical process control and other recently developed methods[27] are useful to compare care sites and to support studies of variation across health care delivery settings. Unlike biologic systems, the organizational systems in which QI takes place are largely under the control of the organization's management. In health care, the process of care delivery, therefore, reflects changes in the behavior of the caregivers themselves. Research involving individuals must use epidemiologic tactics such as careful selection of patients and randomization to allow for the variation in biologic response to treatment. Organizational systems such as health care delivery systems permit much greater potential for investigators to understand the organization's rationale for specific care delivery processes. Study designs that combine quantitative and qualitative methods (known as mixed methods studies) offer the opportunity to uncover innovations in care delivery that are associated with better health care outcomes. Thus, QI methods are applicable to unraveling the many factors

that result in different levels of performance of certain health care organizations or locations. By engaging care providers, these methods also offer the opportunity for more direct feedback into the research process itself.

QI methods are particularly applicable to testing the feasibility of an intervention and to estimating the magnitude of effect. For example, annotated statistical process control charts[28] can be used to identify and quantify the impact of specific changes in care delivery with improved outcomes.

A particular challenge in QI efforts is that the unit of analysis is often the clinical care site, and changes that are made in care delivery are typically applied to many patients or significant subpopulations at a site. Testing interventions at a single site may limit the ability of investigators to have a comparison group. Quasi-experimental methods such as the interrupted time series design and its variations[29] provide a basis for studies in such settings. These designs are useful in excluding the presence of secular trends but cannot overcome the limitations of generalizability that occur when experiments are conducted in a single setting. For this reason, some QI research can best be conducted using multisite studies. Broader testing of care delivery system interventions across diverse clinical settings would produce better evidence about how to apply new knowledge. From a methodologic standpoint, this type of testing requires that investigators use well-established methods for the analysis of clustered data.[30]

To be useful, research about new treatments must provide information about how to apply new treatments in different types of patients in different types of care settings. EDs caring for children differ significantly in many ways that are related to the success of an intervention to control pain. The types of patients seen (pediatric versus combined children and adults), the training of physicians and staff, and the volume and severity of illness all influence the likelihood of being able to implement a new approach to care delivery. The randomized trial provides information about the average effects of therapies. More advanced experiments using factorial designs are better suited to understanding how to implement components of a new complex intervention in different environments. For example, multifactorial experiments, a method to study multiple components of a system at once,[31] are common in other industries but have seen limited use in clinical research. For example, an initial experiment to understand the factors of pain medication, the use of a dedicated pain treatment room, and a new pain monitoring scale might use a complex (23-1 fractional factorial) design to simultaneously test the importance of these changes in controlling pain in children who have obvious deformities and in those who do not have deformities.

Other advantages of QI methods include their value for research execution. Standardizing care can improve outcomes by reducing variability. Care standardization also offers significant advantages to those interested in experimentation because of the potential to increase study power and lower sample sizes, thereby detecting intervention effects.

WHAT RESOURCES AND INFRASTRUCTURE ARE NEEDED TO COMBINE QUALITY IMPROVEMENT AND RESEARCH?

A more effective system for learning about how to improve health care delivery must address barriers that inhibit studies about how to improve care delivery more effectively. First, institutions and organizations must develop systems to address ethical and human subjects issues related to QI, especially QI that uses experimental methods. The Hastings report suggested procedures for ensuring the ethical conduct

of QI, regardless of whether it meets criteria as human subjects research.[11] Although understanding and guidance regarding the gray areas between QI and research are evolving quickly, some general agreement has emerged. Efforts to incorporate accepted standards of care such as evidence-based practice guidelines do not require human subjects review. On the other hand, projects involving randomization or in which patients may receive nonstandard care should be reviewed by human subjects boards. Intent to publish does not automatically imply the need for human subjects review. The institutional review boards at some leading children's hospitals have begun to provide specific, practical guidance regarding QI and human subjects.[32,33] Second, the unit-of-analysis problem (ie, interventions applied to populations rather than to individual patients) means that multiple sites may be needed to produce the sample size required to generate new knowledge about the effectiveness of novel approaches to care delivery. Third, there are limited numbers of children who have adverse outcomes or chronic diseases. Even large children's hospitals may not have enough patients to determine whether specific changes in care delivery are associated with better outcomes. Fourth, to be able to study the effectiveness of changes in care delivery means that health care ''laboratories'' are needed at which care can be redesigned. The ability to study the effectiveness is especially important in an era of rapidly emerging technologies and that emphasizes more personalized medicine. The authors conclude by outlining the unique role for academic centers in redesigning care delivery.

As more advanced applications of QI methods take place, there will be an emphasis on the use of active experimentation in the health care delivery setting, requiring the capacity to deliver care and conduct complex experiments at the same time and overcoming the traditional barriers between clinical care, education, and research. There is an opportunity for health care organizations to improve practice by becoming hubs of innovation and transformation, with linkages across the entire spectrum of

Box 3
Features of a redesigned health care laboratory

Infrastructure for improvement and quality improvement research

Leadership

Use of quality improvement methods to achieve stable and reliable care delivery

Sites for developing and testing new ideas

Appropriate teams and skills

Scientific tools and resources

Health services and outcomes research capacity

Institutional review board familiarity with quality improvement methods and research

Real-time data management capable of collecting data during care delivery and of rapidly analyzing data

Application of advanced quality improvement methods for experimentation

Appropriate staff skills

Frontline staff capable of conducting improvement and research

Ongoing development of managerial and academic leaders through training in improvement methods and quality improvement research

Multidisciplinary project teams spanning translational steps (bench-bedside-community)

research—from basic science to application of new knowledge. The features of such a redesigned health care laboratory will include a greater capacity throughout the health care organization to apply QI methods; an appropriate array of scientific tools and resources, including well-developed health services and outcomes research capacity; and knowledgeable staff (**Box 3**). Some health care organizations, such as the Veteran's Administration, Kaiser Permanente, and CCHMC, have recognized the potential value of integrating their resources in this way, and it is likely that more organizations will do so in the future. For example, CCHMC has developed a chronic illness care innovation laboratory where physicians, staff, and patients work together to conduct experiments in care delivery. CCHMC has also developed a disease-specific outcomes and innovation program aimed at linking discovery-oriented research with the redesign of care delivery around specific conditions such as cystic fibrosis. In addition, CCHMC participates in networks of subspecialty care sites such as inflammatory bowel disease practices to conduct multisite improvement and research.

In summary, the opportunity to mobilize linkages between QI and research is at an early stage. Some of the opportunities and challenges that may be involved are outlined in this article. The authors believe that better integration of QI and research methods offers the possibility of more rapid learning and improvement of care delivery simultaneously.

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