

## Quality Improvement Science and Action

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Outcomes research examines the effects of healthcare interventions and policies on health outcomes for individual patients and populations in routine practice, as opposed to the idealized setting of clinical trials. A national survey from 1998 to 2000 that evaluated the extent to which patients received established processes of care for 30 medical conditions illustrated the importance of outcomes research.<sup>1</sup> Among adults living in 12 metropolitan areas in the United States, only half of patients received proven elements of preventive care, treatments for acute illness, and chronic disease management for which they were eligible. For cardiovascular conditions, the use of proven therapies varied widely from 68% to 25% of patients who received recommended care for coronary artery disease and atrial fibrillation, respectively.<sup>1</sup>

Despite these gaps between ideal and actual care, patient outcomes have improved in many fields. For instance, the age-adjusted mortality from cardiovascular disease in the United States fell by >40% from 1980 to 2000 as a result of improvements in risk factor modification and uptake of evidence-based treatments for coronary artery disease, myocardial infarction, and heart failure.<sup>2,3</sup> Nevertheless, many Americans do not receive the ideal recommended care (either at all or in a timely fashion), whereas others receive too much or the wrong care.<sup>4,5</sup> In the field of cardiovascular diseases, substantial opportunities for improvement remain.

Outcomes research has generated a foundation of knowledge about what constitutes ideal care and what gaps exist between ideal and actual care, but we have less understanding about how to deliver this ideal care to every patient every day. The potential for basic science breakthroughs to reach and improve the health of individual patients and populations may be substantially delayed or may not be realized if science is not efficiently translated to action. Moreover, in many cases, increased delivery of established therapies would save more lives than the next innovation in therapy.<sup>6</sup> Here, we review the underlying reasons for these gaps between ideal and

actual care and potential strategies to address them. The strategies we outline involve primarily activities by clinicians, researchers, managers, and other agents within the healthcare system, but we also highlight the importance of engaging patients as active participants in their own health care as a quality improvement strategy. This article focuses on the current scientific evidence and literature, which come mostly from academic centers and large institutions; less is known about successful strategies for quality improvement in small-scale practices and contextual modifiers (such as practice setting) on quality improvement strategies.<sup>7,8</sup>

### Gaps Between Ideal and Actual Care

Quality improvement research strives to bridge the gap between ideal and actual care.<sup>9</sup> A Clinical Research Roundtable at the Institute of Medicine has defined T1 translational research as “the transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention and their first testing in humans” (p 211)<sup>12</sup> and T2 translational research as “the translation of results from clinical studies into everyday clinical practice and health decision making” (p 211).<sup>10–12</sup> Westfall and colleagues<sup>11</sup> have proposed an additional step, T3 translational research, as “practice-based research to translate distilled knowledge from guidelines and systematic reviews to day-to-day clinical care” (p 211).<sup>12</sup> The journey from science to action (ie, T2 and T3) can take decades. Accelerating these translational research steps requires interaction between and collaboration among different skills and disciplines (Table 1). Furthermore, funding for T2 and T3 translational research by various agencies needs to be clarified and prioritized.<sup>12,13</sup>

The case of using  $\beta$ -blockers in patients after acute myocardial infarction demonstrates the delay between the availability of scientific evidence and widespread practice. The landmark Beta-Blocker Heart Attack Trial (BHAT), published in 1982, showed that the use of  $\beta$ -blockers in patients after acute myocardial infarction lowered mortality at

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(*Circulation*. 2009;119:1962-1974.)

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*Circulation* is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIRCULATIONAHA.108.768895

**Table 1. Disciplines Involved in T1, T2, and T3 Translational Research**

T1 Research (Bench to Humans)	T2 Research (Humans to Guidelines)	T3 Research (Guidelines to Patients)
Basic sciences	Phase 3 clinical trials	Implementation and dissemination
Molecular biology	Observational studies	System redesign
Genetics	Evidence synthesis and guidelines	Communication theory
Technology assessment	Clinical epidemiology	Behavioral and management science
Animal research	Comparative effectiveness	Organizational development
Phase I and II clinical trials	Policy and ethics	Patient encounter research

2 years' follow-up from 9.8% to 7.2%<sup>14</sup>; this finding was confirmed in other trials.<sup>15–18</sup> However, not until 1996, more than a decade after the original publication of scientific evidence, did the American Heart Association/American College of Cardiology guidelines recommend the routine use of  $\beta$ -blockers for all eligible patients after acute myocardial infarction.<sup>19</sup> In 1997, the Joint Commission on Accreditation of Healthcare Organizations and the Center for Medicare and Medicaid Services adopted the prescribing of  $\beta$ -blockers at discharge for patients with acute myocardial infarction as a hospital performance measure for quality of care. In an analysis of the National Registry of Myocardial Infarction data from 1999, nearly 17 years after the publication of the BHAT randomized trial, Bradley and colleagues<sup>20</sup> showed that overall only 60% of patients in the United States were prescribed a  $\beta$ -blocker at hospital discharge. Substantial variation was found between the lowest and highest quartiles of hospitals, with prescription rates of 42% and 78%, respectively. Finally, in 2007,  $\approx 25$  years after the BHAT randomized trial, the National Committee for Quality Assurance, which collects quality performance data from health maintenance organizations, found that  $>90\%$  of patients were prescribed  $\beta$ -blockers at discharge.<sup>21</sup> This prompted the National Committee for Quality Assurance to stop collecting and reporting this performance measure. The  $\beta$ -blocker journey took a quarter century from science to action, and it can be argued that the journey remains incomplete; Ho and colleagues<sup>22</sup> have shown that intermediate adherence to  $\beta$ -blockers at 1 month after discharge was only 70%.

### Factors Contributing to the Gaps and Strategies to Address Them

#### Applicability of Randomized Controlled Trials to Quality Improvement

Translating the findings of randomized controlled trials into routine clinical practice faces several challenges (Table 2). First, randomized controlled trials often focus narrowly on a simple intervention in highly selected patients to establish efficacy (ie, that the therapy works under ideal circumstances). Strict eligibility criteria can result in  $\geq 90\%$  of screened patients not being enrolled. For instance, the Clin-

ical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial screened 35 539 patients and randomized 2287 patients (6.4%) to optimal medical therapy versus percutaneous coronary intervention and optimal medical therapy.<sup>23</sup> Thus, although COURAGE appears to have major implications for the management of stable coronary artery disease in routine practice, the high degree of patient selection in the trial renders efforts to implement the findings from COURAGE problematic (ie, across different patient subgroups that vary in terms of their prognosis and responsiveness to treatment).

Second, patients enrolled in clinical trials compared with those in usual clinical practice have greater access to initial and follow-up care, including medications, tests, and monitoring; for instance, clinical trials often have infrastructure and resources to provide medications and tests at nominal or no cost to the patient. Furthermore, clinicians and healthcare organizations participating in clinical trials may represent superior performers in a specific discipline and differ from those in usual practice settings. Although the findings may be quite informative to patients who received care at these clinical trial sites, there are uncertainties in applying the findings to other settings. These differences in access to care and clinician experience may contribute to disparate results from the same intervention applied at different practice settings.

Even putting aside issues of whether sites and patients that participated in clinical trials represent the range of real-world settings, these same sites that evaluated the efficacy of a new intervention have not always been able to sustain or diffuse that intervention in routine practice. Majumdar and colleagues<sup>24</sup> showed, for example, that sites that had taken part in the Survival and Ventricular Enlargement (SAVE) trial were no more likely to adopt widespread use of angiotensin-converting enzyme inhibitors for patients with acute myocardial infarction than were sites that had not taken part. This observation that passive dissemination does not happen even in the centers that participated in the generation of new knowledge about efficacy emphasizes the degree to which T2 and T3 translation requires active intellectual and capital investments. This need may have increased given the growing number of clinical trials that recruit patients from myriad sites, each of which enrolls only a handful of patients.

#### Strategies to Address the Gap

1. Promote practice-based research that would address the applicability of randomized controlled trials to patients and clinicians in usual practice. This research can take the form of practical randomized trials<sup>25,26</sup> or well-designed observational studies that control for confounding factors that often affect patient selection and choice of treatments in routine practice.
2. Determine what strategies need to be concomitantly implemented with a specific intervention (eg, additional infrastructure or support personnel) to achieve results in routine practice comparable to those in randomized controlled trials.

#### Tension Between Action and Evaluation in Quality Improvement

The Institute of Medicine reports on safety and quality<sup>4,5</sup> achieved their intended aim of galvanizing all sectors of the

**Table 2. Factors Contributing to the Gaps in Quality of Care and Strategies to Address Them**

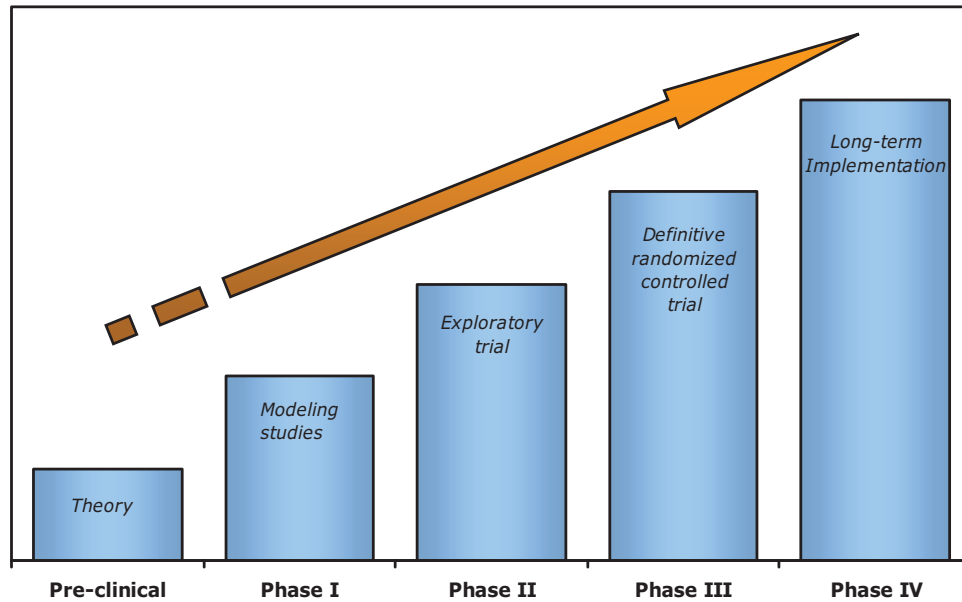
Factors Contributing to Gaps in Quality	Strategies to Address the Gaps in Quality
Limited applicability of randomized controlled trials Narrow focus on a simple intervention Strict eligibility criteria for enrollment Trials are typically conducted with resources (infrastructure, staff) that may not be present in community practices	Promote practice-based research that would address the applicability of randomized controlled trials to patients and clinicians in usual practice Determine what strategies need to be implemented concomitantly with a specific intervention to achieve results in routine practice comparable to those in randomized controlled trials
Tension between action and evaluation Quality improvement is needed now and should not be delayed by evaluation and research Clinical research methods are not suitable to evaluate complex and rapidly changing quality improvement interventions	Adopt clinical research framework to evaluate distinct phases of quality improvement interventions Differentiate research techniques to apply in early phases (theory, modeling, and exploratory trials) to find candidate quality improvement interventions vs techniques to apply in later phases to evaluate the generalizability of such interventions for widespread dissemination
Lack of collaboration between academic medical center researchers and community clinicians Academic researchers have focused primarily on patient recruitment for clinical trials Diversity of the community clinicians' practice locations, sizes, and types of services Competition for community clinicians' time and resources, particularly under productivity models of reimbursement	Develop practice-based research networks to link the academic researchers with community clinicians Collaborate to identify the gaps between ideal and actual care, prioritize the needs of the community clinicians for strategies to close those gaps, and provide a laboratory for testing system improvements Design practice-based research that both is relevant and generates value to community clinicians and practices
Lack of expertise and experience to undertake quality improvement in health care Health care lags in translational efficiency and does not use general methodologies to improve systems compared with other industries Commonly used approaches in healthcare quality improvement such as provider education, provider reminders, and audit and feedback have generally shown small to modest effects on target quality problems	Learn and apply approaches for quality improvement in health care that have been used successfully by other industries Design quality improvement projects with measurement, evaluation, and scholarship Choose specific quality improvement interventions on the basis of a clear understanding of the underlying causes of the targeted quality problem Pay attention to important mediating effects, including components of the intervention itself and the context in which the interventions are being delivered
Differences between physicians and managers Professional vs administrative theory Education, socialization, and goals	Develop models for partnership and shared accountability between physicians and managers with an overall goal for both effectiveness and efficiency of patient care Interdisciplinary education for physicians to learn management science and managers to observe patient care encounters

healthcare system (providers, payors, policy makers, regulators, and the public) to engage in addressing widespread quality and safety problems. However, the sense of urgency has also created controversy about how best to implement candidate quality improvement interventions in a timely manner while evaluating the extent to which care in fact improved as a result of the intervention<sup>27–29</sup> (Table 2). The debate has ranged from pragmatic concerns about evaluating complex interventions in real-world practice to more philosophical debates, with some arguing that quality improvement interventions are intrinsically too complex and change too rapidly to study with standard clinical research methods.<sup>28</sup>

Although some real differences undoubtedly exist between these points of view, much of this debate may reflect blurring of the stages of quality improvement research; techniques used in early phases of research in which candidate interventions are developed at a single center differ from evaluations of the generalizability of such interventions for widespread dissemination (Figure). The UK Medical Research Council has outlined a framework for describing the phases of research for complex interventions, including those related to the organization and delivery of care (eg, disease management clinics for congestive heart failure) and interventions

directed at health professionals' behavior (eg, strategies for increasing uptake of guidelines).<sup>30</sup> In this framework, the early phases of research focus on developing quality improvement interventions with efficacy in at least 1 setting, often using methodologies drawn from industrial quality improvement, the social sciences, cognitive psychology, human factors engineering, and organizational theory, among others. These fields and approaches represent the basic sciences of quality improvement, just as cellular biology and molecular biology represent the basic sciences for clinical research.

Once the early phases of research produce an intervention that has worked in 1 or a few settings, the next question is its generalizability. In some cases, the interventions are so idiosyncratic to a specific institution that there are no candidate interventions to apply elsewhere (eg, as is often the case with parochial plan-do-study-act [PDSA] projects). In other cases, interventions may not be intrinsically tied to the features of a single institution, so the question of its potential effects across a broad range of settings thus arises. Such interventions (eg, the chronic care model for disease management, medication reconciliation, and crew resource management for improving teamwork) may require modi-



**Figure.** Continuum of increasing evidence for complex interventions. The figure depicts the progression of research on complex interventions (such as those in quality improvement) by analogy with the phases of clinical research, beginning with preclinical basic science and animal studies and proceeding through to phase III clinical trials and phase IV surveillance studies. In the case of complex interventions, the preclinical phase includes development of a candidate intervention based on theoretical and empirical understanding of the target quality problem. Modeling studies (phase I) identify the key components of the intervention and the mechanisms by which they achieve their intended effects. Exploratory trials (phase II) characterize the version of the intervention that could be disseminated (including distinguishing constant and variable intervention elements) and demonstrate a feasible protocol for comparing the intervention with usual care or some alternative intervention. A definitive randomized controlled trial (phase III), often clustered and almost always multicentered, evaluates the effectiveness of the intervention, providing an estimate of the expected effect magnitude across a range of representative settings. Finally, analogous to postmarket surveillance studies, phase IV studies examine long-term consequences of the intervention, evaluating the sustainability of target effects and the emergence of unintended (adverse) effects. Adapted from the UK Medical Research Council Framework for Evaluating Complex Interventions.<sup>30</sup>

fications during implementation, but core strategies can be identified. Given the direct expenses and opportunity costs of implementing these complex interventions, evaluating the magnitude of effect across a spectrum of settings should precede widespread adoption. Here we enter the later phases of quality improvement research, and here randomized controlled trials offer the most rigorous evaluation of effectiveness. Controlled preimplementation and postimplementation studies and interrupted time series can provide reasonable compromises between the ideal of randomized controlled trials and the practical complexity of carrying out such trials.<sup>31,32</sup> However, complexity by itself is not a compelling argument against evaluating quality improvement interventions, when in fact such complex interventions have been studied with randomized controlled trial designs.<sup>33–35</sup>

### Strategies to Address the Gap

1. Differentiate research techniques to apply in early phases (theory, modeling, and exploratory trials) to find candidate quality improvement interventions versus techniques to apply in later phases to evaluate the generalizability of such interventions for widespread dissemination.
2. Integrate qualitative methods in traditional quantitative studies of quality improvement to understand the subtle variations in performance and more complex aspects of

organizational change and innovation adoption. An example of using qualitative methods is the Door-to-Balloon Quality Alliance, which identified key strategies used by the best-performing hospitals to improve reperfusion times at a national level for patients with ST-elevation myocardial infarction.<sup>36,37</sup>

### Lack of Collaboration Between Academic Medical Centers and Community Clinicians

Researchers at academic medical centers have historically engaged community clinicians and practices with the primary intent of recruiting patients for clinical trials. Researchers and community clinicians, however, have not typically collaborated to identify the gaps between ideal and actual care, to prioritize the needs of the community clinicians for strategies to close those gaps, and to provide a clinical practice laboratory for testing system improvements (Table 2). The diversity of community clinicians' practice locations, practice sizes, and types of services, as well as competition between community and academic practices for patients and personnel, presents potential barriers for collaboration. In addition, competition for the community clinicians' time and resources, particularly under productivity models of reimbursement, limits their ability to engage in translational research.

Consider, for instance, that prehospital ECGs used to activate the catheterization laboratory while the patient is en route to the hospital have been shown to decrease door-to-balloon times in patient with ST-elevation myocardial infarction.



tion.<sup>38,39</sup> Equipment to obtain prehospital ECGs is widely available,<sup>40</sup> and paramedics can be trained to interpret or wirelessly transmit the data.<sup>41</sup> The primary challenge is not simply being able to obtain these data but rather integrating the prehospital ECG with systems of care to improve processes and patient outcomes. This requires collaboration across historical silos, including academic researchers, community clinicians, and paramedics, who heretofore have not worked together to design patient-centered, seamless, and integrated systems of care.

### Strategies to Address the Gap

1. Develop practice-based research networks to link the academic researchers with community clinicians. The Agency for Healthcare Research and Quality has been the leader in funding practice-based research networks in primary care and family medicine, but funding for this agency has been disproportionately meager compared with budgets for basic science and T1 translational research. In 2006, the National Institute of Health funded 24 academic centers with Clinical and Translational Science Awards to promote translational and practice-based research.<sup>12</sup>
2. Design practice-based research that both is relevant and generates value to community clinicians and practices, including, for example, the development of community-based personnel and systems that allow the collection and reporting of data for this research.
3. Promote sharing of best practices and what works in 1 community practice with other practices within and across networks.

### Lack of Expertise and Experience to Undertake Quality Improvement

Healthcare systems and other industries strive to deliver services or products that have value to their customers, which can be defined as incremental benefit such as quality, safety, and service divided by incremental cost. Andrew Grove, the former chairman of Intel, noted that both healthcare and the microchip industry have highly dedicated and well-trained people who provide a service or product that is based on a foundation of science.<sup>42</sup> Beyond the obvious difference that one produces health care and the other produces microchips, another major difference arises from their respective capability and efficiency to translate science to action to deliver value to their customers. Industry has characterized this translational efficiency as *knowledge turns*, referring to the cycle time required for an experiment to proceed from hypothesis to results and results to products brought to market, before a new cycle is started. The knowledge turns in the microchip industry require only 1 to 2 years, as encapsulated in Moore's law, the 40-year-old prediction turned empiric observation that the number of transistors that can be practically included on a microchip (the basic determinant of computing speed) doubles every 1 to 2 years.<sup>43,44</sup>

Probably no field of health care has ever achieved knowledge turns such that some important outcome improves by a factor of 2 within such a short timeline, never mind sustaining such a pattern continuously, as has occurred in the microchip

industry. In fact, the interaction between health care and the computing industry (eg, the implementation of electronic medical records and computerized order entry) represents a particularly striking example of translational inefficiency and the prolonged duration of knowledge turns in health care. Despite discussion in the medical literature of the promise of information technology dating back to the late 1960s and the widespread, ready availability of relevant technology for at least 15 to 20 years, <1 in 4 medical organizations used any form of electronic medical record in 2006.<sup>45,46</sup> Far fewer had an integrated electronic medical record that included outpatient, inpatient, laboratory, and imaging data in a single application or an electronic medical record that was patient centered and portable across different healthcare organizations. This slow and incomplete penetration of computing technology into routine clinical practice contrasts sharply with the rapid and widespread dissemination of sophisticated information systems and e-commerce throughout myriad industries in the last 10 years. Some may point out that the slow adoption of electronic medical record does not reflect irrational refusal by healthcare organizations to modernize current systems of care. Implementation of clinical information systems represents a challenging task and requires a high level of integration, coordination, data interoperability and portability, investment of resources, and methodologies used by industry to improve quality, safety, and reliability at a system level. But, the complexity and demands of these tasks only underscore the need for more structured (and disciplined) approaches to managing change than have previously been used in health care.

Structured approaches to management, including standard tools and methods for quality improvement, have been adopted in other industries for decades. W. Edwards Deming introduced these methods to Japanese executives and engineers after World War II, which have transformed automobile manufacturing and resulted in higher quality, faster production speed, and lower cost such as the Toyota Production System.<sup>47–49</sup> Health care has failed to achieve comparable performance, partly because of the complex nature of human systems but also because quality improvement methodologies have not been routinely learned or widely used by healthcare professionals. Historically, healthcare organizations have focused on inspection and detection of defects, which suffers from lack of reporting of both actual defects and near misses and does not lead to proactive redesign of systems of care. Quality improvement methodologies that have been used successfully by industry include PDSA, six-sigma, lean thinking, and the Malcolm Baldrige model for performance excellence (Table 3).

### Plan-Do-Study-Act

Probably the most commonly encountered quality improvement methodology in health care, PDSA relies on rapid cycles (measured in days to weeks) of learning by trial and error.<sup>50</sup> The first phase (plan) includes forming the team, agreeing on the problem, selecting valid measures, and generating ideas for improvement. The second phase (do) involves implementing potential solutions in a small subset. The third phase (study) includes measuring and evaluating results before and after intervention. The interventions are judged on the direction and magnitude of intended and

**Table 3. General Methodologies to Improve Systems Successfully Applied by Service-Oriented Industries**

Methodology	Description	Examples of Use
PDSA	Rapid cycle tests of change on a small subset to determine which interventions work and which do not and repeating the rapid cycles	Has been applied in many areas in health care such as development of protocols and order sets
Six-sigma	Systematic approach to define, measure, analyze, improve, and control output from a process Relies on data collection and rigorous statistical analyses Strives to eliminate defects and variation	Reduce medication errors from wrong drug, dose, or frequency Reduce pacemaker failure or malfunction rates
Lean thinking	Simultaneously improves quality and speed of production at a lower cost Define value from perspective of the end customer Specify each step in a process by value-stream mapping Make each step valuable, capable, available, adequate, and flexible Seek to eliminate waste and waiting Link each step with continuous flow whenever possible Use pull rather than push when continuous flow is not possible	Reduce cycle time for blood or radiology test results Improve patient flow in clinical areas such as emergency room, radiology, and cardiac catheterization laboratory Improve first-time quality of patient appointment scheduling system
Malcolm Baldrige Model for Performance Excellence	Evaluate organizational performance in 7 categories: leadership, strategic planning, customer focus, measurement and knowledge management, workforce focus, process management, and results Formal feedback with opportunities for improvement Build alignment and consensus within an organization	Organizational self-assessment Strategic planning and prioritization Sharing best practices within and across organizations

unintended results. The fourth phase (act) involves reviewing the results and deciding what tests of change to try next. Eventually, a series of lessons and strategies will be generated that can be applied to the entire cohort for quality improvement. Although the use of PDSA has been ubiquitous in health care, formal evaluations have been small in number and limited in scope and have failed to show substantial benefit in patient outcomes.<sup>32,34</sup>

### **Six-Sigma**

Six-sigma was developed by Motorola, Allied Signal, and General Electric as a metric and methodology based on rigorous statistical analyses to eliminate defects and to reduce variation.<sup>51,52</sup> As a metric, a six-sigma process produces 3.4 defects per 1 million opportunities, resulting in a yield of 99.99966%. A defect is defined as any product not meeting customer specifications. Most healthcare processes perform at two- or three-sigma, 3.1 defects per 10 opportunities (yield of 69.15%) or 6.7 defects per 100 opportunities (yield of 93.32%), respectively. As a methodology, the basic concept of six-sigma is that any output  $Y$  is a function of multiple inputs  $X_1, X_2, X_3, \dots$  and can be expressed by the following formula:  $Y = f(X_1, X_2, X_3, \dots)$ .

Sigma refers to the number of standard deviations a process can deviate from its central measure and still be within the acceptable boundaries of performance. Six-sigma methodology uses a systematic framework to define, measure, analyze, improve, and control to improve the observed versus expected outputs and to minimize variation in a control chart tracking every output. Six-sigma methodology has been applied in redesigning health-care systems,<sup>53–56</sup> and in 1 example, the rate of inappropriate transfusions of red blood cells was decreased from 16% to 5%.<sup>53</sup> However, most healthcare processes are far from the defect rates of a six-sigma process, and other methods such as PDSA or “lean” are often used initially or jointly to improve performance.

### **Lean**

Lean thinking, also called continuous flow or the Toyota Production System, has been used by industry to achieve higher quality at faster production speed and with lower cost, ultimately providing higher value for the end customer.<sup>48,49,57–61</sup> Lean thinking strives to eliminate 3 types of waste: *Muda* represents overproduction, unnecessary motion, or hand-offs, waiting, inventory, and rework; *Mura* represents unevenness in product or information flow; and *Muri* repre-

sents unreasonableness for the capability of a person or equipment. Typically, lean projects are completed by a team over 90 to 100 days and include defining the project charter and goals, agreeing on the current state value-stream map that shows every step from beginning to end in the current process, developing a future state value-stream map by eliminating or changing steps, implementing multiple interventions, and measuring and evaluating results, which typically include cycle time (time to complete entire process) and first-time quality (defined as the percent of time that every step in the process can be completed the first time without any errors). Lean thinking focuses on the entire system, from when a customer enters and exits the system, as opposed to islands of discrete services or products. For example, a lean project would strive to improve the entire system of care for patients with acute coronary syndrome from initial medical contact with paramedics to hospital discharge rather than simply the processes in the catheterization laboratory or in the emergency department.

#### **Malcolm Baldrige Model for Performance Excellence**

The Malcolm Baldrige National Quality Award was created by Public Law 100–107 and signed on August 20, 1987.<sup>62</sup> The Baldrige Award is administered by the National Institute for Standards and Technology and is given by the president of the United States to industry sectors, including manufacturing, service, education, and health care. The Baldrige model for performance excellence measures overall organizational performance across 7 categories: leadership, strategic planning, customer focus, measurement and knowledge management, workforce focus, process management, and results. Organizations undertake a formal self-assessment of performance in each category, followed by a site visit by certified Baldrige evaluators, including interviews with physicians, managers, and front-line staff. Organizations are provided a written report of their strengths and opportunities for improvement in each category, which can be used to develop a balanced scorecard, to prioritize strategic goals, and to align all members of the organization to those strategic priorities. A few healthcare organizations have used the Baldrige model as a general framework to assess overall performance and to improve quality.<sup>63,64</sup>

#### **Quality Improvement Approaches Commonly Used in Health Care**

The above approaches to quality improvement represent general methodologies for approaching quality problems, developing solutions, and redesigning systems. However, a number of specific approaches have been commonly applied within health care such as provider education (including traditional educational conferences and workshops but also educational outreach or academic detailing), provider reminder (paper or computer based),<sup>65</sup> audit and feedback,<sup>66</sup> patient education, promotion of patient self-management,<sup>67</sup> patient reminder, disease and case management,<sup>68,69</sup> and financial incentives<sup>70,71</sup> (Table 4). These approaches have generally shown small to modest effects, with substantial variations both within and across target quality problems.<sup>31,72</sup>

One important reason for the generally poor performance of these established quality improvement interventions is that they are often lifted off the shelf with little thought to the degree that the selected solution matches the target quality problem.<sup>31</sup> For instance, undertaking provider education assumes 3 conditions: the targeted gap between ideal and actual care is due to a knowledge deficit among providers; correcting the knowledge deficit will improve actual care; and sustained, meaningful increases in knowledge are achievable. Similarly, implementing a provider reminder system (paper or computer based) implies that the quality problem of interest reflects memory or attention factors for providers; addressing these factors will improve the targeted aspect of care; and the reminder system will effectively address the posited provider memory and attention problems.

Another explanation might be that personnel undertaking the quality improvement interventions may not consider the degree to which the above conditions are met (eg, by examining local data or the published literature) and instead proceed on intuition as to the basis of the targeted quality problem. For instance, in a meta-analysis of 66 trials of quality improvement interventions for outpatient diabetes care, the average reduction in hemoglobin A<sub>1c</sub> achieved was only 0.42% (95% CI, 0.29 to 0.54), an effect of borderline clinical significance even at the population level.<sup>73</sup> Individual types of interventions (such as those shown in Table 4) showed modest or smaller effects with just 1 exception: Nurse or pharmacist case managers who could adjust medications, without waiting for physician approval, reduced hemoglobin A<sub>1c</sub> by 0.80% (95% CI, 0.51 to 1.10) compared with only 0.32% (95% CI, 0.14 to 0.49) for all other interventions ( $P=0.002$ ). This finding implies that  $\geq 1$  of the above conditions were not met for each of the main categories of quality improvement interventions and that clinical inertia was the dominant underlying problem in outpatient diabetes care.<sup>74</sup> Ideally, the cause of the quality problem would be identified in the planning stages for the quality improvement interventions rather than after reflecting on the results of multiple, failed clinical trials.

Finally, a third explanation for the limited impact of quality improvement interventions involves the inattention to important mediating effects, including components of the intervention itself and contextual factors related to the implementation setting. For instance, opinion leaders are often invoked in efforts to achieve quality improvement goals, without any attention to who exactly counts as such a person and what methods successfully identify them. This is not an abstract problem. If opinion leaders can really facilitate the uptake of a guideline, then one has to make sure that one identifies true opinion leaders. In some cases, picking a physician with a prominent administrative title (director of a department or clinical unit) might suffice, but in others, one might need to undertake a social networking process to identify physicians identified by their colleagues as the individuals whom they most frequently consult or rely on for difficult cases. Other frequently ignored elements of interventions include their intensity (eg, the number of educational sessions or the

**Table 4. Quality Improvement Approaches Commonly Used in Health Care**

Quality Improvement Approach	Examples of Use
<b>Provider education</b> Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target condition or patient population	Workshop or conference detailing recommendations for management of a particular condition Distribution of printed or electronic educational materials with same Educational outreach visits or “academic detailing” targeting more specific aspects of care such as first-line choices of medications for treating hypertension
<b>Provider reminder</b> Paper-based or electronic system intended to prompt a health professional to recall information relevant to a specific patient or encounter If accompanied by a recommendation, the strategy would be subclassified as decision support	Sheet on front of chart or pop-up in electronic medical record alerting clinician to the date of the patient’s most recent INR and its result Computer-generated recommendations to intensify management of chronic heart failure <sup>65</sup>
<b>Audit and feedback</b> Summary of clinical performance of health care delivered by an individual provider or clinic over a specified period of time that is then transmitted back to the provider	Reports to individual provider or groups summarizing percentages of their eligible patients who have achieved a target outcome (eg, cholesterol below a certain value) or received a target process of care (eg, proven medications after myocardial infarction), usually accompanied by recommended targets or benchmarks for adherence to these targets <sup>66</sup>
<b>Patient education</b> Interventions designed to promote increased understanding of target condition, teach specific prevention or treatment strategies, or in-person patient education	Individual or group sessions with diabetic nurse educator Distribution of printed or electronic educational materials
<b>Promotion of patient self-management</b> Materials or resources to promote patient self-management, including simple technologies	Provision of materials that facilitate compliance with recommendations for patients to monitor their condition (eg, supplying home blood pressure cuffs) Access to a resource that supports day-to-day self-care decisions (eg, system for electronically transmitting home blood pressure measurements or weight and receiving recommended changes in antihypertensive or diuretic medications based on those data) <sup>67</sup>
<b>Patient reminder</b> Any effort directed toward patients encouraging them to keep appointments or to adhere to other aspects of self-care	Postcards or telephone calls to remind patients about upcoming appointments or reinforce important aspects of self-care
<b>Disease and case management programs</b> Any system for coordinating diagnosis, treatment, or ongoing patient management (eg, arrangement for referrals and follow-up of test results) by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider	Various case management and disease management programs <sup>68</sup> Team or staffing changes; creation of multidisciplinary teams, expansion of professional roles, addition of a new professional to usual care team such as pharmacists for heart failure patients <sup>69</sup>
<b>Financial incentives, regulation, and policy</b> Financial incentives to clinicians for performing specific processes of care or achieving specific outcomes Financial incentives directed at the patient solely for the purpose of increasing compliance were classified under patient reminders or promotion of self-management	Change from fee-for-service to salaried, pay-for-performance, or capitated reimbursement systems <sup>70,71</sup> Financial bonuses for achieving target level of compliance with targeted processes of care

INR indicates international normalized ratio.

frequency of contact with case managers) and mode of delivery (eg, delivery of audit and feedback interventions in person or by mail, case manager contact predominantly by telephone or in person).

Contextual factors (eg, organizational culture, teaching status, size, and personalities of key personnel involved in delivering the intervention) are often ignored despite having clear potential to modify the effects of quality improvement interventions. Furthermore, published reports of quality improvement interventions rarely describe contextual factors,<sup>75,76</sup> which may be critical to understanding and replicating the results of the study. These

omissions are not surprising given the traditional focus of healthcare research on clinical therapies, the effectiveness of which has not been thought to depend as much on context as on the diagnosis of the patient and skill of the clinician. Hence, the system in which the clinician worked has been given less attention. However, because quality improvement has as a premise that quality is a property of the system, it requires acknowledgment that the system features may influence clinical quality. Therefore, to advance the field of quality improvement in clinical care, recognition of and research concerning the context in which care is delivered are paramount.



### Strategies to Address the Gap

1. Learn and apply general methodologies for quality improvement that strive to redesign systems of care and have been used successfully by other industries, including PDSA, six-sigma, lean thinking, and the Malcolm Baldrige Model for Performance Excellence.
2. Design and frame quality improvement projects with measurement, evaluation, and scholarship, recognizing the importance of systems and group interactions in studies of organizational and clinical improvements.
3. Choose specific quality improvement interventions (eg, educational strategies, reminder systems, audit and feedback, case management, financial incentives) only on the basis of a clear understanding of the underlying causes of the targeted quality problem.
4. Pay attention to important mediating effects, including components of the intervention itself and the context in which the interventions are being delivered.

### Differences Between Physician and Managerial Roles

Recognizing the distinct roles and norms of clinicians and managers is important to quality improvement efforts and related research. From an organizational development perspective, healthcare delivery systems often reflect a mixing of cultures between the physician role (providing patient care) and the managerial role (ensuring the organization's viability) (Table 2). Physicians and managers have distinct responsibilities and accountabilities, and their ability to work collaboratively is a key determinant of the success of any quality improvement initiative. However, such collaboration requires a balancing of sometimes contradictory interests and goals. The different perspectives between physicians and managers arise from their disparate education, socialization, and roles.

Physicians view their work and role from an occupational or professional theory perspective.<sup>77</sup> Physicians receive MD degrees based on a large body of content knowledge, learn their trade serving as apprentices during clinical training, and value professional autonomy in their day-to-day work. Managers view their work and role from an administrative theory perspective.<sup>77</sup> Managers receive education from diverse programs (MBA, MHA, MPH, or nursing), learn their skills through supervision and mentoring by other managers on the job, and value teamwork to achieve organizational goals.

The socialization of physicians and managers also differs substantially. Physicians derive their identities by acquiring unique skills and believe that their work has social importance such as saving or improving the lives of their patients. Physicians value peer review of their work and establish professional organizations to determine the basic requirements to become a member of their social network. Managers have less cohesive professional identities and can come from varied backgrounds such as business, finance, engineering, or nursing. Managers work in well-defined hierarchies defined by organizational charts, have operational responsibility for service lines and cost centers, and value effective teamwork and communication.

Given their differing roles, physicians and managers experience conflict regarding perceived loyalties and goals. Physicians believe that their primary loyalty is to their patients and endeavor to improve their patients' health and survival, whereas managers believe that their primary loyalty is to their organization and seek to improve the health and survival of their organization. These discrepant loyalties are sometimes fully, partially, or not aligned. Hence, it is not surprising that taking action for quality improvement hits roadblocks when physicians and managers, with different perspectives, must work together toward a common goal. Furthermore, physicians can take on management roles within an organization and must strive to avoid being perceived negatively by their physician colleagues.

Nevertheless, collaboration and shared accountability between physicians and managers are paramount to successful performance improvement efforts. Bradley and colleagues<sup>78</sup> performed a national survey of 105 hospital quality management directors to evaluate their views on quality improvement organizations for their impact on the quality of care for patients hospitalized with acute myocardial infarction. A major recommendation from surveyed staff about how quality improvement organizations could be more effective was to enhance engagement with physicians and senior management. Managers felt that they could not unilaterally change systems of care without active physician participation: "Go to the physicians directly. We can monitor all those indicators, but it's in the physicians' power. If they don't prescribe aspirin at discharge, it is not the hospital's fault. We monitor that, but there are things that the hospital can't control" (p 471).<sup>78</sup> Similarly, managers believed that senior administrative engagement was crucial: "I think they need to work more with upper administration. My biggest struggle was I didn't have really good physician buy-in. I don't think they understood the importance of the project. So if they could do better with hitting the chief executive officers on how important this is, it could trickle down and do better" (p 472).<sup>78</sup>

### Strategies to Address the Gap

1. Develop models for partnership and shared accountability between physicians and managers with an overall goal for both effectiveness and efficiency of patient care. The differences and unique skills of physicians and managers can become key strengths of the partnership in which success and failure are not measured by whether conflict exists between physicians and managers but rather by how the conflict is managed and resolved.
2. Pursue interdisciplinary education for physicians to learn management science and managers to observe patient care encounters. Teaching quality improvement and management science to physicians is challenging; hence, it is imperative to measure educational effectiveness, including the learners' knowledge and skills, as well as clinical outcomes.<sup>79</sup>

3. Encourage physicians and managers to collaborate and focus on improving systems of care. The clinical practice is the ideal laboratory for intervention and evaluation.
4. Report system performance, which includes managerial and clinical performance, through balanced scorecards for quality of care. Measures of quality of care should be valid, timely, and transparently shared with physicians and managers in relevant work units.

### Patient Encounter Research

The most reliable healthcare system could fall short of meeting the needs of patients if it fails to recognize the patient's role in cocreating the healthcare experience. For example, achieving rapid door-to-balloon time for patients with ST-elevation myocardial infarction is less relevant for those who seek care after prolonged delays after onset of symptoms or decide not to seek care at all. For clinicians to engage patients as active participants to optimize their health rather than as passive receivers of care, patients need access to educational offerings and effective knowledge transfer to make medical decisions based on their personal preferences and the best evidence. Without adequate understanding of the medical decision, clinicians should not expect patients to comply with medical recommendations. This task would be simple if patients did not have their own goals for health care (ie, although almost all people may want to live without suffering for as long as possible, not everyone is willing to take on the same burdens all the time). Furthermore, many patients who suffer from multiple chronic medical conditions must balance choices between health care such as medications, follow-up visits and tests, and self-management and personal, lifestyle, and professional goals.<sup>80</sup> Developing and evaluating novel ways to seek concordance of healthcare goals between clinicians and patients represent a new challenge for outcomes research.

At the macro level, there are many ongoing efforts to engage patients and consumers, ranging from the formulation of health policies to the design of local community healthcare offerings.<sup>81</sup> Optimal approaches have yet to emerge. At the micro level, there are efforts to involve patients in participatory forms of decision making so that clinical decisions would be consistent with both the best available research evidence and the values and preferences of the informed patient.<sup>82,83</sup>

In the parlance of evidence-based medicine, medical decision making should incorporate the clinical context of the patient, the pertinent best research evidence, and the values and preferences of the informed patient.<sup>84</sup> Yet, this is a health care–centric view. For instance, patients make decisions about whether to start and continue taking medications often outside the clinical visit without telling their clinician (and clinicians are inaccurate in determining the extent to which the patient is adhering to the prescribed therapies).<sup>85</sup> In this reality, clinicians would be wiser to reframe the goals for evidence-based decision making as follows: how to help patients incorporate knowledge and clinician recommendations, applied to their own circumstance, for making choices

about health care. This is the challenge of the optimized healthcare visits and the target of patient encounter research.

One approach for involving patients is empathic decision making. By this process, clinicians constantly and fluidly adapt their decision making style to match that desired by the patient now (for this decision, under these circumstances). After thoroughly sharing information about the various options, clinicians can make recommendations (clinician as best agent to the patient), engage in shared deliberation and consensus choice (shared decision making), or invite the patient to make an independent choice with minimal clinician input (informed decision making).<sup>86</sup> Empathic decision making requires specific elements such as sufficient encounter duration for the specific agenda; clinician expertise in facilitating empathic decision making, the clinical issue, and relevant options; and availability of tools (such as decision aids) to support patient decision making.

Decision aids are tools to help patients and clinicians make healthcare decisions. A systematic review of clinical trials of treatment decision aids has found that these tools enhance patient knowledge of the options, help patients feel more informed, promote patient participation in decision making, and result in greater patient satisfaction.<sup>82</sup> These tools can decrease healthcare use as some patients choose to forgo testing with uncertain downstream benefits (such as screening for prostate cancer) and invasive treatments (such as mastectomy) or increase use (such as hepatitis B vaccination). However, the most important feature of decision aids is their ability to generate a conversation between the healthcare team and the patient and potentially to allow a better match between the option chosen and the patient circumstances, pertinent research evidence, and patient preferences.<sup>83</sup>

The opportunities in cardiovascular care are abundant if one considers the multitude of class I recommendations that require patient participation in their execution and those weaker recommendations that highlight preference-sensitive interventions. For instance, in the Statin Choice trial, 98 patients with type 2 diabetes and their clinicians were randomly assigned to use a decision aid versus usual care to discuss statin treatment for primary prevention.<sup>87</sup> The decision aid expanded the duration of the visit by 10%; clinicians were able to deliver the intervention with fidelity despite minimal training; both clinicians and patients found the use of the decision aid acceptable; and the odds of self-reported adherence to statins at 3 months was 3.4 times higher in the intervention than in the control arm. These findings are consistent with behavioral theories such as self-determination<sup>88</sup>; decision aids enhance patient autonomy, competence, and the patient-clinician relationship and in turn make it more likely that patients will start and continue to use efficacious interventions.

### Conclusions

The physician's primary role is to continuously strive to improve the lives and survival of their patients. This has been accomplished by acquiring a foundation of knowledge and

skills, translating that knowledge to evaluation and diagnosis of the patient's symptoms and signs, and in turn recommending a treatment plan in partnership with the patient. In the case of quality improvement, the patient is the healthcare system, and the symptoms are shortfalls in safety, effectiveness, equity, efficiency, timeliness, and patient-centeredness. Outcomes research has illuminated what gaps exist in quality of care and patient outcomes as well as factors contributing to these gaps; a diagnosis has been made. Here, we review potential strategies to advance quality improvement research, which include developing collaborations between academic researchers and community clinicians to undertake practice-based research, learning how to improve systems of care and performance that have been successfully applied in other industries, promoting shared partnership and accountability between physicians and managers to improve systems, engaging patients as active participants in their own health care as a quality improvement strategy, and advocating for additional funding for quality improvement research. We present a framework for undertaking quality improvement research by analogy with the phases (I through IV) of clinical research and complex interventions research, with early phases of research focused on developing and evaluating interventions for efficacy in at least 1 setting and later phases focused on evaluating effectiveness in multiple settings and surveillance studies for sustainability of target effects and occurrence of unintended effects.

### Sources of Funding

Dr Bradley is supported by the Patrick and Catherine Weldon Donaghue Medical Research Foundation Investigator Award. Dr Shojania receives support from the Government of Canada Research Chairs Program.

### Disclosures

None.

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KEY WORDS: outcomes research ■ quality improvement ■ health care

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*Circulation*. 2009;119:1962-1974

doi: 10.1161/CIRCULATIONAHA.108.768895

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:

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