

## OVERVIEW OF HEALTHCARE QUALITY

Rebecca C. Jaffe, MD, Alexis Wickersham, MD, Bracken Babula, MD

### The Growing Focus on Quality

The quality of the US healthcare system is not what it could be. Around the end of the twentieth century and the start of the twenty-first, a number of reports presented strong evidence of widespread quality deficiencies and highlighted a need for substantial change to ensure high-quality care for all patients. Among the major reports driving the imperative for quality improvement were the following:

- “The Urgent Need to Improve Health Care Quality” by the Institute of Medicine (IOM) National Roundtable on Health Care Quality (Chassin and Galvin 1998)
- IOM’s *To Err Is Human: Building a Safer Health System* (Kohn, Corrigan, and Donaldson 2000)
- IOM’s *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM 2001)
- The *National Healthcare Quality Report*, published annually by the Agency for Healthcare Research and Quality (AHRQ) since 2003
- The National Academies of Sciences, Engineering, and Medicine’s *Improving Diagnosis in Health Care* (National Academies 2015)

Years after these reports were first published, they continue to make a tremendous, vital statement. They call for action, drawing attention to gaps in care and identifying opportunities to significantly improve the quality of healthcare in the United States.

#### **“The Urgent Need to Improve Health Care Quality”**

Published in 1998, the IOM’s National Roundtable report “The Urgent Need to Improve Health Care Quality” included two notable contributions to the quality movement. The first was an assessment of the current state of quality (Chassin and Galvin 1998, 1000): “Serious and widespread quality problems exist throughout American medicine. These problems . . . occur in small and

large communities alike, in all parts of the country, and with approximately equal frequency in managed care and fee-for-service systems of care. Very large numbers of Americans are harmed.” The second contribution was the categorization of quality defects into three broad categories: underuse, overuse, and misuse. This classification scheme has become a common nosology for quality defects and can be summarized as follows:

- Underuse occurs when scientifically sound practices are not used as often as they should be. For example, only 72 percent of women between the ages of 50 and 74 reported having a mammogram within the past two years (White et al. 2015). In other words, nearly one in four women does not receive treatment consistent with evidence-based guidelines.
- Overuse occurs when treatments and practices are used to a greater extent than evidence deems appropriate. Examples of overuse include imaging studies for diagnosis of acute low-back pain and the prescription of antibiotics for acute bronchitis.
- Misuse occurs when clinical care processes are not executed properly—for example, when the wrong drug is prescribed or the correct drug is prescribed but incorrectly administered.

### ***To Err Is Human: Building a Safer Health System***

Although the healthcare community had been cognizant of its quality challenges for years, the 2000 publication of the IOM’s *To Err Is Human* exposed the severity and prevalence of these problems in a way that captured the attention of a large variety of key stakeholders for the first time. The executive summary of *To Err Is Human* begins with the following headlines (Kohn, Corrigan, and Donaldson 2000, 1–2):

The knowledgeable health reporter for the *Boston Globe*, Betsy Lehman, died from an overdose during chemotherapy. . . .

Ben Kolb was eight years old when he died during “minor” surgery due to a drug mix-up. . . .

[A]t least 44,000 Americans die each year as a result of medical errors. . . . [T]he number may be as high as 98,000. . . .

Total national costs . . . of preventable adverse events . . . are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one-half.

Although many people had spoken about improving healthcare in the past, this report focused on patient harm and medical errors in an unprecedented way, presenting them as perhaps the most urgent forms of quality defects. *To Err Is Human* framed the problem in a manner that was accessible

to the public, and it clearly demonstrated that the status quo was unacceptable. For the first time, patient safety became a unifying cause for policy makers, regulators, providers, and consumers.

### ***Crossing the Quality Chasm: A New Health System for the 21st Century***

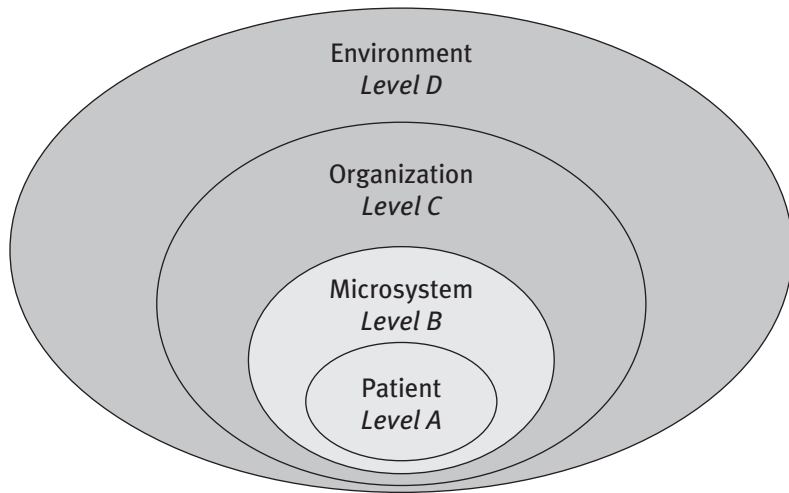
In March 2001, soon after the release of *To Err Is Human*, the IOM released *Crossing the Quality Chasm*, a more comprehensive report that offered a new framework for a redesigned US healthcare system. *Crossing the Quality Chasm* provides a blueprint for the future that classifies and unifies the components of quality through six aims for improvement. These aims, also viewed as six dimensions of quality, provide healthcare professionals and policy makers with simple rules for redesigning healthcare. They can be known by the acronym STEEEP ( Berwick 2002):

1. *Safe*: Harm should not come to patients as a result of their interactions with the medical system.
2. *Timely*: Patients should experience no waits or delays when receiving care and service.
3. *Effective*: The science and evidence behind healthcare should be applied and serve as standards in the delivery of care.
4. *Efficient*: Care and service should be cost-effective, and waste should be removed from the system.
5. *Equitable*: Unequal treatment should be a fact of the past; disparities in care should be eradicated.
6. *Patient-centered*: The system of care should revolve around the patient, respect patient preferences, and put the patient in control.

Improving the quality of healthcare in the STEEEP focus areas requires change to occur at four different levels, as shown in exhibit 1.1. Level A is the patient’s experience. Level B is the microsystem where care is delivered by small provider teams. Level C is the organizational level—the macrosystem or aggregation of microsystems and supporting functions. Level D is the external environment, which includes payment mechanisms, policy, and regulatory factors. The environment affects how organizations operate, operations affect the microsystems housed within organizations, and microsystems affect the patient. “True north” lies at level A, in the experience of patients, their loved ones, and the communities in which they live (Berwick 2002).

### ***National Healthcare Quality Report***

Mandated by the US Congress to focus on “national trends in the quality of healthcare provided to the American people” (42 U.S.C. 299b-2(b)(2)), the

**EXHIBIT 1.1****The Four Levels of the Healthcare System**

AHRQ’s annual *National Healthcare Quality Report* highlights progress and identifies opportunities for improvement. Recognizing that the alleviation of healthcare disparities is integral to achieving quality goals, Congress further mandated that a second report, the *National Healthcare Disparities Report*, focus on “prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations” (42 U.S.C. 299a-1(a)(6)). AHRQ’s priority populations include women, children, people with disabilities, low-income individuals, and the elderly. The combined reports are fundamental to ensuring that improvement efforts simultaneously advance quality in general and work toward eliminating inequitable gaps in care.

These reports use national quality measures to track the state of healthcare and address three questions:

1. What is the status of healthcare quality and disparities in the United States?
2. How have healthcare quality and disparities changed over time?
3. Where is the need to improve healthcare quality and reduce disparities greatest?

In its 2016 *National Healthcare Quality and Disparities Report*, the AHRQ (2016) notes several improvements, including improved access to healthcare, better care coordination, and improvement in patient-centered care. Despite these improvements, many challenges and disparities remain with regard to insurance status, income, ethnicity, and race.

## ***Improving Diagnosis in Health Care***

The National Academies of Sciences, Engineering, and Medicine's (2015) report on *Improving Diagnosis in Health Care* claims that most people will experience at least one diagnostic error—defined as either a missed or delayed diagnosis—in their lifetime. Diagnostic errors are thought to account for up to 17 percent of hospital-related adverse events. Likewise, up to 5 percent of patients in outpatient settings may experience a diagnostic error.

Previous reports had steered clear of discussing diagnostic error, perhaps fearing that the topic assigns blame to clinicians on a personal level. This report, however, proposes an organizational structure for the diagnostic process, allowing for analysis of where healthcare may be failing and what might be done about it. The National Academies recommend that healthcare organizations involve patients and families in the diagnosis process, develop health information technologies to support the diagnostic process, establish a culture that embraces change implementation, and promote research opportunities on diagnostic errors (National Academies 2015).

## ***How Far Has Healthcare Come?***

More than fifteen years after the prevalence of medical errors was brought to light in *To Err Is Human*, the healthcare in the United States has seen a call to arms for the improvement of quality and safety. But has anything really changed? A 2016 analysis published by the *British Medical Journal* suggests not. The article, titled “Medical Error—The Third Leading Cause of Death in the US,” delivers a shocking realization of the scope of medical error in healthcare today. Using death certificate records along with national hospital admission data, Makary and Daniel (2016) conclude that, if medical errors are tracked as diseases are, they account for more than 250,000 deaths annually in the United States—outranked only by heart disease and cancer.

*To Err Is Human* and *Crossing the Quality Chasm* were catalysts for change in healthcare, and they led to increased recognition and reporting of medical error and improved accountability measures set by governing bodies. Nonetheless, more work needs to be done to shrink the quality gap in US healthcare. The remainder of this chapter will focus on frameworks for quality improvement, providing a deeper dive into the STEEEP goals and examining stakeholder needs, measurement concepts, and useful models and tools.

## **Frameworks and Stakeholders**

The six STEEEP aims (Berwick 2002), as presented in *Crossing the Quality Chasm*, provide a valuable framework that can be used to describe quality at any of the four levels of the healthcare system. The various stakeholders involved

in healthcare—including clinicians, patients, health insurers, administrators, and the general public—attach different levels of importance to particular aims and define *quality of care* differently as a result (Bodenheimer and Grumbach 2009; Harteloh 2004).

### **The STEEEP Framework**

#### **Safety**

*Safety* refers to the technical performance of care, but it also includes other aspects of the STEEEP framework. Technical performance can be assessed based on the success with which current scientific medical knowledge and technology are applied in a given situation. Assessments of technical performance typically focus on the accuracy of diagnoses, the appropriateness of therapies, the skill with which procedures and other medical interventions are performed, and the absence of accidental injuries (Donabedian 1988a, 1980).

#### **Timeliness**

*Timeliness* refers to the speed with which patients are able to receive care or services. It inherently relates to access to care, or the “degree to which individuals and groups are able to obtain needed services” (IOM 1993). Poor access leads to delays in diagnosis and treatment. Timeliness can also manifest as the patient experience of wait times—either the wait for an appointment or the wait in the medical facility. Timeliness is often a balance between quality of care and speed of care.

#### **Effectiveness**

*Effectiveness* refers to standards of care and how well they are implemented. Perceptions of the effectiveness of healthcare have evolved over the years to increasingly emphasize value. The cost-effectiveness of a given healthcare intervention is determined by comparing the potential for benefit, typically measured in terms of improvement in individual health status, with the intervention’s cost (Drummond et al. 2005; Gold et al. 1996). As the amount spent on healthcare services grow, each unit of expenditure ultimately yields ever-smaller benefits until no further benefit accrues from additional expenditures on care (Donabedian, Wheeler, and Wyszewianski 1982).

#### **Efficiency**

*Efficiency* refers to how well resources are used to achieve a given result. Efficiency improves whenever fewer resources are used to produce an output. Because inefficient care uses more resources than necessary, it is wasteful care, and care that involves waste is deficient—and therefore of lower quality—no matter how good it may be in other respects. “Wasteful care is either directly

harmful to health or is harmful by displacing more useful care” (Donabedian 1988a, 1745).

### **Equity**

Findings that the amount, type, or quality of healthcare provided can relate systematically to an individual’s characteristics—particularly race and ethnicity—rather than to the individual’s need for care or healthcare preferences have heightened concern about *equity* in health services delivery (IOM 2002; Wyszewianski and Donabedian 1981). Many decades ago, Lee and Jones (1933, 10) asserted that “good medical care implies the application of all the necessary services of modern, scientific medicine to the needs of all the people. . . . No matter what the perfection of technique in the treatment of one individual case, medicine does not fulfill its function adequately until the same perfection is within the reach of all individuals.”

### **Patient Centeredness**

The concept of patient centeredness, originally formulated by Gerteis and colleagues (1993), is characterized in *Crossing the Quality Chasm* as encompassing “qualities of compassion, empathy, and responsiveness to the needs, values, and expressed preferences of the individual patient” and rooted in the idea that “health care should cure when possible, but always help to relieve suffering” (IOM 2001, 50). The report states that the goal of patient centeredness is “to modify the care to respond to the person, not the person to the care” (IOM 2001, 51).

### **Stakeholders**

Virtually everyone can agree on the value of the STEEEP attributes of quality, but clinicians, patients, payers, managers, and society at large attach varying levels of importance to each attribute and thus define *quality of care* differently from one another.

### **Clinicians**

Clinicians tend to perceive the quality of care foremost in terms of technical performance. Their concerns focus on aspects highlighted in IOM’s (1990, 4) often-quoted definition: “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

Reference to “current professional knowledge” draws attention to the changing nature of what constitutes good clinical care. Because medical knowledge advances rapidly, clinicians strongly believe that assessing care provided in 2010 on the basis of knowledge acquired in 2013 is neither meaningful nor

appropriate. Similarly, “likelihood of desired health outcomes” aligns with clinicians’ widely held view that, no matter how good their technical performance is, predictions about the ultimate outcome of care can be expressed only as a probability, given the presence of influences beyond clinicians’ control, such as a patient’s inherent physiological resilience.

As healthcare has evolved, standards for clinicians have moved beyond technical performance and professional knowledge. Clinicians today are increasingly asked to ensure that their care is patient centered and offered in a way that demonstrates value and efficiency.

### **Patients**

Patients care deeply about technical performance, but it may actually play a relatively small role in shaping their view of healthcare quality. To the dismay of clinicians, patients often see technical performance strictly in terms of the outcomes of care; if the patient does not improve, the physician’s technical competence is called into question (Muir Gray 2009). Additionally, patients may not have access to accurate information regarding a clinician’s technical skill. Given the difficulty of obtaining and interpreting performance data, patients may make decisions about their care based their assessment of the attributes they are most readily able to evaluate—chiefly patient centeredness, amenities, and reputation (Cleary and McNeil 1988; Sofaer and Firminger 2005).

As health policy changes, patients, much like clinicians, are becoming more likely to consider cost as part of the quality equation. From the patients’ vantage point, cost-effectiveness calculations are highly complex and depend greatly on the details of their insurance coverage. A patient who does not have to pay the full price of medical care may have a very different view of the value of the treatment, compared to a patient who incurs a higher percentage of the cost.

### **Payers**

Third-party payers—health insurance companies, government programs such as Medicare, and others who pay on behalf of patients—tend to assess the quality of care on the basis of costs. Because payers typically manage a finite pool of resources, they tend to be concerned about cost-effectiveness and efficiency.

Though payer restrictions on care have commonly been considered antithetical to the provision of high-quality care, this opinion is slowly changing. Increasing costs, without concomitant improvements in overall quality, have led to more clinicians and patients focusing on the value of care and therefore accepting some limitations. Clinicians continue to be duty bound to do everything possible to help individual patients, including advocating for high-cost interventions even if those interventions have only a small positive probability of benefiting the patient (Donabedian 1988b; Strech et al. 2009). Third-party



payers—especially governmental units that must make multiple trade-offs when allocating money—are more apt to view the spending of large sums for diminishing returns as a misuse of finite resources. The public, meanwhile, has shown a growing unwillingness to pay higher insurance premiums or taxes needed to provide populations with the full measure of care that is available.

### **Administrators**

The chief concern of administrative leaders responsible for the operations of hospitals, clinics, and other healthcare delivery organizations is the quality of the nonclinical aspects of care over which they have the most control— primarily, amenities and access to care. Administrators' perspective on quality, therefore, can differ from that of clinicians and patients with respect to efficiency, cost-effectiveness, and equity. Because administrators are responsible for ensuring that resources are spent where they will do the most good, efficiency and cost-effectiveness are of central concern, as is the equitable distribution of resources.

### **Society/Public/Consumers**

At a collective, or societal, level, the definition of *quality of care* reflects concerns about efficiency and cost-effectiveness similar to those of governmental third-party payers and managers, and much for the same reasons. In addition, technical aspects of quality loom large at the collective level, where many believe care can be assessed and safeguarded more effectively than it can be at the level of individuals. Similarly, equity and access to care are important to societal-level concepts of quality, given that society is seen as being responsible for ensuring access to care for everyone, particularly disenfranchised groups.

### **Are the Five Stakeholders Irreconcilable?**

Different though they may seem, stakeholders—clinicians, patients, payers, administrators, and the public—have a great deal in common. Although each emphasizes the attributes differently, none of the other attributes is typically excluded. Strong disagreements do arise, however, among the five parties' definitions, even outside the realm of cost-effectiveness. Conflicts typically emerge when one party holds that a particular practitioner or clinic is a high-quality provider by virtue of having high ratings on a single aspect of care—for example, patient centeredness. Those objecting to this conclusion point out that, just because a practice rates highly in that one area, it does not necessarily rate equally highly in other areas, such as technical performance, amenities, or efficiency, for instance (Wyszewianski 1988). Clinicians who relate well to their patients, and thus score highly on patient centeredness, nevertheless may have failed to keep up with medical advances and, as a result, provide care that is deficient in technical terms. As with this example, an aspect of quality that a given party overlooks is seldom in direct conflict with that party's own overall concept of quality.

## Measurement

Just as frameworks and stakeholders are useful for advancing one's understanding of quality of care, so is measurement, particularly with respect to quality improvement initiatives.

### ***Structure, Process, and Outcome***

As Avedis Donabedian first noted in 1966, all evaluations of the quality of care can be classified in terms of one of three measures: structure, process, or outcome.

#### **Structure**

In the context of measuring the quality of care, *structure* refers to characteristics of the individuals who provide care and of the settings where care is delivered. These characteristics include the education, training, and certification of professionals who provide care and the adequacy of the facility's staffing, equipment, and overall organization.

Evaluations of quality based on structural elements assume that well-qualified people working in well-appointed and well-organized settings provide high-quality care. However, although good structure makes good quality more likely, it does not guarantee it (Donabedian 2003). Licensing and accrediting bodies have relied heavily on structural measures of quality because the measures are relatively stable, and thus easier to capture, and because they reliably identify providers or practices lacking the means to deliver high-quality care.

#### **Process**

Process—the series of events that takes place during the delivery of care—can also be a basis for evaluating the quality of care. The quality of the process can vary on three aspects: (1) appropriateness—whether the right actions were taken, (2) skill—the proficiency with which actions were carried out, and (3) the timeliness of the care.

Ordering the correct diagnostic procedure for a patient is an example of an appropriate action. However, to fully evaluate the process in which this particular action is embedded, we also need to know how promptly the procedure was ordered and how skillfully it was carried out. Similarly, successful completion of a surgical operation and a good recovery are not enough evidence to conclude that the process of care was of high quality; they only indicate that the procedure was performed skillfully. For the entire process of care to be judged as high quality, one also must ascertain that the operation was indicated (i.e., appropriate) for the patient and that it was carried out in time. Finally, as is the case for structural measures, the use of process measures for assessing the quality of care rests on a key assumption—that if the right

things are done and are done right, good results (i.e., good outcomes of care) are more likely to be achieved.

### **Outcome**

Outcome measures capture whether healthcare goals were achieved. Because the goals of care can be defined broadly, outcome measures may include the costs of care as well as patients' satisfaction with their care (Iezzoni 2013). In formulations that stress the technical aspects of care, however, outcomes typically involve indicators of health status, such as whether a patient's pain subsided or condition cleared up, or whether the patient regained full function (Donabedian 1980).

Clinicians tend to have an ambivalent view of outcome measures. Clinicians are aware that many factors that determine clinical outcomes—including genetic and environmental factors—are not under their control. At best, they control the process, and a good process only increases the likelihood of good outcomes; it does not guarantee them. Some patients do not improve in spite of the best treatment that medicine can offer, whereas other patients regain full health even though they receive inappropriate or potentially harmful care. Despite this complexity, clinicians view improved outcomes as the ultimate goal of quality initiatives. Clinicians are unlikely to value the effort involved in fixing a process-oriented gap in care if it is unlikely to ultimately result in an improvement in outcomes.

### **Which Is Best?**

Of structure, process, and outcome, which is the best measure of the quality of care? The answer is that none of them is inherently better and that the appropriateness of each measure depends on the circumstances (Donabedian 2003). However, this answer often does not satisfy people who are inclined to believe that outcome measures are superior to the others. After all, they reason, the outcome addresses the ultimate purpose, the bottom line, of all caregiving: Was the condition cured? Did the patient improve?

As previously noted, however, a good outcome may occur even when the care (i.e., process) is clearly deficient. The reverse is also possible: Even when the care is excellent, the outcomes might not be as good because of factors outside clinicians' control, such as a patient's frailty. To assess outcomes meaningfully across providers, one must account for such factors by performing complicated risk adjustment calculations (Goode et al. 2011; Iezzoni 2013).

What a particular outcome ultimately denotes about the quality of care crucially depends on whether the outcome can be attributed to the care provided. In other words, one has to examine the link between the outcome and the antecedent structure and process measures to determine whether the care was appropriate and provided skillfully. Structures and processes are essential but not sufficient for a good outcome.

## **Metrics and Benchmarks**

To assess quality using structure, process, or outcome measures, one needs to establish metrics and benchmarks to know what constitutes a good structure, a good process, and a good outcome.

Metrics are specific variables that form the basis for assessing quality. Benchmarks quantitatively express the level the variable must reach to satisfy preexisting expectations about quality. Exhibit 1.2 provides examples of metrics and benchmarks for structure, process, and outcome measures in healthcare.

The way healthcare metrics and benchmarks are derived is changing. Before the 1970s, quality-of-care evaluations relied on consensus among groups of clinicians selected for their clinical knowledge, experience, and reputation (Donabedian 1982). In the 1970s, however, the importance of scientific literature to the evaluation of healthcare quality gained new visibility through the work of Cochrane (1973), Williamson (1977), and others. At about the same time, Brook and colleagues (1977) at RAND began using systematic reviews and evaluations of scientific literature as the basis for defining criteria and standards for quality. The evidence-based medicine movement of the 1990s, which advocated medical practice guided by the best evidence about efficacy, reinforced the focus on the literature and stressed consideration of the soundness of study design and validity (Evidence-Based Medicine Working Group 1992; Straus et al. 2005). As a result, derivation of metrics and benchmarks has come to revolve more around the strength and validity of scientific evidence than around the unaided consensus of experts (Eddy 2005, 1996).

The main insight that can be drawn from a deeper understanding of concepts related to the measurement of healthcare quality is that the type of measure used—structure, process, or outcome—matters less than the measure’s

### **EXHIBIT 1.2**

Examples of Metrics and Benchmarks for Structure, Process, and Outcome Measures in Healthcare

<b>Type of Measure</b>	<b>Focus of Assessment</b>	<b>Metric</b>	<b>Benchmark</b>
Structure	Nurse staffing in nursing homes	Hours of nursing care per resident day	At least four hours of nursing care per resident day
Process	Patients undergoing surgical repair of hip fracture	Percentage of patients who receive prophylactic antibiotics on the day of surgery	100 percent receive antibiotic on the day of surgery
Outcome	Hospitalized patients	Rate of falls per 1,000 patient days	Fewer than five falls per 1,000 patient days

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relationship to the others. Structural measures are only as good and useful as the strength of their link to desired processes and outcomes. Similarly, process and outcome measures must relate to each other in measurable and reproducible ways—as demonstrated by efficacy studies—to be truly valid measures of quality.

## Quality Improvement Models

A number of systems exist to guide the process of quality improvement. At their core, all of these systems are approaches to complex problem solving. Just as the scientific method guides research inquiry in the lab, and just as the diagnostic process guides clinical reasoning, quality improvement models structure the approach to system improvement. All of the models discussed in this section were initially developed for industries outside of healthcare. Their adoption in and adaptation to the field of healthcare quality improvement demonstrate the field's willingness to learn from the success of others, as well as the relative youth of the quality movement in the healthcare arena. Although these models have different names, they have certain core commonalities. Most share the following basic format:

1. Identify the problem
2. Measure current performance
3. Perform a cause analysis
4. Develop and implement an improvement strategy
5. Measure the effect of the intervention
6. Modify, maintain, or spread the intervention

“Form follows function,” a concept rooted in the field of architecture, stresses the importance of understanding what you are trying to accomplish before you determine how you are going to do it. Applied to healthcare quality, the phrase highlights the need to understand the purpose behind the effort—the goal—at the individual, departmental, and organizational levels before deciding what improvement process or approach to adopt. The following approaches, though not an exhaustive list, are the ones most commonly applied:

- The Plan-Do-Study-Act (PDSA) cycle
- The model for improvement
- Lean, or the Toyota Production System
- Six Sigma
- Human-centered design

### ***The Plan-Do-Study-Act Cycle***

Walter A. Shewhart (1891–1967) developed the PDSA cycle during the 1920s, and the cycle was further described by W. Edwards Deming (1900–1993), who is often regarded as the “father” of quality. Deming (2000b), a statistics professor and physicist by trade, stressed the importance of practicing continuous improvement and thinking of manufacturing as a system. As part of his “system of profound knowledge,” Deming (2000a) promoted the idea that about 15 percent of poor quality was because of workers and 85 percent was because of improper management, systems, and processes. In most, but not all, contexts, the stages of this model are plan, do, study, and act. Some may replace the “study” with “check,” making the cycle PDCA. Nevertheless, the principles remain the same. In practical terms, the stages of the PDSA cycle can be broken down as follows.

#### **Plan**

- Understand the problem and the underlying causes for a gap in quality.
- Establish an objective. What are you trying to accomplish? By how much do you aim to improve, and by when?
- Ask questions and make predictions. What do you think will happen?
- Plan to carry out the cycle. Who will perform the functions? What steps will be performed?
- When will the plan be implemented and completed? Where will the plan/work take place?

#### **Do**

- Educate and train staff.
- Carry out the plan (e.g., try out the change on a small scale).
- Document problems and unexpected observations.
- Begin analysis of the data.

#### **Study**

- Assess the effect of the change, and determine the level of success achieved, relative to the goal/objective.
- Compare the results with your predictions. Did you meet your aim for improvement? Did anything get worse?
- Summarize the lessons learned.
- Determine what changes need to be made and what actions will be taken next.

#### **Act**

- Act on what you have learned.
- Determine whether the plan should be repeated with modification, or whether a new plan should be created.

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- Make necessary changes.
- Identify remaining gaps in the process or performance.
- Carry out additional PDSA cycles until the goal/objective is met.

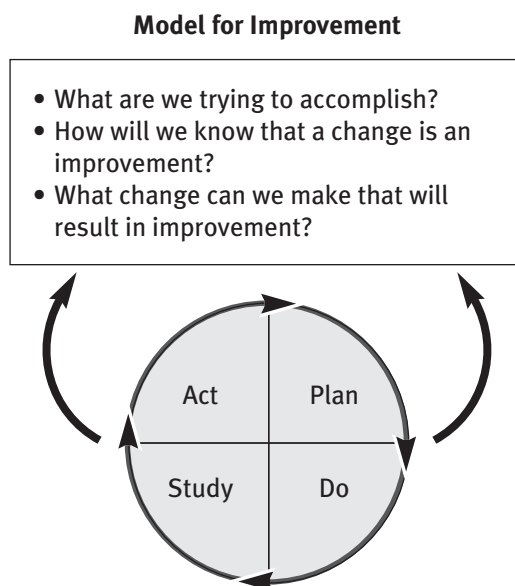
### **Model for Improvement**

Tom Nolan and Lloyd Provost, cofounders of Associates in Process Improvement (API), developed a simple model for improvement based on Deming's PDSA cycle. As shown in exhibit 1.3, the model uses three fundamental questions as a basis for improvement: (1) What are we trying to accomplish? (2) How will we know that a change is an improvement? (3) What change can we make that will result in improvement?

Setting measurable aims is essential for any quality improvement effort. The effort required to bring about improvement may vary depending on the problem's complexity, whether the focus is on a new or an old design, or the number of people involved in the process (Langley et al. 1996). The Institute for Healthcare Improvement (IHI) has adopted the API approach as its organizing improvement model.

### **Lean, or the Toyota Production System**

The Massachusetts Institute of Technology first used the term *Lean* in 1987 to describe product development and production methods that, when compared with traditional mass production processes, produce more products with fewer defects in a shorter time. Lean thinking, or Lean manufacturing, grew out of



**EXHIBIT 1.3**  
API Model for  
Improvement

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the work of Taiichi Ohno (1912–1990), who began developing the concepts as early as 1948 at Toyota Motor Corporation in Japan. As a result, it is also known as the Toyota Production System (TPS).

The goal of Lean is to develop a way to specify the meaning of value, to align steps/processes in the best sequence, to conduct activities without interruption whenever someone requests them, and to perform the activities more effectively (Womack and Jones 2003). Lean focuses on the removal of *muda*, or waste, which is defined as anything that is not needed to produce an item or service. Ohno identified seven types of waste: (1) overproduction, (2) waiting, (3) unnecessary transport, (4) overprocessing, (5) excess inventory, (6) unnecessary movement, and (7) defects. Lean also emphasizes the concept of continuous (one-piece) flow production. In contrast to a batch-and-queue process, continuous flow creates a standardized process in which products are constructed through a single, continuous system one at a time, ultimately producing less waste, greater efficiency, and higher output.

Lean methodology places the needs of the customer first by following five steps:

1. Define *value* as determined by the customer, based on the provider's ability to deliver the right product or service at an appropriate price.
2. Identify the value stream—the set of specific actions required to bring a product or service from concept to completion.
3. Make value-added steps flow from beginning to end.
4. Let the customer *pull* the product from the supplier; do not *push* products.
5. Pursue perfection of the process.

When waste is removed and flow is improved, quality improvement results. The simplification of processes reduces variation, reduces inventory, and increases the uniformity of outputs (Heim 1999).

### **Six Sigma**

Six Sigma is a system for improvement developed by Hewlett-Packard, Motorola, General Electric, and other organizations during the 1980s and 1990s (Pande, Neuman, and Cavanagh 2000). The central concepts of Six Sigma are not new; they build on the foundations of quality improvement established from the 1920s through the 1950s, including Shewhart's research on variation and his emphasis on precise measurement. Six Sigma creates clear roles and responsibilities for executives and other individuals, who may achieve the ranks of champion, green belt, black belt, or master black belt as they develop through higher levels of training and expertise.



With Six Sigma, the aim is to reduce variation and eliminate defects in key business processes. It aims for a rate of no more than 3.4 defects per million opportunities. By using a set of statistical tools to understand the fluctuation of a process, managers can predict the expected outcome of that process. If the outcome is not satisfactory, management can use associated tools to learn more about the elements influencing the process. The primary theory of Six Sigma is that a focus on reducing variation leads to a more uniform process output. Secondary effects include less waste, less throughput time, and less inventory (Heim 1999).

The Six Sigma improvement model consists of five steps that together form the acronym DMAIC:

1. *Define*. Identify the customers and their problems. Determine the key characteristics that important to the customer, along with the processes that support those key characteristics.
2. *Measure*. Categorize key characteristics, verify measurement systems, and collect data.
3. *Analyze*. Convert raw data into information that provides insights into the process. These insights include identifying the fundamental and most important causes of defects or problems.
4. *Improve*. Develop solutions to the problem, and make changes to the process. Measure process changes, and judge whether the changes are beneficial, or whether another set of changes is necessary.
5. *Control*. If the process is performing at a desired and predictable level, monitor the process to ensure that no unexpected changes occur.

### **Human-Centered Design**

Quality improvement initiatives are increasingly incorporating design concepts as part of an effort to restore the central role of patients and frontline healthcare providers in the improvement process. Existing improvement models emerged primarily out of the manufacturing industry, where reduction in defects, speed of production, and reduction of waste are the primary concerns. Design methods, on the other hand, originate from such industries as architecture, product development, and fashion. Priorities in these fields extend beyond those of manufacturing and include such concerns as customer satisfaction, functional performance, and creativity. When applied to the healthcare setting, human-centered design can encompass a broad array of concepts and practices, including human factors engineering (HFE) and the process of co-creating devices, spaces, and processes with patients or end users. This approach might involve, for instance, purposefully forming a team of industrial designers, patients, and occupational therapists to design a new type of prosthetic device for amputees,

or bringing together designers, medical professionals, patients, and family members to create a better waiting room experience (Guinn 2017).

The steps of the design process are as follows:

1. *Empathize*. Thoroughly understand the motivations, needs, and concerns of the client or user.
2. *Define*. Translate the perspectives gained from interviewing and observing the end user into clear design challenges and goals.
3. *Ideate*. Generate a broad array of potential solutions, with minimal self-editing or concern for real or imagined limitations.
4. *Narrow*. Identify the most promising solutions, usually through the application of specific criteria.
5. *Prototype*. Create tangible products representing the potential future solutions, with the goal of communicating back to the end user and further exploring/refining ideas.
6. *Test*. Share prototypes and gather feedback, working toward a final solution.

Two key elements of the design process are empathy building and prototyping. Empathy is key to realizing the promise of patient/person centeredness in the improvement of healthcare services. The depth to which designers aim to understand their users is pivotal to the creation of superior products and services. Prototyping exists in other improvement models, but usually in the form of small-scale implementation of a solution in the actual environment. At its extreme, prototyping may take the form of a pilot, but more frequently it is a lower-fidelity expression of a final product, such as a physical model, storyboard, or simulation. Like the PDSA cycle, application of the design process is cyclical and continues until the goal is met.

## Quality Improvement Tools

Understanding the difference between quality improvement models and quality improvement tools is difficult. A quality model is akin to the process of designing and then constructing a house. The tools are the materials and activities that take the design from an abstract concept to a physical structure. An architect does not simply walk onto a building site with an idea in her head. Instead, she creates blueprints that communicate the building plan. The blueprint is a tool that makes the design process visible. Similarly, contractors use physical tools, such as hammers and saws, as well as organizing tools, such as checklists and work schedules, to ensure that the house is built correctly. Similarly, in quality improvement, different tools have different functions and are used at distinct

stages. They are not interchangeable, just as you could not substitute a hammer for a saw. We can observe people using the tools of the system, but the system or model itself (e.g., Six Sigma, Lean) is invisible and cannot be observed.

Quality improvement tools can be organized into seven categories, following a framework developed by the American Society for Quality (ASQ) (Tague 2004):

1. Cause analysis
2. Evaluation and decision making
3. Process analysis
4. Data collection and analysis
5. Idea creation
6. Project planning and implementation
7. Knowledge transfer and spread techniques

This section is not intended to be a comprehensive reference on quality tools and techniques; rather, it aims to highlight some of the more widely used tools in each category.

### **Cause Analysis**

Once a gap in quality has been identified, the next step is usually to figure out why actual performance is lagging behind optimal performance or benchmarks. This process is known as *cause analysis*. Skillful cause analysis allows improvement teams to link their solutions and interventions with the underlying reasons for the gaps in care they are working to fix.

### **Five Whys**

The “five whys” exercise is a basic method for drilling down through the symptoms of a process or design failure to identify the root cause. Easy to understand and to perform, it involves simply asking “why?” five times. Users of this technique will quickly identify the more proximal conditions contributing to a quality gap, instead of assuming that the obvious surface conditions are the most important. The benefit of this approach is that it forces users to look beyond their first answer. Any time a breach in protocol is assumed to be the reason for a bad outcome, one must dig deeper, asking why the protocol was not followed, until a root cause is identified. The key to successful use of this technique is not to stop the analysis too early, thus misidentifying the root cause.

### **Cause-and-Effect/Fishbone Diagram**

Most complex problems have multiple root causes, which can be missed using five whys, because that tool encourages one path to be followed at the exclusion of others. Cause-and-effect diagrams, also referred to as *Ishikawa* or *fishbone*

*diagrams*, help to broaden the search for possible root causes. In a fishbone diagram, the problem (effect) is stated in a box on the right side of the chart, and likely causes of the problem are listed around major category headings to the left, resembling the bones of a fish (ASQ 2014). Possible category headings, as shown in exhibit 1.4, include *Technology*, *Team*, *Individual*, *Organization/management*, *Protocols*, and *Environment*.

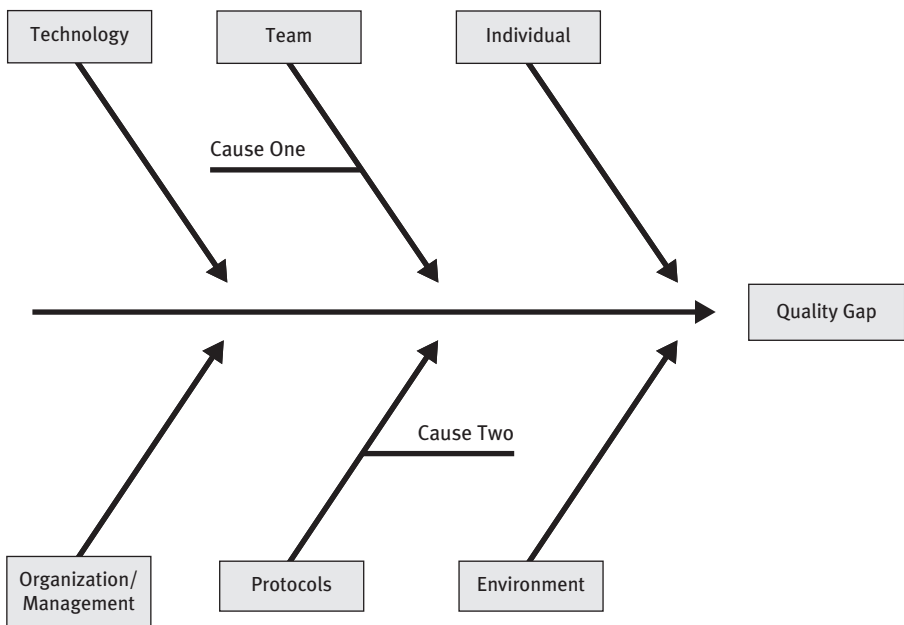
### **Evaluation and Decision Making**

Deciding exactly where in a system to intervene to bring about change often involves a more quantitative approach to cause analysis. Visualizing data can help to identify correlations and patterns to help guide decisions.

### **Scatter Diagram**

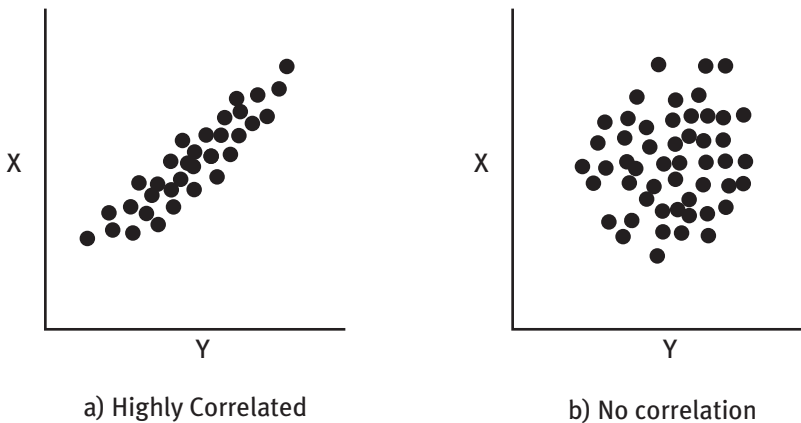
Scatter diagrams, also known as *scatter plots* or *x-y graphs*, enable users to identify whether a correlation exists between two variables or sets of numerical data. As shown in exhibit 1.5, when a high correlation exists between the two elements, the data will display as a tight line or curve; when the elements have little correlation, the data will display as a more scattered or “shotgun” distribution. Although correlation does not imply causation, targeting a variable that is highly correlated with the outcome of interest may be more likely to improve performance.

**EXHIBIT 1.4**  
Schematic of  
a Fishbone  
Diagram Used in  
Cause Analysis



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**EXHIBIT 1.5**  
 Scatter  
 Diagrams  
 Demonstrating  
 Two Data Sets

### Pareto Chart

The Pareto chart developed from the work of the Italian economist Vilfredo Pareto (1848–1923), who observed that 80 percent of the wealth in Italy was held by 20 percent of the population. Joseph M. Juran (1904–2008), working as an internal consultant to Deming with Western Electric on the subject of industrial engineering, applied this principle more broadly and proclaimed that 80 percent of the variation of any characteristic is caused by only 20 percent of the possible causes.

A Pareto chart displays the occurrence frequency for a range of causes of variation, demonstrating the small number of significant contributors to a problem. It enables a project team to identify the frequency with which specific errors are occurring and thus to concentrate resources appropriately (Tague 2004). Pareto charts overlay a histogram and a line graph, showing the contribution of each error or cause to the total variation in the system. The charts have two  $x$  axes, with frequency of occurrence on the left-hand axis and cumulative percentage on the right. Causes are arranged in descending order of frequency, and those on the right-hand side account for the majority of the variation in outcomes (see exhibit 1.6).

### Process Analysis

Many improvement initiatives target changes in process to achieve better outcomes. Fully understanding an existing or proposed process is a vital step in improvement.

### Flowchart

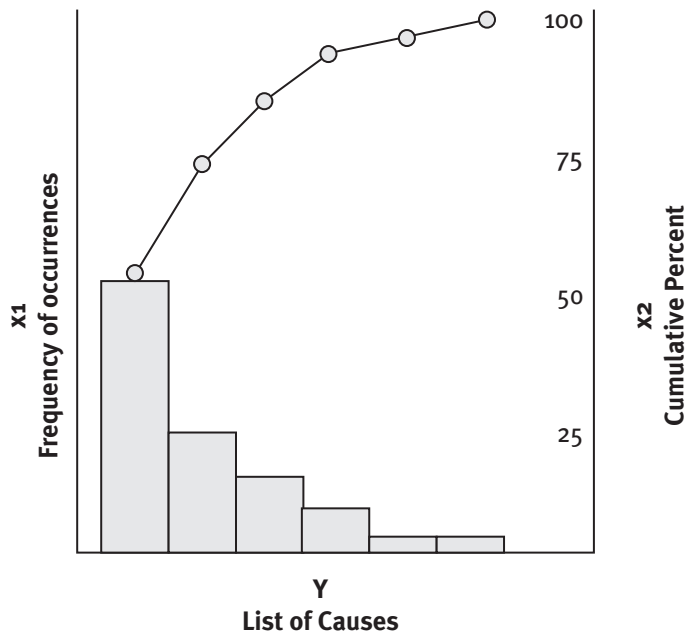
Flowcharts, also called *process maps*, are used to visually display the steps of a process in sequential order. As shown in exhibit 1.7, each step in a flowchart is

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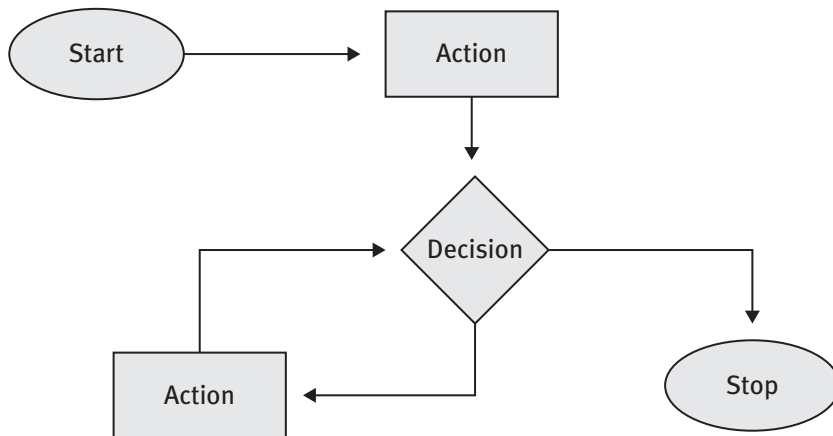
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**EXHIBIT 1.6**

A Pareto Chart Showing the Frequency with Which Causes Contribute to Error

**EXHIBIT 1.7**

A Simplified Process Map Demonstrating Flow from Start to Stop with One Decision Point



displayed as a symbol that represents a particular action (e.g., start/stop, process step, direction, decision, delay). Flowcharts are useful in quality improvement for identifying unnecessary or high-risk steps in a process, developing a standardized process, and facilitating communication between staff involved in the same process (Tague 2004). Specific improvement models include their own variations on flowcharts, such as value stream mapping in Lean.

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### **Failure Mode and Effects Analysis / Mistake Proofing**

Failure mode and effects analysis (FMEA) examines potential problems and their causes and predicts undesired results. Normally, FMEA is used to predict future product failure from past part failure, but it also can be used to analyze future system failures. By basing activities on FMEA, organizations can focus their efforts on steps in a process that have the greatest potential for failure before failure actually occurs. Prioritization of failure points, or modes, is based on the detectability of the potential failure, its severity, and its likelihood of occurrence.

Mistake proofing, or *poka yoke*, is a related concept developed in the 1960s by Japanese industrial engineer and TPS cofounder Shigeo Shingo (1909–1990). The goal of mistake proofing is to make a potential failure impossible, or at least to make failure easily detectable before significant consequences result. Mistake proofing techniques can be used to address potential failures identified during FMEA.

### **Data Collection and Analysis**

Identifying measures, setting benchmarks, and trending performance data lie at the heart of quality improvement. Various methods emphasize the ability to understand variation and recognize when trends represent true change.

### **SMART Aims**

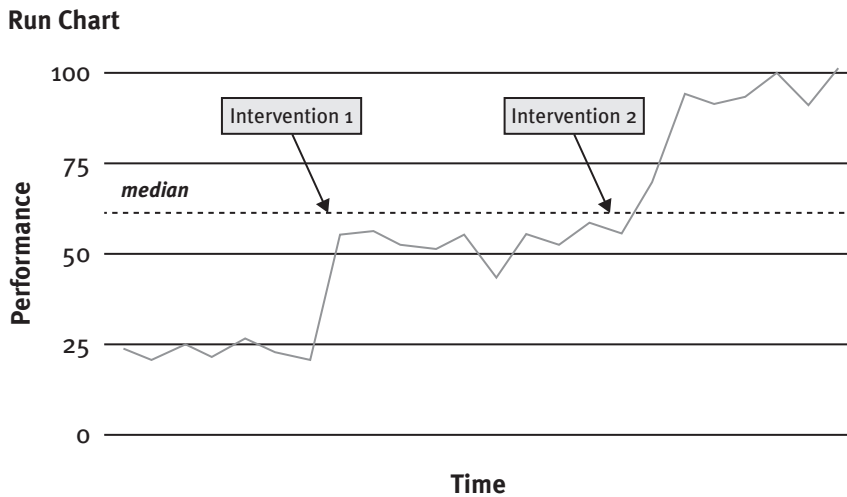
Improvement projects need to have SMART aims—aims that are specific (S), measurable (M), achievable (A), relevant (R), and time bound (T). A well-conceived aim allows a team to communicate with stakeholders, assess progress, galvanize efforts, and advertise its success.

Importantly, aims are not tied to a particular intervention. They do not specify how a team will achieve success, just what success will look like and by when. Usually, the initial aim for improvement is not to achieve a perfect performance. Instead, the aim represents a feasible incremental improvement—say, increasing the frequency of a positive outcome from 40 to 60 percent. When a team reaches its initial aim, a new one will be set. This technique emphasizes that improvement is a continuous process and that multiple improvement cycles are usually necessary to close quality gaps.

### **Run Charts and Control Charts**

Run charts graph performance over time, as shown in exhibit 1.8. They can display process or outcome measures, and their ability to display change over time makes them more useful than simple “pre” and “post” data. Often, run charts display important events in a project (such as the interventions labeled in the exhibit), helping users to assess the impact of a process change and to identify or correct any problems that arise (Tague 2004). Statistical process

**EXHIBIT 1.8**  
Run Chart  
Showing  
Performance  
on a Given  
Measure over  
Time



*Note:* Important events in a project can be added to the chart.

control charts, or simply control charts, are closely related to run charts. Control charts contain three lines: a central/control line (median), an upper control limit, and a lower control limit. These boundaries define statistically significant change and are used to monitor performance and variation.

### **Idea Creation**

When a team is seeking solutions to a quality problem, stakeholders should be engaged and encouraged to think broadly. The best solution might not be the one the team thinks of first, and outside opinions might be necessary to better understand how a proposed solution will affect real people and processes. Not all ideas are created equal. Exhibit 1.9 presents a hierarchy for improvement, with strategies such as exhortation and education at the bottom and systems-based interventions such as checklists, automation, and forcing functions at the top. Proposed solutions to quality projects are sometimes referred to as *countermeasures*.

### **Project Planning and Implementation**

Once a countermeasure is chosen, the team must begin implementing the new process or equipment. Depending on the nature of the countermeasure, this step may be extremely complex. Tools that help to organize, prioritize, and communicate are vital to keeping the team on track.

### **Stakeholder Analysis**

In truth, stakeholder analysis should be listed as a quality improvement tool in each of the seven sections. From cause analysis to knowledge transfer and spread, the management of stakeholders is key to a successful improvement initiative.

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**EXHIBIT 1.9**  
 Framework  
 Showing  
 Relative  
 Strength of  
 Interventions  
 for Quality  
 Improvement  
 Initiatives

Source: Adapted from Gosbee and Gosbee (2005).

Engaging stakeholders early allows teams to better understand processes and problems from multifaceted perspectives. In healthcare, stakeholders usually consist of the “three Ps”: patients, providers, and payers.

Although stakeholder involvement is vital, it is important to recognize that not all stakeholders are of equal importance. Stakeholders can generally be broken down into three categories. The most important stakeholders *control* the success of the project. Others have *influence* on the project and should be kept informed. The third tier will simply be *interested* in the results. Teams can decide how to manage stakeholders by understanding which of the three categories each stakeholder group is in, as well as to what extent the stakeholders already support the work of the team. An individual with control who is strongly against the project will require intensive management. An interested party who is already moderately supportive is likely sufficiently engaged.

### Checklists

Checklists are a generic tool with which to organize the steps of a project or process. They can also be used as countermeasures when improvement teams aim to standardize the workflow of frontline providers. For example, the surgical time-out before every surgery is a checklist step designed to prevent wrong-patient or wrong-site surgery and to establish a culture of safety in the operating room. Checklists can also be used to capture data measured repeatedly over time for purposes of identifying patterns, trends, defects, or causes of defects. Data collected through a checklist can be easily converted

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into performance tools such as histograms or Pareto charts (Tague 2004). The use of checklists reached near mythological status after the publication of Atul Gawande's (2010) *The Checklist Manifesto*, which revealed their ubiquity in highly reliable industries and demonstrated their potential in healthcare.

### 2×2 Matrix

The 2×2 matrix is a tool for comparing and organizing items according to two important criteria. Criteria can be chosen by the user, but they often compete or conflict in some way. Exhibit 1.10 shows a specific type of 2×2 matrix known as an *effort vs impact matrix*, which compares the potential impact of a countermeasure versus the effort needed for implementation. Potential stakeholders can be sorted by how important they are to the success of the project versus how supportive they are of the team or countermeasure, and designs can be sorted by their potential utility versus their visual appeal. 2×2 matrixes enable team members to systematically discuss, identify, and prioritize ideas and to evaluate different strategies (ASQ 2014).

### 5S

A concept from Lean methodology, 5S is a systematic program that allows workers to take control of their workspace. The aim is for the workspace to help workers complete their jobs, rather than being a neutral or, as is commonly the case, a competing factor. The program is so named because each step, in Japanese, starts with the letter S:

**EXHIBIT 1.10**  
2×2 Matrix  
Showing Effort  
Versus Impact

		Effort	
		Low	High
Impact	Low		
	High		

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1. *Seiri* (sort) means to keep only items that are necessary for completing one's work.
2. *Seiton* (straighten) means to arrange and identify items so that they can be easily retrieved when needed.
3. *Seiso* (shine) means to keep items and workspaces clean and in working order.
4. *Seiketsu* (standardize) means to use best practices consistently.
5. *Shitsuke* (sustain) means to maintain gains and commit to continuing to apply the first four items.

### **Knowledge Transfer and Spread Techniques**

A key aspect of any quality improvement effort is the ability to replicate successes in other areas of the organization. Failure to transfer knowledge effectively can cause an organization to produce waste, perform inconsistently, and miss opportunities to achieve benchmark levels of operational performance. Barriers to spread and adoption (e.g., organizational culture, communication, leadership support) can exist in any unit, organization, or system.

In 1999, the Institute for Healthcare Improvement (IHI) chartered a team to address this challenge, and IHI published a white paper titled “A Framework for Spread: From Local Improvements to System-Wide Change” in 2006. The report identified “the ability of healthcare providers and their organizations to rapidly spread innovations and new ideas” as a “key factor in closing the gap between *best* practice and *common* practice” (Massoud et al. 2006, 1). It identified the following important questions that organizations need to address when attempting to spread ideas to their target populations (Massoud et al. 2006, 6):

- Can the organization or community structure be used to facilitate spread?
- How are decisions about the adoption of improvements made?
- What infrastructure enhancements will assist in achieving the spread aim?
- What transition issues need to be addressed?
- How will the spread efforts be transitioned to operational responsibilities?

### **Kaizen Blitz/Event**

*Kaizen*, which can be translated as “continuous improvement,” was developed in Japan shortly after World War II, and it is a central concept in Lean thinking. Kaizen in any organization involves ongoing improvement that is supported and implemented at all levels of an organization. The key aspect of kaizen is the sustained focus on improving a system or process regardless of how well the system or process is currently functioning. A kaizen event, or “blitz,” is

a highly focused improvement effort aimed at addressing a specific problem. Kaizen events are short in duration—typically three to five days—and intended to produce rapid changes and immediate results. The approach taken during a kaizen blitz typically involves common improvement methodologies (e.g., DMAIC, PDSA, value stream mapping) and the participation of teams with decision-making authority from multiple departments and levels of leadership.

### Rapid-Cycle Testing and Pilots

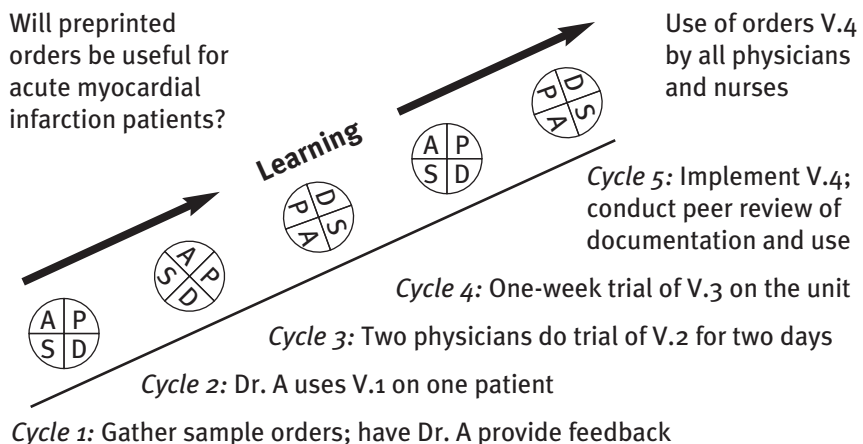
Two important characteristics of an effective spread model are (1) staff buy-in and (2) proof that the change will improve performance. Developed by IHI and shown in exhibit 1.11, rapid-cycle testing (or rapid-cycle improvement) uses various tests with small sample sizes and multiple PDSA cycles that build on lessons learned over a short period. The process is meant to concomitantly gain buy-in from staff involved in the change. Successful tests are applied to other units in the organization, whereas unsuccessful tests continue to be revised for potential spread and further implementation later.

Rapid-cycle testing is designed to reduce the cycle time of new process implementation from months to days. To prevent unnecessary delays in testing or implementation, teams or units using this approach must avoid overanalysis and remain focused on testing solutions. Rapid-cycle testing can be resource intensive, and it relies on flexibility and distributed autonomy. Therefore, it may require top-level leadership support.

Closely related to rapid-cycle testing is the act of conducting pilots. When piloting an intervention, the goal is to assess efficacy on a small scale and then modify and refine the approach before broad implementation. Pilots can

**EXHIBIT 1.11**  
Example of  
Rapid-Cycle  
Testing

#### Using Rapid Cycle to Implement Preprinted Orders



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help identify barriers to success and workarounds, presenting an opportunity to fix problems early. If successful, they can also provide quick wins that help build buy-in and goodwill among stakeholders.

## Conclusion

An organization's success depends on the foundation on which it is built and the strength of the systems, processes, tools, and methods it uses to sustain benchmark levels of performance and to improve performance when expectations are not being met. Quality improvement theory and methodologies have been available since the early 1900s, but their widespread acceptance and application have been slower in healthcare than in other industries (e.g., manufacturing). Two landmark Institute of Medicine publications—*Crossing the Quality Chasm* (IOM 2001) and *To Err Is Human* (Kohn, Corrigan, and Donaldson 2000)—described significant concerns about the US healthcare system and prompted a movement that greatly increased healthcare institutions' focus on better care and patient safety (Leape and Berwick 2005). However, the combination of technical complexity, system fragmentation, a tradition of autonomy, and hierarchical authority structures presents, in the words of Leape and Berwick (2005, 2387), a “daunting barrier to creating the habits and beliefs of common purpose, teamwork, and individual accountability.” Overcoming this barrier will require continued focus and commitment.

Sustainable improvement is further defined through will, ideas, and execution. Nolan (2007) writes: “You have to have the *will* to improve, you have to have *ideas* about alternatives to the status quo, and then you have to make it real—*execution*.” The principles described in this chapter have demonstrated success in many healthcare organizations. As technology advances and access to care improves, healthcare must continue to build on these principles as it strives to reach and maintain benchmark levels of performance. Successful coordination of care across the healthcare continuum will consistently provide the right care for every patient at the right time.

### Case 1: Mr. Roberts and the Us Healthcare System

*Note: This patient story was edited by Matthew Fitzgerald, director of the Center for Health Data Analysis at Social & Scientific Systems. It was originally composed by Heidi Louise Behforouz, MD, assistant professor of medicine at Harvard Medical School, associate physician in the Division of Global Health Equity at Brigham and Women's Hospital, and medical and executive director of the Prevention and Access to Care and Treatment Project.*

(continued)

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Mr. Roberts is a 77-year-old gentleman who is retired and living in Florida with his wife. A child of the Depression, he grew up to become an accomplished, affluent person. At age 13, he began working as a longshoreman and barracks builder. He started to experience back pain in his early 20s. At that time, he did not receive particularly good medical advice and did not pursue alternative therapies. World War II, 25 years in Asia, and life as a busy executive took priority, and the pain became a constant but secondary companion.

At age 50, the pain became unbearable. He returned to New York and spent the better part of a year “on his back.” In 1980, he underwent the first of four major spine surgeries. Since then, he has had multiple intervertebral discs partially or completely removed. Despite these operations, his pain has been worsening over the past two to three years, and his functional status has been decreasing.

Living with pain is difficult, and Mr. Roberts is not sure he deals with it very well. He does not want to take narcotics, because they interfere with his ability to stay sharp and active, and he has stomach problems that prohibit the use of many nonnarcotic medications. Most of the time, he experiences only mild or temporary relief of his pain.

The pain is exhausting and limits his ability to do what he wants, but Mr. Roberts remains active and gets out as much as he can, even taking his wife dancing on Saturday nights. The worst thing about the pain is that it is changing—worsening—and he is uncertain of its future trajectory. As the pain increases, how will he survive? What are the possibilities that he will remain active and independent?

Mr. Roberts states that he has had “reasonably good” doctors. He is also well informed, assertive, and an active participant in his healthcare. He feels he is privileged because he has connections and advocates for himself, enabling him to expand his healthcare options and seek the best providers and institutions. Nonetheless, even though his overall experience in the healthcare system has been favorable, many instances of his care have been less than ideal.

### ***Communication Deficits and Lack of a Team Approach***

Mr. Roberts has observed that the lack of communication between providers is a huge problem. He has multiple specialists who care for different parts of his body; however, no one person is mindful of how these systems interact to create the whole person or illness. He is never sure whether one physician knows what the other is doing or how one physician’s prescriptions might interfere or interact with another’s. The physicians never seem

inclined to “dig deeply” or communicate as team members treating one person. On many occasions, physicians have recommended therapies that have already been tried and failed. On other occasions, they disagree on an approach to a problem and leave Mr. Roberts to decide which advice to follow. No system is in place to encourage teamwork. “Unless the physician is extremely intelligent, on the ball, or energetic, it just doesn’t happen,” he says.

Seldom do physicians listen to his full story or elicit his thoughts before jumping to conclusions. Mr. Roberts suggests that physicians should carefully analyze their therapeutic personalities. They cannot assume that all patients are alike or that all patients will react similarly to a given intervention. Each patient needs to be treated as an individual, and service needs to be respectful of individual choice.

Record keeping and transfer of information are also faulty. Despite the fact that the physicians take copious notes, the information is often not put to use. Mr. Roberts has expended a great deal of time and energy ensuring that his medical records are sent to a new consultant’s office, only to find within a few minutes of the encounter that the consultant has not reviewed the chart or absorbed the information. This realization has affected how he uses care. For instance, at one point, Mr. Roberts’s stomach problems were worsening. His gastroenterologist was away on vacation for four weeks, and there was no covering physician. The thought of amassing his patient records for transfer to another physician (who likely would not review them and would suggest the same tests and therapies) was so unpleasant that he chose to go without care.

### ***Removing the Question Mark from Patient–Provider Interactions***

Mr. Roberts is particularly concerned with patients’ inability to know the true qualifications of their physicians or evaluate their prescriptions. At one point, he was experiencing severe arm and finger pain. Assuming these symptoms were related to his spine, he sought the advice of a highly recommended chief of neurosurgery at a premier academic center. After eliciting a brief history and performing a short examination, the chief admitted him to the hospital.

The following day, an anesthesiologist came into the room to obtain his consent for surgery. Mr. Roberts had not been told that surgery was under consideration. He asked to speak to the neurosurgeon and insisted on additional consultations. Three days later, a hand surgeon reassured him that his problem was likely self-limiting tendonitis and prescribed conservative therapy. Within a few weeks, his pain had been resolved. Mr.

*(continued)*

Roberts was grateful that he had followed his instinct but was concerned for other patients who might not have asserted themselves in this manner.

### ***Mismatch Between Supply and Demand***

Mr. Roberts also noticed a profound disconnect between supply and demand in the healthcare system. In 1992, his pain had become particularly disabling, and his mobility was extremely restricted. His physicians suggested that he see a neurosurgeon, but there was only one neurosurgeon in the county. Despite his health emergency, he was not able to make an appointment to see this neurosurgeon for more than ten weeks. No other solutions were offered.

In pain and unable to walk because of progressively worsening foot drop and muscle weakness, he sought the help of a physician friend. This friend referred him to a “brash, iconoclastic” Harvard-trained neurologist, who in turn referred him to a virtuoso neurosurgeon at a county hospital 100 miles away. After only 20 minutes with this neurosurgeon, he was rushed to the operating room and underwent a nine-hour emergency procedure. Apparently, he had severe spinal cord impingement and swelling. The neurosurgeon later told him that he would have been a paraplegic or died had he not undergone surgery that day.

Mr. Roberts subsequently had a series of three more spinal operations. Postoperative care was suboptimal; he had to travel 100 miles to see the surgeon for follow-up. Eventually, this surgeon chose to travel to a more centralized location twice per month to accommodate patients in outlying areas.

Mr. Roberts states that we need to “overcome petty bureaucracies” that do not allow matching of supply with demand. The ready availability of quality care should be patient driven and closely monitored by a third party that does not have a vested interest in the market.

### ***Knowledge-Based Care***

Mr. Roberts is concerned about the status of continuing medical education. He guesses that physicians in large, urban teaching hospitals can easily to keep abreast of the latest diagnostic and therapeutic advances but that the majority of other physicians may not have similar opportunities. The system does not necessarily encourage physicians to keep up to date. This lack of current, in-depth knowledge is particularly important as issues of supply and demand force consumers to seek care in “instant med clinics.” For example, Mr. Roberts believes “emergency care” to be an oxymoron.



On many occasions, he has gone to the emergency department and had to wait four to five hours before being treated. This experience is unpleasant and forces people to seek alternative facilities that may not provide the best care for complex, chronically ill patients.

Mr. Roberts also feels that we need to learn from our errors as well as from our successes and that groups of physicians should be required to regularly review cases and learn how to deliver care in a better way. This analysis needs to occur internally within institutions as well as externally across institutions. Ideally, the analysis would directly involve patients and families to gain their perspectives. In addition, the learning should be contextual; we should not only learn how to do better the next time but also know whether what we are doing makes sense within our overall economic, epidemiological, and societal context.

Mr. Roberts believes that high-quality healthcare is knowledge based. This knowledge comes not only from science but also from analysis of mistakes that occur in the process of delivering care. Patients should be involved in the collection and synthesis of these data. The transfer of knowledge among patients, scientists, and practitioners must be emphasized and simplified.

### ***Nonphysician/Nonhospital Care***

Mr. Roberts has been impressed with the quality of the care he has received from nonphysician clinicians, and he believes the growth of alternative healthcare provider models has been a definite advance in the system. As an example, Mr. Roberts cites the effectiveness of his physical therapists as healthcare providers; they have been alert, patient conscious, conscientious, and respectful. Mr. Roberts believes that their interventions “guide people to better life,” and his functional status has improved as a result of their assistance. In addition, these providers are careful to maintain close communication with physicians. They function as members of a team.

Postoperative care also has improved. At the time of his first surgery more than two decades ago, Mr. Roberts spent two weeks in the hospital. Now, after three days he is discharged to a rehabilitation facility that is better equipped to help him recuperate and regain full function.

Mr. Roberts knows how crucial his family and friends are to his medical care. Without their support, recommendations, constant questioning, and advocacy, his condition would be more precarious. The system needs to acknowledge patients’ other caregivers and involve them in shared decision making and knowledge transfer.

## Case 2: Stopping Catheter-Related Bloodstream Line Infections at the Johns Hopkins University Medical Center and Hospitals Across the United States

Evidence indicates that medical errors result in part from the lack of a patient safety culture—a culture that encourages detection of quality problems—and from poor communication and teamwork in addressing quality problems. In response to these findings, in 2001 a team of researchers at the Johns Hopkins University Quality and Safety Research Group developed an innovative, comprehensive program to improve patient safety at the Johns Hopkins Hospital, a 1,015-bed tertiary care facility that treats more than 268,000 patients annually from across the United States and around the world. This case illustrates many of the improvement concepts and tools described in this chapter.

The efforts of the Johns Hopkins team led to the creation of the Comprehensive Unit-Based Safety Program (CUSP). CUSP is a program of continuous measurement, feedback, and improvement that was designed to

- be implemented sequentially in work units,
- improve the culture of safety,
- enable staff to focus safety efforts on unit-specific problems, and
- include rigorous data collection through which tangible improvements in patient safety are empirically derived to educate and improve awareness about eliminating central line–associated bloodstream infections (CLABSI).

It engages frontline staff and uses a combination of tools and compliance reports to achieve improvement goals.

Implementation of CUSP consists of five major steps:

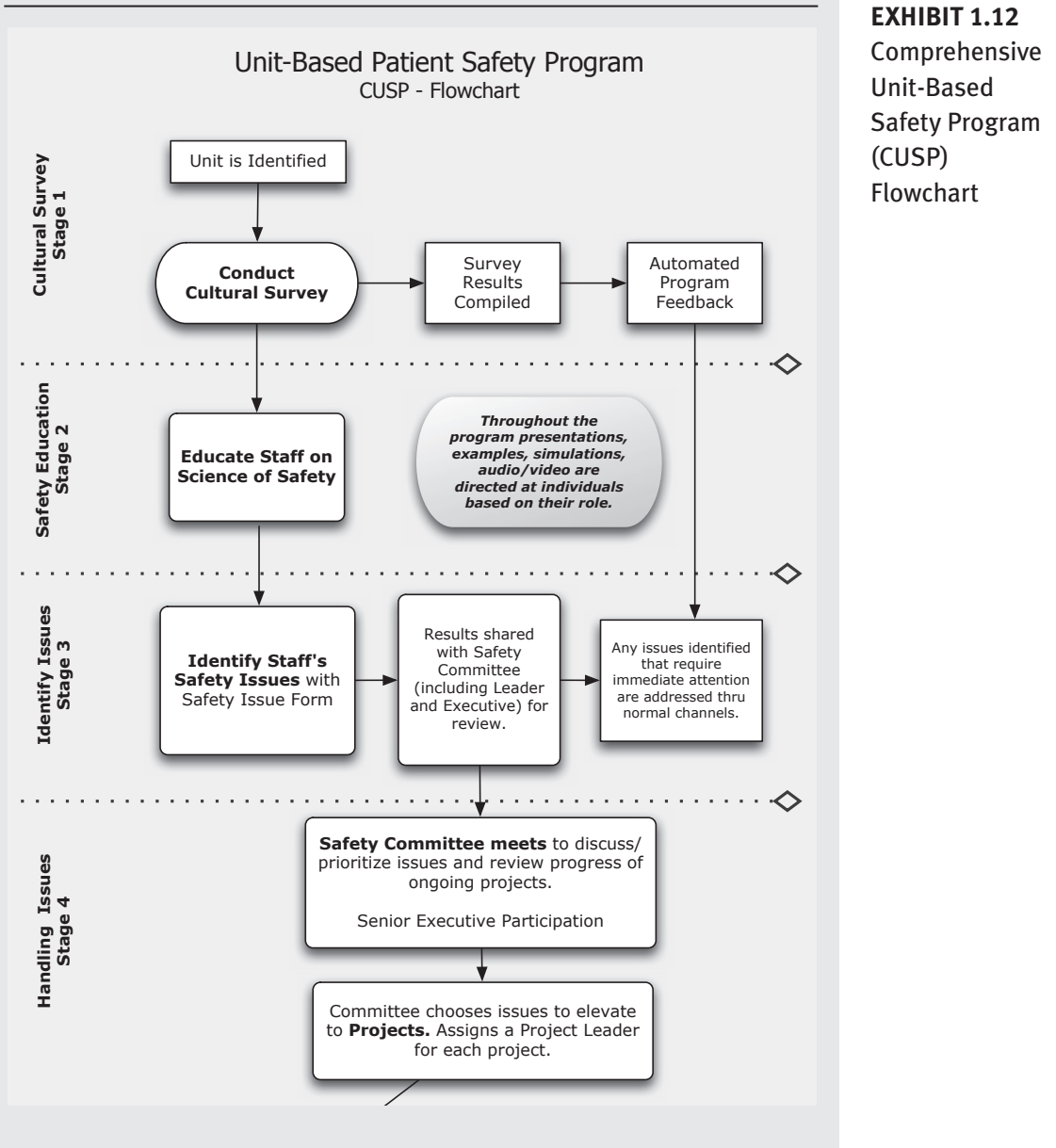
1. Train staff in the science of safety (e.g., basic strategies for safe design, including standardized processes and independent checklists for key processes).
2. Engage staff in identifying defects (e.g., ask staff how the next patient could be harmed on their unit).
3. Perform senior executive partnership/safety rounds (i.e., have hospital executives interact and discuss safety issues with staff on hospital units).
4. Continue to learn from defects by answering four questions:
  - a. What happened?
  - b. Why did it happen?

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- c. What was done to reduce risk?
  - d. How do we know that risk was actually reduced?
5. Implement tools for improvement (e.g., morning briefs, daily goals checklists, operating room debriefings).

A detailed flowchart of CUSP is provided in exhibit 1.12.

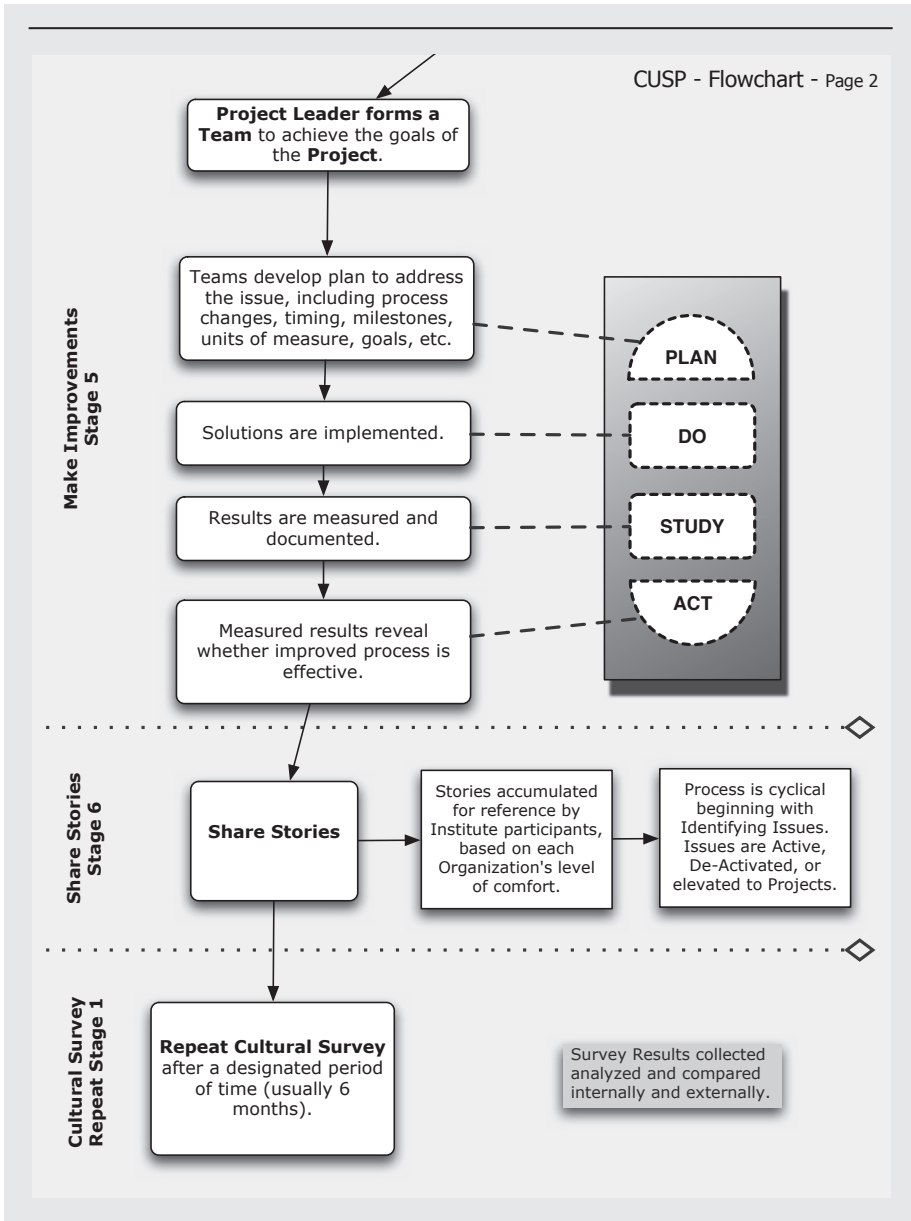


**EXHIBIT 1.12**  
Comprehensive  
Unit-Based  
Safety Program  
(CUSP)  
Flowchart

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**EXHIBIT 1.12**  
Comprehensive  
Unit-Based  
Safety Program  
(CUSP)  
Flowchart  
(continued)



Source: Published with permission of Johns Hopkins HealthCare LLC.

The program was first piloted in two Johns Hopkins Hospital surgical intensive care units (ICUs). Errors are more common in ICUs because of the severity of patients' conditions. Furthermore, errors in ICUs are likely to cause significant adverse outcomes because of the high-risk nature of the patient population.

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In implementing the program, at least one physician and one nurse from each unit were required to participate. These individuals had to dedicate four to eight hours per week to CUSP implementation and serve on the improvement team. Program expenses were the costs associated with CUSP team members' time.

Upon initial investigation of the work, researchers uncovered encouraging findings:

- *Length of stay (LOS)*: LOS decreased from 2 days to 1 day in one unit and from 3 days to 2.3 days in the other unit.
- *Medication errors*: The medication error rate dropped from 94 percent to 0 percent in one unit and from 40 percent to 0 percent in the other unit.
- *Nursing turnover*: The nurse turnover rate decreased from 9 percent to 2 percent in one unit and from 8 percent to 2 percent in the other unit.
- *Safety culture*: The percentage of staff who self-reported a positive safety climate increased from 35 percent to 52 percent in one unit and from 35 percent to 68 percent in the other unit.

Because of the considerable success of the pilot program, CUSP was implemented in approximately 170 clinical areas across the Johns Hopkins Hospital. Subsequently, CUSP was implemented at hospitals across the state of Michigan in collaboration with the Michigan Health and Hospital Association's Center for Patient Safety and Quality.

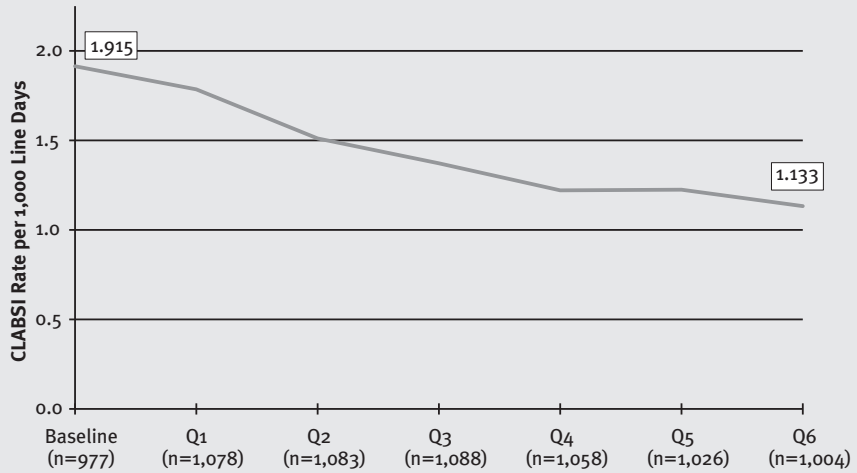
A total of 108 ICUs initially participated in the Michigan program. The program brought about dramatic decreases in CLABSI rates in Michigan hospitals, from a mean of 2.7 infections per 1,000 catheter days to 0 infections per 1,000 catheter days 18 months after implementation.

The success of the program did not go unnoticed. AHRQ awarded the Health Research and Educational Trust (HRET), a nonprofit research and educational affiliate of the American Hospital Association, an \$18 million contract to spread CUSP to hospitals across the United States to reduce CLABSI. The new program—On the CUSP: Stop BSI—was implemented in 44 states as well as throughout Spain and England. More than 1,000 hospitals and 1,800 hospital units across the 44 states, the District of Columbia, and Puerto Rico have collectively reduced the national CLABSI rate from a baseline of 1.915 infections per 1,000 line days to 1.133 infections, a relative reduction of 41 percent (see exhibit 1.13).

(continued)

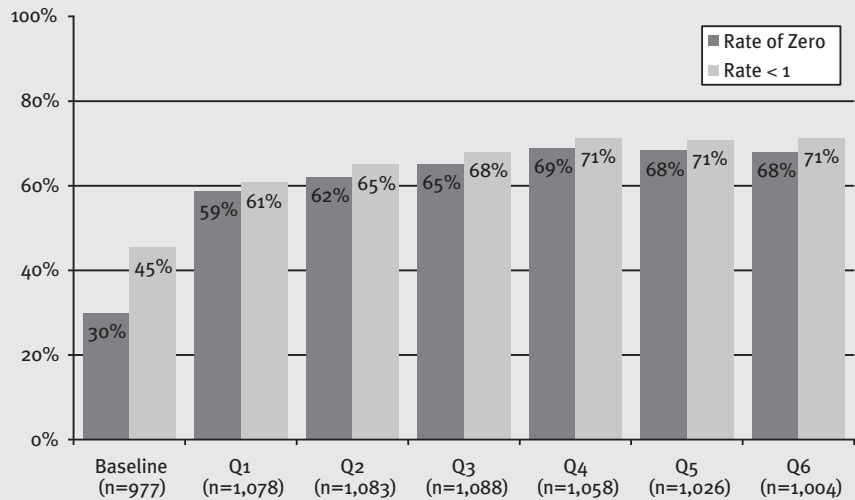
**EXHIBIT 1.13**

Average  
CLABSI Rates  
(infections per  
1,000 catheter  
days) per Unit



Source: AHRQ (2013). Used with permission.

**EXHIBIT 1.14**  
Percentage of  
Reporting Units  
with CLABSI  
Rate of 0/1,000  
or Less than  
1/1,000 Central  
Line Days



Source: AHRQ (2013). Used with permission.

The percentage of participating units with a 0 percent CLABSI rate also increased drastically, from 30 percent to 68 percent of all units (see exhibit 1.14). Additionally, the percentage of units reporting a CLABSI rate of less than one per 1,000 line days increased over time from 45 percent to 71 percent.

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Building on the success of the On the CUSP: Stop BSI program, HRET also led the implementation of a neonatal CLABSI prevention program in partnership with the Perinatal Quality Collaborative of North Carolina (PQCNC). This effort resulted in a decrease in CLABSI rates from 2.043 at baseline in August 2011 to 0.855 in August 2012—a 58 percent relative reduction.

In addition to the expanded efforts to reduce CLABSI rates, the CUSP toolkit is now being applied to address other hospital-acquired infections, most notably catheter-associated urinary tract infections (CAUTI). HRET is working with numerous partners on the On the CUSP: Stop CAUTI project to reduce CAUTI rates by 25 percent over 18 months.

The path to improvement has not been simple; it has required collaboration between a variety of multidisciplinary stakeholders. Nonetheless, the perseverance of clinical leaders and organizations across the United States continues to make the On the CUSP: Stop BSI program and its many successive iterations a notable success.

*Sources:* AHRQ (2017); Health Research and Educational Trust, Johns Hopkins University Quality and Safety Research Group, and Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality (2013, 2011); Johns Hopkins Medicine (2018); Patient Safety Group (2013); Pronovost et al. (2006).

## Study Questions

1. Think of an experience you, a family member, or a friend has had with healthcare. Gauge the experience against IOM's six aims, and identify any opportunities for improvement.
2. Describe three instances in which outcomes would not be a good measure of healthcare quality, and explain why.
3. Do you agree that care can be both high quality and inefficient? Why or why not?
4. What are some of the challenges to spreading change? Identify two key questions/issues that need to be considered when applying change concepts in an organization or system.
5. How would a healthcare organization choose elements to measure and tools for measurement when seeking to improve the quality of care?
6. What are some of the key elements common to the various tools discussed in this chapter?
7. What is the difference between a quality improvement method and a quality improvement tool? Provide examples of each.

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