



CHAPTER ONE

FOUNDATIONS OF HEALTH CARE QUALITY

Chapter Outline

Defining Quality

Contributions of Quality Theorists—Nothing New under the Sun

Quality Management Methodologies

Organizations Making an Impact on Quality and Safety Standards

Centers for Medicare and Medicaid Services

Institute for Healthcare Improvement

Agency for Health Research and Quality

National Quality Forum

The Leapfrog Group

Data: The Foundation of Quality Management

Summary

Key Terms

Quality Concepts in Action

References

Suggestions for Further Reading

Useful Websites

Key Concepts

- Understand issues involved in defining the concept of quality in health care.
- Introduce important quality theorists.

- Describe quality methodologies.
- Explain the role of agencies and groups that have an impact on health care quality.
- Review the role of data as the foundation of quality management.

Quality, which is easily recognized—and even more easily recognized in its absence—is surprisingly hard to define. One knows it when one experiences it, be it in a car, a restaurant, or a health care organization, and one knows when it is missing. It can be considered an attitude or orientation, a dedication of individuals in an organization to strive for excellence, or quality can be based on an individual's perception and his or her value system.

Perhaps the least controversial definition of quality was proposed in 1990 by the Institute of Medicine (IOM), an independent, nonprofit organization that advises decision makers and the public about health care issues: "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" (Lohr, 4). It should be noted that "desired health outcomes" are difficult to define and measure, and may be dependent on knowing the population and the community served. To understand quality, it is useful to know the history of how quality management has evolved, the significant thinkers and theorists who have contributed to defining quality, and the organizations that have influenced how health care is delivered in the United States.

Defining Quality

Quality standards are not fixed entities but rather should be thought of as a moving target, going between better quality or worse quality, defined by the expectations of customers. If customer expectations are met, quality is considered to be high. However, meeting customer expectations is complicated because customers themselves may not even be aware of or able to articulate their expectations regarding quality. For this reason, many organizations conduct satisfaction surveys and analyze complaints in order to better understand what customers want from their health care experience.

In fact, health care quality has to meet the expectations of many groups of customers: patients and their families, physicians, organizations, regulators, payers, and communities. Each of these customers may have different expectations of quality, such as access to care (do customers/patients get the care they need?) and effectiveness of care (are they better?). Medical outcome expectations, or effectiveness, are usually set through professional organizations and

adopted as standards of care. Today, patients and payers have information and opinions about their care that is eroding the primacy of physicians to be the sole setters of expectations. Patients, communities, governmental agencies, and payers are setting standards in addition to physicians.

Contributions of Quality Theorists—Nothing New under the Sun

Many of the early quality theorists defined methods, tools, and techniques that are still being used today in health care settings. Many of the problems identified by these quality thinkers still exist today. Many of the solutions they proposed are still being discussed today. Each of these prominent theorists contributed something to our understanding of what quality means and how to provide quality outcomes. A brief introduction to some of the highlights of their work in quality follows.

Florence Nightingale

In thinking about medical quality, the place to start is with Florence Nightingale (1820–1910), an English social reformer and statistician. She is considered to be the founder of modern nursing and became famous for her nursing skills with wounded soldiers during the Crimean War. However, her work encompassed more than improving nursing practice and broadening nursing education. In addition, she was an advocate for health care reform and wrote works to educate laypeople about medical knowledge. Nightingale was also a social reformer, especially of women's rights and hunger relief. She had the good fortune to be born into a wealthy family to a progressive-thinking father who encouraged her education, especially her exceptional mathematical and analytic skills.

Nightingale can be credited with creating the framework for quality management, using data as the bases for graphics about monthly improvements in mortality associated with her sanitary reforms. She understood the association among overcrowding, sanitation, infection, and mortality. In this way, she linked cause with effect. She pioneered the visual representation of statistical information, using the pie chart (see Figure 1.1) and the histogram (see Figure 1.2) to illustrate sources of patient mortality.

These figures reveal the same information in different formats. Both, however, make it clear at a glance that the majority of deaths (60 percent) were the result of poor hygiene and sanitation, double the number of deaths from battle wounds. Graphical displays are powerful representations of information.

Nightingale's comprehensive statistical analysis of rural India's sanitation was instrumental in reform. In 1873, she reported that mortality among the

FIGURE 1.1. CAUSES OF PATIENT MORTALITY PIE CHART

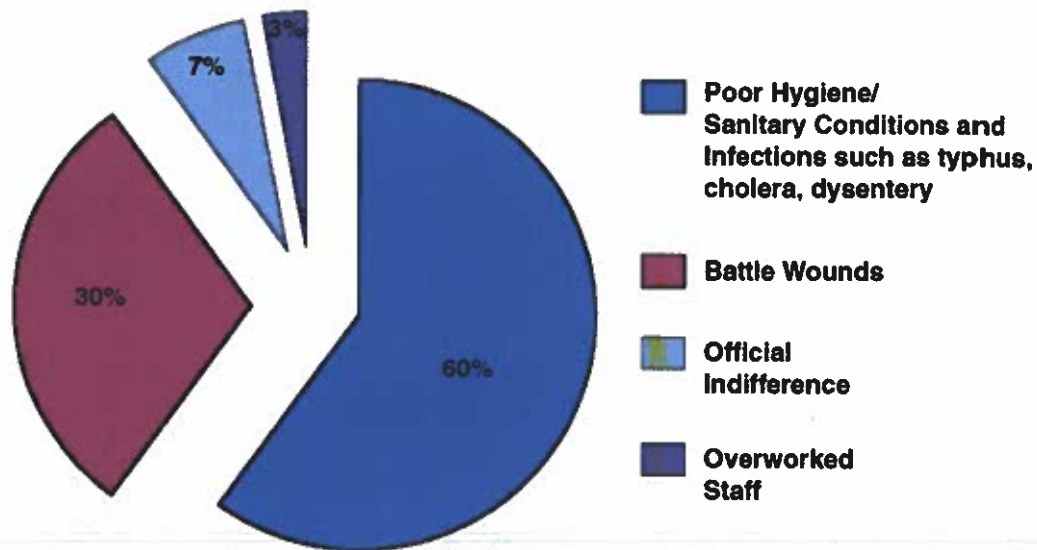
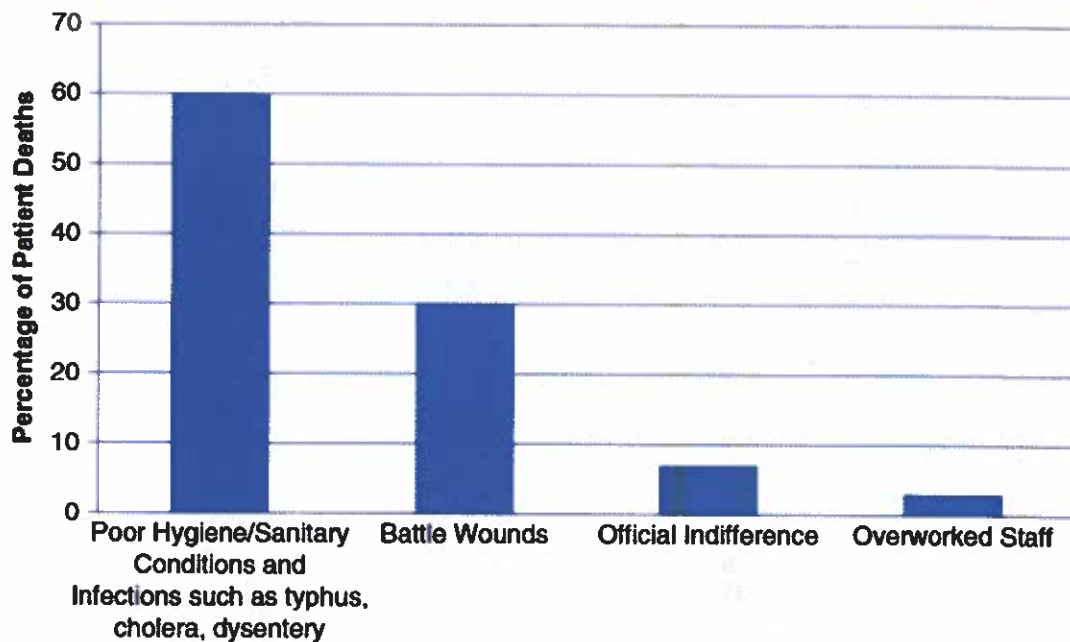


FIGURE 1.2. CAUSES OF PATIENT MORTALITY HISTOGRAM



soldiers in India had declined from 69 to 18 per 1,000. She knew that “statistics of a hospital ought to include not only the nominal list of the dead, but the cause of death” as well (Joint Commission on Accreditation of Healthcare Organizations [JCAHO] 1999, 146). Today, 150 years after her work, the health care community sees the value of using **outcomes measurements**

(data describing a patient's health state) in identifying quality care and cost effectiveness. Nightingale "realized that if judgments of outcomes were to matter, it would require attention to accurate data collection and accurately defined measures" (Batalden and Mohr 1999, 11).

In addition to understanding and exposing cause and effects and promoting outcomes measurements based on creditable data, Nightingale also understood that problems could be caused not by individuals alone but by systems. She understood the structures, processes, and waste in health care organizations; she set standards for staffing. All these ideas are still being discussed in quality management departments today. Many people think they are discovering new ideas, but Nightingale was using these ideas, and most productively, long ago.

Ernest A. Codman

Like Nightingale, Ernest Amory Codman (1869–1940) was a medical reformer who sought to improve medical care by analyzing outcomes, or what he called **end results**. He tracked his patients on end-results cards, noting demographic data, diagnosis, treatment, and outcomes—data that health care organizations are still attempting to accurately collect and analyze today. Codman worked to standardize care and reduce variation in order to create efficiency as well as good outcomes. He was the first physician to promote the study of outcomes and **evidence-based medicine** (making judicious use of the most current research and information to make medical decisions); before Codman, only Florence Nightingale had concerned herself with these ideas.

Codman believed that physicians should be held accountable for the success of their care, and if their patients did not have good outcomes, physicians should question why not and change their practice accordingly. Codman's idea was straightforward: "The common sense notion that *every* hospital should follow *every* patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, 'If not, why not?' with a view to preventing similar failures in the future" (Codman 1934, Preface).

The surgeons who were his colleagues at Massachusetts General Hospital were not eager to embrace this level of accountability, and in frustration Codman quit and opened up his own End Result Hospital, where he was able to practice what he preached, using performance measurements to evaluate care and make improvements. This concept of end results was a forerunner of what is today termed *evidence-based medicine*. At his hospital, between 1911 and 1916, of the 337 patients who were discharged, Codman recorded 123 errors. Not only did he record these results but he published them to promote what we now call **transparency** (access to reliable accurate information about care). Codman believed physicians should admit to and learn from their mistakes.

Codman was concerned with the types of medical errors that might prevent good results and developed a classification system for errors: lack

of technical skill, poor surgical judgment, and lack of diagnostic skill or failures in equipment. Today we talk about “waste” and “value,” concepts that Codman was concerned with decades ago. Today we think of waste as overuse, underuse, misuse of medical services, failure of care coordination, administrative complexity, and fraud (Health Policy Brief 2012). Codman’s concept of waste involved unnecessary deaths caused by ill-judged operations or poor diagnoses, functions associated with surgeons. He wanted to use the data accompanying the evaluations to publicly rank surgeons. Unsurprisingly, he was not popular with his peers. Even today, physicians are reluctant to work from standards, claiming that it impinges on their individual judgment and promotes “cookbook” medicine. They prefer the evidence of their experience rather than the recorded experience of others.

A tireless crusader for quality, Codman was instrumental in founding the American College of Surgeons and its Hospital Standardization Program, which later became the Joint Commission on Accreditation of Healthcare Organizations (now called The Joint Commission, TJC), a not-for-profit accrediting agency that evaluates quality of care and patient safety. Codman’s ideas are promoted today by government and regulatory agencies (such as the Centers for Medicare and Medicaid Services [CMS] and TJC), as well as private professional groups (e.g., Institute for Healthcare Improvement [IHI] and the Leapfrog Group). Remarkably, a century later, Codman’s commonsense approach to the evaluation of care is still not universally accepted by the medical establishment.

William Andrew Shewhart

William Andrew Shewhart (1891–1967), a physicist, engineer, and statistician, is another pioneering quality theorist, known for developing **statistical quality control** (using statistical methods to assess and improve quality) and the Shewhart improvement cycle of **Plan-Do-Study-Act (PDSA)**. Employed in industry for Western Electric and Bell Telephone, among others, his work highlighted the importance of reducing variation (i.e., changes) in a process and continuously monitoring that process. What now seems obvious, that variation leads to poor quality, was a new idea with Shewhart.

An example of the importance of standardization could be taken from any arena, not just manufacturing or health care. Think of building a house. If the roof is too small, the rain and snow will come in; if a door is too big, it won’t close. We expect no variation in our products, not some of the time but all of the time. We want standardization. But health care quality management professionals today are unable to convince clinicians of the importance of standardization and lack of variation. As Dr. Donald Berwick, president emeritus and senior fellow at the Institute for Healthcare Improvement and the former administrator of the Centers for Medicare and Medicaid Services, admonished many years after standardization was first proposed by Shewhart:

“Professionals need to embrace the scientific control of variation in the service of their patients and themselves” (1991, 1212).

Shewhart described how lack of standardization increased variation and degraded quality, and he framed variation as the result of one of two causes, either assignable (or special) cause variation or chance (or common) cause variation. Significantly, in 1924 he described the first **control chart** for distinguishing between the two (see Chapter 7). Control charts launched the idea of statistical process control and quality improvement. Shewhart said that data contained both signal and noise, and it was important to separate the two. He realized that bringing a process into statistical control where there is only a chance cause of variation would enable accurate predictions of future outcomes as well as be efficient economically; in other words, control would reduce waste and improve quality.

Among Shewhart’s goals was to help management make good decisions, based on data rather than subjective experience. To combine creative management with statistical analysis, he developed what he called the Learning and Improvement cycle, now known as the PDSA cycle of quality improvement (see Chapter 6). Shewhart believed that constant (re)evaluation of practice would lead to successful outcomes. He worked with and influenced the thinking of Edward Deming and Joseph Juran, and his concept of statistical control led to the development of the **Six Sigma** improvement process (a data-driven methodology to identify and eliminate defects in a process) later adopted by General Electric under Jack Welch, which transformed that organization.

William Edwards Deming

W. Edwards Deming (1900–1993) was also an engineer and statistician who worked with Shewhart and is often associated with his teachings. He was also a proponent of the PDSA cycle of performance improvement (which Deming called the Shewhart cycle and others call the Deming cycle). He worked in Japan after World War II and had a significant impact on improving that country’s devastated manufacturing process.

The Japanese had studied Shewhart’s techniques, and after the war, as part of their reconstruction efforts, they looked for an expert to teach them about statistical control. Deming trained Japanese managers and business executives in concepts of quality as well as statistical control. His message was that improving quality would result in decreased costs. He believed that variation caused waste. When Japanese businesses applied Deming’s philosophy, they were enormously successful. The result of this success was an international demand for Japanese products. Although Deming never used the term, he is credited with developing **Total Quality Management**.

Deming encouraged business leaders to think about manufacturing as an interrelated system with a common aim rather than as a series of individual pieces. His philosophy was that when the focus of the organization and top

leaders was on quality, quality increased, costs were reduced, and market share increased, but when the focus was primarily on costs, over time, costs would rise and quality would suffer.

According to his obituary published in *The New York Times* (Holusha 1993), when he was brought in to Ford to help explain why the sales numbers of Hondas and Toyotas were superior to Ford's, he said: "Can you blame your competitor for your woes? No. Can you blame the Japanese? No. You did it yourself." He exhorted managers to treat workers like partners and encourage them to identify problems in the workplace without fear of reprisals. Today, in the health care setting, we are still wrestling with issues of fear, reprisals, and problem-solving methods.

DEMING'S PHILOSOPHY OF QUALITY

Deming's philosophy of quality is summarized in what he called a System of Profound Knowledge, which is comprised of four key ideas:

1. Appreciation of a system
2. Understanding variation
3. A theory of knowledge
4. Understanding human behavior and psychology

When Deming was hospitalized and he received inefficient care, he realized that health care organizations had serious problems: There were many treatment delays, the showers didn't work, and so on. He blamed leaders. He saw how hard nurses worked and realized that "the design of this system to reduce unwanted variation in care could only be improved by a leadership that was obviously lacking" (Best and Neuhauser 2005, 311). He wanted organizations to be customer-focused and for leaders to be aware of and meet customer expectations. Today, the CMS has developed patient surveys (Hospital Consumer Assessment of Healthcare Providers and Systems [HCHAPS]) to determine whether customer expectations were met or not.

Avedis Donabedian

Avedis Donabedian (1919–2000) was born in Lebanon to Armenian parents who fled to an Arab village north of Jerusalem. He trained as a physician there before moving to America and teaching in medical schools, among them Harvard and the University of Michigan. Often called the father of health care quality, he was very interested in health services research, especially in assessing quality of care. In *Evaluating the Quality of Medical Care* (written in 1966),

Donabedian discusses the importance of evaluating quality through examining structure, process, and outcome, referred to as the Donabedian model of patient safety. The structure, process, and outcome model remains today the dominant paradigm for evaluating health care quality.

Donabedian adopted and adapted the systems approach of industrial quality theorists to the delivery of health care services. His writings lay out seven “pillars” of quality health care: efficacy, efficiency, optimality, acceptability, legitimacy, equity, and cost. Every one of Donabedian’s pillars is being discussed today, sometimes as if it was a novel idea.

Donabedian had modern and sophisticated ideas about how to assess quality, discussing in his writings issues related to access to care, the importance of measuring and evaluating quality, the completeness and accuracy of medical records, observer bias, patient satisfaction, and cultural preferences in health care, all still relevant today. However, his thinking about quality in health care was also quite personal. He said:

Systems awareness and systems design are important for health professionals, but are not enough. They are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system’s success. Ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can then work backward to monitor and improve the system. (Mullan 2001, 137)

An excellent quality management program includes internalized caring and compassion for the patient.

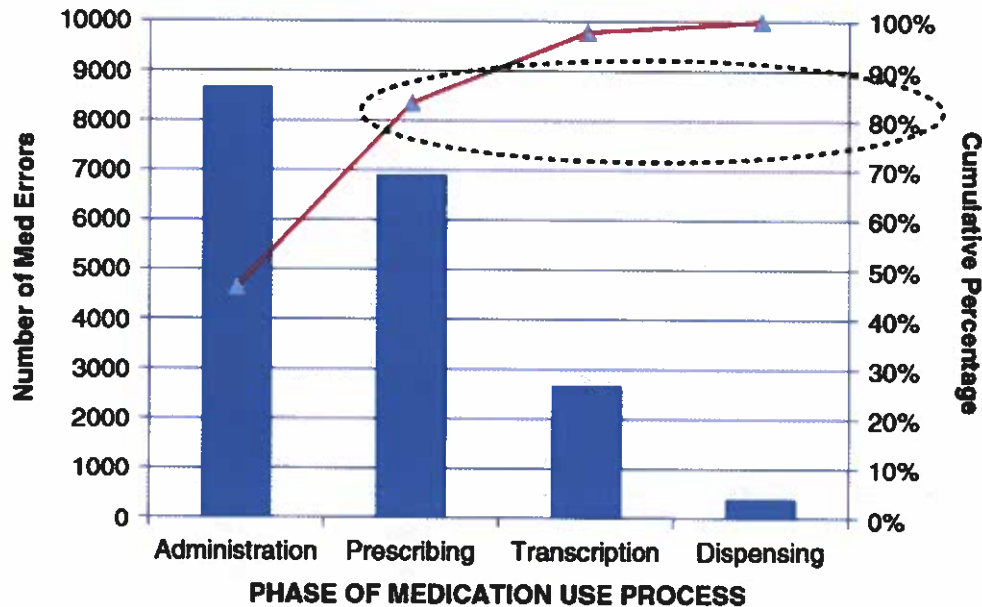
Joseph M. Juran

Joseph M. Juran (1904–2008), another influential quality theorist, was an engineer and management consultant who also worked in post–World War II Japan, helping to rebuild the country’s economy through improved manufacturing practices. Along with Shewhart and Deming, Juran is considered among the three founders of modern quality improvement. His philosophy involves three managerial processes, sometimes referred to as the “Juran trilogy”:

1. Quality planning to meet customer expectations
2. Quality control to ensure that processes are working efficiently
3. Quality improvement to optimize results.

Juran was also the first to apply the **Pareto principle**, developed by the Italian economist Vilfredo Pareto, to quality—the idea that 80 percent of a problem is caused by 20 percent of the causes. Therefore, if improvements were focused on the 20 percent, the results would have big effects.

FIGURE 1.3. MEDICATION ERROR RATE PARETO CHART, JANUARY 2011–JUNE 2011



A Pareto chart is basically a bar chart with the highest bar, representing the largest amount of defects or problems, on the left and the shortest bar, representing the fewest problems, on the right (see Figure 1.3). The left vertical axis shows the frequency of the occurrence and the right vertical axis shows the cumulative percentage which is tracked by a line graph.

Figure 1.3 shows that the vast majority of medication errors, in fact 80 percent, occur during the administrative and prescribing phases of the medication use process. Juran was at the forefront of linking quality and cost. One might say that, with a Pareto chart, you know where your buck will return the biggest bang. The chart is useful in prioritizing issues for resource expenditure, in this case improving processes related to medication administration and prescription.

Among Juran's greatest contributions to quality theory was his realization that organizational culture is responsible for the inertia that must be overcome in order to implement change. Juran credited his insight to Margaret Mead's *Cultural Patterns and Technical Change* (1955) (Best & Neuhauser, 2006), which convinced him that only by understanding an organization's cultural barriers to change could change be implemented; change had to conform to the organization's values. Today quality management professionals are still struggling to implement methods to change health care culture to encourage staff to accept and adopt changed practices.

Philip Crosby

Philip Crosby (1926–2001) was a business management expert who contributed to quality theory. His work became popular in the 1970s when American manufactured goods were losing market share to Japanese products because they were superior in quality to American-made products. Crosby is best known for promoting the concept of **zero defects** in a process. In 1979 he published a book, *Quality Is Free*, in which he said that to improve quality, “do it right the first time” (DIRFT), an approach that is surprisingly difficult to implement, as evidenced by unresolved gaps in safety that haunt hospitals today. His writings were popular with the public, especially when he described the cost of poor quality. Crosby, like his contemporary quality theorists, realized that poor quality or good quality was dependent on leaders setting up expectations for quality.

Crosby promoted four fundamental principles of quality:

1. Quality is defined as conformance to product/customer requirements.
2. Quality should involve prevention of errors.
3. The performance standard for quality is zero defects.
4. Quality can be quantified by the price of nonconformance (the cost of non-valued activities).

Issues of conforming to requirements, focus on prevention, zero defects, and understanding the cost of poor quality are still discussed in health care improvement efforts (Creech 1994, 478).

CONTRIBUTIONS OF QUALITY THEORISTS

Florence Nightingale

- Link causes with effects.
- Use data to understand outcomes.
- Analyze problems as flawed systems.

Ernest Codman

- Track end results to understand problems in care.
- Reduce variation to create efficiency.
- Insist that physicians be accountable for the results of their treatments.

William Shewhart

- Use statistical quality control.
- Improve with Plan-Do-Study-Act cycle.
- Monitor variation, which leads to poor quality.
- Understand cause of variation through control charts.

William Deming

- Use statistical quality control.
- Link improved quality with decreased cost.
- Eliminate variation, which causes waste.
- Hold leaders accountable for quality.

Avedis Donabedian

- Analyze structure, process, and outcomes as the basis of quality.
- Maintain the seven pillars of health care quality: efficacy, efficiency, optimality, acceptability, legitimacy, equity, and cost.

Joseph Juran

- Meet customer expectations.
- Link quality and cost.
- Recognize the importance of organizational culture to excellent quality.
- Allocate resources using Pareto chart analysis.

Philip Crosby

- Demand zero defects.
- Focus on error prevention.
- Eliminate variation.
- Link quality and cost.

Quality Management Methodologies

Many methods of managing quality have been proposed and used over the years. Regardless of specifics, they all use data to analyze processes of care and stress effective communication strategies to move information among caregivers and across levels of care.

Total Quality Management

Many of the ideas of prominent quality theorists, such as Crosby, Juran, and Deming, among others, have led to an approach to quality called Total Quality Management (TQM), which shifts the responsibility for quality from a hierarchical and bureaucratic approach to a holistic or decentralized one. TQM is a customer-focused management system that uses data and effective communication techniques to integrate quality into the culture of an organization, congruent with the organization's mission, vision, and goals.

All employees are expected to adopt this customer-focused approach, which targets satisfying customer expectations. If employees are to be empowered to take risks and speak their minds, then there can be no fear of reprisal in the workplace; management and leaders have to support quality efforts and encourage effective communication strategies both among employees and between employees and managers.

TQM stresses processes, which takes inputs from internal or external sources and transforms them, through defined steps, to outputs for customers. Performance measures are used to monitor the process and check for unexpected variation. TQM expects continued assessment and improvement (such as with the PDSA cycle) to meet expectations and lower costs. In addition to leadership commitment, TQM stresses teamwork to realize common objectives of long-term quality improvement.

Continuous Quality Improvement

Continuous Quality Improvement (CQI) is a general theory of quality based on the work of Shewhart, Deming, and Juran. Although the principles of CQI predate these theorists, their recognition of the importance of applying the scientific method to quality contributed to the theory.

In 1989, Dr. Brent James published *Quality Management for Health Care Delivery*, which summarized a multihospital initiative to develop quality monitoring and management tools. He said a successful quality improvement model should ask three questions:

1. Are we doing the right things?
2. Are we doing things right?
3. How can we be certain that it's done right the first time, every time? (13)

These fundamental questions are still being asked today, and attempts to answer these questions seem to be getting ever more complicated. In order to achieve a system that delivers high-quality care and appropriately controls expenses, two principles have to be central:

1. Eliminate inappropriate variation.
2. Document continuous improvements.

Both these principles depend on accurate measurements and a valid database to provide the groundwork for quality management. In addition, health professionals need to translate theory into practice to transform the hospital culture so that quality management theory is internalized and recognized as being more than simply compliance with regulatory standards.

DEFINING QUALITY TERMS

It may be useful to distinguish among terms often used in discussions of quality: *quality assurance*, *quality control*, *quality improvement*, and *quality management*.

- *Quality assurance (QA)* is focused on ensuring that the product—in this case, the delivery of health care services—is meeting expectations through the identification of problems or defects in the system, developing solutions, and monitoring the effectiveness of the solutions. QA is used widely by state and federal regulatory agencies, such as state departments of health and The Joint Commission, to reinforce identifying problems in the delivery of care and developing corrective actions to improve them. QA is also focused on compliance with regulatory expectations.
- *Quality control (QC)*, often used interchangeably with quality assurance, is a system that monitors the desired level of quality to ensure that specific goals or criteria are met through continuous inspection and that makes corrections when problems are identified.
- *Quality improvement (QI)* is aimed at performance improvements through assessing current conditions and developing strategies for improvements. Unlike QA, which identifies problems, QI is focused on identifying common causes and on processes that require improvements rather than outcomes. The goal is to prevent errors rather than repair them. For example, QA might investigate a patient's death by conducting a review of the patient's record to identify any gaps in care. QI would examine all the records of all mortality in a defined population and identify commonalities that could be the focus of improvement efforts.
- *Quality management (QM)* is an organization-wide philosophy that oversees activities that have an impact on ensuring the excellence of processes, policies, and practices. The focus is on the prevention of errors, the use of data-driven decision making, and continuous performance improvement. QM depends on quality planning, QC, QA, and QI to evaluate and achieve consistent quality standards, using a deliberate methodology to monitor and effect change. QM professionals need to understand organizational processes and statistical analytics.

Organizations Making an Impact on Quality and Safety Standards

Many agencies, both governmental and private, have had an impact on improving patient safety, especially since media attention has brought gaps in safety to the attention of the public. The organizations discussed next have driven

changed practices and really forced health care organizations to better assess and improve their quality and safety.

Institute of Medicine

The IOM is a nonprofit, nongovernmental advisory agency that is part of the National Academy of Sciences. Although founded by Congress in 1970, it is an independent organization, comprised of volunteer experts and scientists, with the mission of advising policy makers, professionals, and health and science leaders about improving the nation's health.

Highly publicized incidents of patients dying in well respected health care institutions spurred the IOM to explore issues related to patient safety. The result was the 1999 report, *To Err Is Human: Building a Safer Health System* (edited by Kohn, Corrigan, and Donaldson). This report stated that not only is health care of poor quality but it is actually dangerous. As many as 98,000 people die in hospitals every year due to medical errors, a startling observation that brought patient safety to the forefront of national attention. That staggering number revealed to the public that something was seriously broken in our health care system. The IOM made these recommendations to respond to what was obviously a crisis in health care delivery:

1. Improve leaders and knowledge.
2. Identify and learn from errors.
3. Set performance standards and expectations for safety.
4. Implement safety systems in health care organizations.

In 2001, the Committee on Quality of Health Care in America of the IOM published another report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, which recommended a redesign of the American health care system, offering performance expectations; direction for policy makers and health care leaders; guidance for improving the patient-physician relationship; suggestions as to how to align efficiency, cost savings, and quality; and other innovations to try to close the quality gap or, rather, the quality chasm. The report proposed six aims for improvement, saying health care should be: safe, efficient, effective, patient-centered, timely, and equitable. Although none of these concepts is new, the publicity surrounding these recommendations was a powerful motivator for health systems to examine their delivery systems. The IOM stressed that performance standards needed to be set to ensure improved safety.

Unfortunately, even with this spur to action, health care has not changed very much, and patient safety and efficiency of services are still poor. Improvements have been glacially slow in coming. In fact, a 2013 study in the *Journal of Patient Safety* estimates that as many as 440,000 patient deaths a year are caused by preventable medical errors (J. James 2013). It is not obvious why health care has resisted meaningful change. Whether due to a lack of professional

oversight, unwillingness of leaders to invest resources in improving and sustaining safe practices, reluctance of clinicians to value quality data, or fear of malpractice suits, medical care remains fragmented, highly individualized, costly—and frequently unsafe.

In 2006, the IOM published yet another report, sponsored by the CMS, on the prevalence and cost of preventable medication errors, and outlined a national agenda to reduce and prevent them. The report, titled *Preventing Medication Errors*, found that medication errors are surprisingly common and costly, estimating that conservatively over 1.5 million preventable adverse drug events (ADEs) occur in the United States each year, with an annual cost of \$887 million for treating ADEs in the Medicare population alone.

To improve this situation, the report recommends changing the way health care does business. Physicians, caregivers, pharmacists, and patients have to improve communication. The paternalistic tradition of “doctor knows best” and patient knows nothing has to be transformed so that physicians listen to patients and educate them about their medications, informing them “about the risks, contraindications, and possible side effects of the medications they are taking and what to do if they experience a side effect” (<http://iom.nationalacademies.org/~media/Files/Report%20Files/2006/Preventing-Medication-Errors-Quality-Chasm-Series/medicationerrorsnew.ashx>).

The second step the report recommends is to make use of information technology (IT) in prescribing and dispensing medications and to put effective monitoring programs in place to track the incidence of ADEs and improvements. The third recommendation of the report is to improve packaging and labeling of medications to avoid look-alike, sound-alike medications that could be easily confused. These few reasonable changes do not seem difficult to implement or even technologically expensive and would increase the quality and safety of patient care; yet many organizations have not fully implemented these recommendations.

The Joint Commission

TJC is a nonprofit accrediting agency that has made a huge impact on improving patient safety by defining standards of care and surveying hospitals to assess whether they attain those standards. Over the years, TJC has articulated specific goals for patient safety and developed standards of care that need to be met for accreditation. Its mission is to continuously improve health care by evaluating and inspiring health care organizations to provide safe and effective care of high quality and value.

The organization has its roots in the work of Ernest Codman’s concept of “end results” and his proposal that hospitals adhere to specific standards. As early as 1917, the American College of Surgeons (ACS) developed a one-page document called *Minimum Standard for Hospitals*. One year later, in 1918, when the ACS surveyed hospitals, only 89 of 692 hospitals met the minimum

safety standards outlined in the document (http://www.employeescreen.com/wp-content/uploads/sites/6/joint_commission_history.pdf).

By 1951, the ACS was joined by other professional groups (the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association) to create the Joint Commission on Accreditation of Hospitals as an independent, not-for-profit accrediting organization. By the 1960s, accreditation by TJC was necessary in order to participate in Medicare and Medicaid programs. Few health care organizations could afford to ignore the Joint Commission on Accreditation of Hospitals' standards for accreditation, and efforts were made to comply. In 1987, the name of the organization was changed to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to reflect its expanded scope, which included standards for home care agencies, managed care groups, ambulatory care, and laboratory certification, among others, and in 2007, the organization was renamed The Joint Commission (TJC).

Today TJC accredits over 20,000 health care organizations and publishes an annual report identifying hospitals that attain excellent standards. It also reports hospitals that use evidence-based standards that result in excellent patient outcomes based on performance measurements. TJC also rates top-performing hospitals on key quality measures for specified conditions, such as heart attack, heart failure, pneumonia, surgical care, children's asthma, inpatient psychiatric services, stroke and venous thromboembolism. Organizations and patient groups take these ratings very seriously.

In 2002, TJC established its National Patient Safety Goals (NPSGs) program, which targets specific areas of concern with regard to patient safety. The goals identify areas in which patient safety is vulnerable, such as the spread of infection due to multidrug-resistant organisms, catheter-related bloodstream infections, and surgical site infections. Solutions to these problems are recommended, based on evidence.

The NPSGs' focus on prevention efforts are fueled by the public's heightened awareness of medical errors. Because issues of safety are part of a national effort to improve health care, and organizations are required to measure improved outcomes and preventive efforts for accreditation, the goals have an impact. Both TJC and the CMS require that the NPSGs be met. Specific sets of NPSGs have been defined by these two organizations for different types of health care organizations: hospitals, long-term care facilities, behavioral health organizations, laboratories, networks, ambulatory centers, and office-based surgical centers.

Other TJC standards directly address the patient experience. For example, TJC has pain assessment and management standards to deal with chronic or acute pain. These standards apply to different kinds of health care organizations: ambulatory care facilities, behavioral health care organizations, critical access hospitals, home care providers, hospitals, office-based surgery practices,

and long-term care providers. The standards require that patients be asked about their pain, and if appropriate, care and treatment should be provided. Patients should be screened initially and then on an ongoing basis for pain and should be educated about pain management.

In 2010, the CMS determined that it would oversee TJC's accreditation.

NATIONAL PATIENT SAFETY GOALS

The following list illustrates the kinds of problems the 2013 Hospital National Patient Safety Goals address and their suggested solutions:

Identify Patients Correctly

- Use at least two ways to identify patients. For example, patient name and date of birth.

Improve Staff Communication

- Get important test results to the right staff person on time.

Use Medicines Safely

- Label medicines that are not labeled (in syringes, cups, and basins).
- Take extra care with patients on blood thinning medications.
- Record and transfer information about patient medications.
- Make sure the patient knows which medicines to take at home.

Prevent Infection

- Follow hand hygiene guidelines from the Centers for Disease Control or World Health Organization.
- Use proven guidelines (evidence-based standards) to prevent infections after surgery, such as from catheters and from central lines.

Identify Patient Safety Risks

- Find out which patients are most likely to attempt suicide.

Prevent Mistakes in Surgery

- Make sure that the correct surgery is done on the correct patient at the correct place on the patient's body.
- Mark the correct place on the patients' body where the surgery is to be done.
- Pause before the surgery (time out) to ensure that a mistake is not being made.

Source: http://www.jointcommission.org/assets/1/6/2016_NPSG_HAP_ER.pdf

Centers for Medicare and Medicaid Services

The CMS is the government agency that reimburses hospitals for patients enrolled in the Medicare and Medicaid programs. Hoping to encourage health care organizations to participate in transparent quality and patient safety initiatives, the CMS is using its clout as the primary payer for health care services to offer financial incentives to hospitals that successfully report their compliance with specific quality measures. Quality measures can help health care organizations and consumers assess how well an organization provides care to its patients. These measures are based on scientific evidence and often reflect professional guidelines and established standards of care.

Organizations that do not report quality measures are penalized with reduced reimbursement. Oversight by the government agency that effectively holds the purse strings is among the most effective driving force for improved quality and changing practices that consumers have. Knowing that quality measures are being made available to the curious, increasingly educated, and cynical consumer of health care is helping to create accountability and further transparency of information.

Hospital Compare

The measures collected enable the CMS to track and trend patient safety issues over time and to publicly report quality of care indicators on their website. This resource for health care consumers is: www.hospitalcompare.hhs.gov. Hospital Compare, as this program is called, enables consumers to compare multiple hospitals on performance measures related to heart attack, heart failure, pneumonia, surgery, and other conditions.

It also displays information regarding 30-day mortality for heart attack and heart failure and mortality rates for pneumonia. Other additions include information on outpatient facilities, emergency departments, surgical process measures, as well as 30-day readmission measures for heart attack, heart failure, and pneumonia patients. Readmission rates serve as both a quality measure and a measure of organizational efficiency. Organizations are encouraged to investigate why patients return within 30 days. Was their discharge premature, was the care inadequate, or was the cause due to other factors?

Figure 1.4 shows a webpage from the Hospital Compare website that compares two hospitals for unplanned readmission for heart failure patients. Hospital A has more readmissions than the national average rate of 23 percent. Hospital B is just at the average. Neither hospital is below average, and it should be noted that the average is still quite high. If you or a member of your family were being treated for heart failure, you might want to find a hospital in the “green” zone—that is, one that performs better than the national average.

FIGURE 1.4. HOSPITAL COMPARE WEBPAGE FOR UNPLANNED READMISSIONS

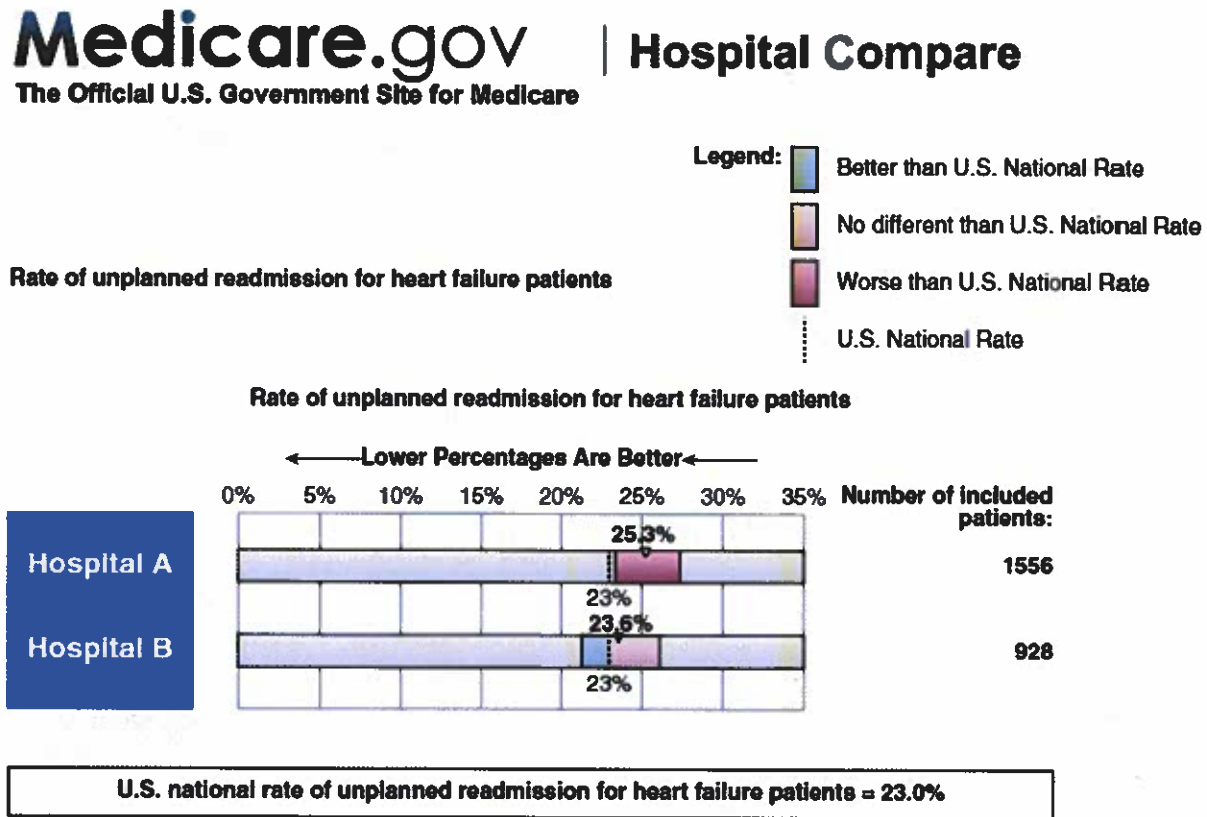


Figure 1.5 shows another type of graphical information available to consumers, the “Average time patients spent in the emergency department before they were seen by a healthcare professional.” The data show the number of minutes of three hospitals as well as the state average and the national average. If you live in an area with several hospitals, you might want to know this information. In an emergency, you would want to be seen quickly and the graph shows that hospital A has a shorter waiting time than hospital B or C.

Not only does the CMS publish information about process of care measures as part of Hospital Compare, but it has added a patient experience survey called Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). HCAHPS uses a standardized survey and collects and reports reliable data on the patient experience, such as noisiness, and perspective on hospital care, such as effective communication (see Chapter 4).

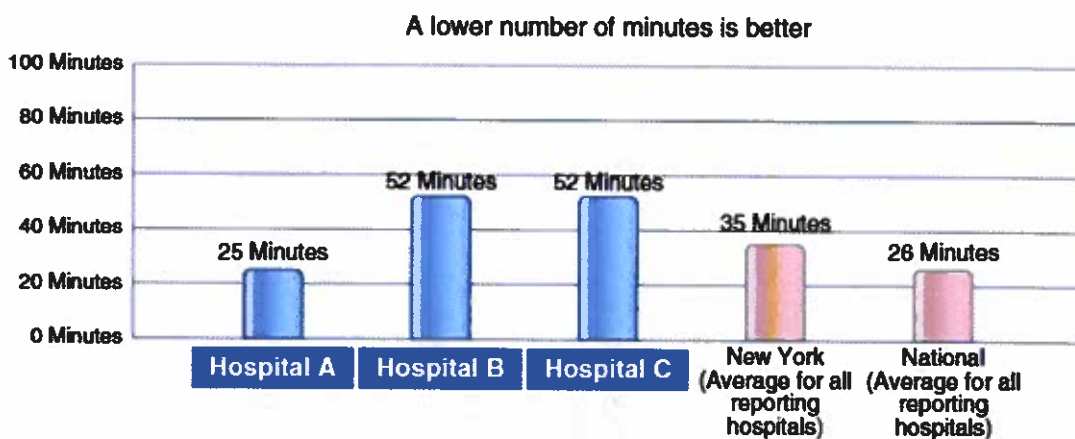
Patient Education

The CMS also promotes patient education by requiring hospitals to devise processes for clear communication about health status and care. For example, the CMS and TJC require documentation that patients who smoke and have

FIGURE 1.5. HOSPITAL COMPARE FOR WAITING TIMES

Medicare.gov | Hospital Compare
The Official U.S. Government Site for Medicare

Average time patient spent in the emergency department, before they were seen by a healthcare professional



For this measure, the rate for the top 10% of hospitals was 13 minutes.

specific conditions (e.g., heart attack, pneumonia) are supposed to receive counseling about smoking cessation during their hospitalization. It would seem only common sense that patients who smoke receive cessation counseling because it is well known that smoking results in poor health outcomes. National guidelines also recommend inpatient education because research shows that educated patients are more likely than uneducated patients to stop smoking (Keating 2016). Yet, despite common sense, experience, and guidelines, few hospitals have complied with this recommendation. Therefore, the government decided to get involved and reward compliant hospitals with financial incentives to improve care.

Pay for Performance

In response to the IOM’s reports (Committee on Quality of Health Care in America, IOM 2001; Kohn et al. 1999) on the poor quality and high cost of care, the CMS launched the pay-for-performance (P4P) initiative as part of its breakthrough initiatives to change the way care is delivered and improve the quality and efficiency of care. The CMS has defined the goal of P4P: to provide the right care for the right patient every time. “Right” care is based

on the IOM definition of providing patients with care that is safe, efficient, effective, patient-centered, timely, and equitable.

P4P is a new model for financing health care, breaking with the traditional fee-for-service–based payment, which reimburses providers for what was done *to* the patient. P4P refocuses the payment model to reimburse providers based on what was done *for* the patient. Providers who provide their patients with better outcomes would be financially rewarded; providers would be penalized for poor performance and poor outcomes, such as preventable complications or medical errors. The P4P program attempts to use the payment structure for medical care to improve quality of care and reduce costs (see Chapter 2).

Never Events

In yet another effort to improve poor clinical performance, the CMS has attached a financial consequence to never events, which are defined as serious and preventable events (e.g., wrong-site surgery, retained foreign object) that should never occur. By making organizations effectively pay for poor-quality care, the CMS is hoping to force providers to develop methods to control preventable problems. The never event initiative has the further advantage of involving the chief financial officer in quality metrics for clinical care and improvement efforts. Money is a powerful incentive to improve. In addition to financial consequences, because never events are publicly reported, there are public relations and market share consequences as the public becomes aware of which organizations have not eliminated never events.

In collaboration with other organizations, such as the National Quality Forum (NQF), the Centers for Disease Control and Prevention, the Federal Drug Administration, the Agency for Healthcare Research and Quality (AHRQ), the CMS has defined a list of errors and mistakes that should never happen. The list of never events is divided into six categories: surgical, product or device, patient protection, care management, environment, and criminal. Examples include: medication errors, hospital-acquired pressure injuries, hospital-acquired infections, patient falls, postoperative complications, wrong-site surgery, foreign object retained after surgery, blood incompatibility, and many others. A complete list of never events can be found on the AHRQ website at <http://psnet.ahrq.gov/primer.aspx?primerID=3>.

Institute for Healthcare Improvement

The IHI is an independent, not-for-profit organization dedicated to optimizing health care delivery through accelerating improvements. It focuses on building a will for change, encouraging new ideas for improvements, and working with health systems to put new ideas into action. Its goal is to help to close the quality “chasm” identified by the IOM (Committee on Quality of Health Care in America, IOM 2001) through stressing the importance of quality

improvement not only as an approach for ensuring good care but also as a business strategy. Good care is cost effective; poor care is expensive.

The IHI has initiated important projects that many health care organizations have adopted. Transforming Care at the Bedside is one such plan that focuses on improving the discharge process and the transition to home in order to reduce or avoid readmission. Another project measures patient harm through reviewing patient records for “triggers” (i.e., clues to identifying patients who have experienced adverse events). Many hospitals now call multidisciplinary Rapid Response Teams to the bedside when a patient’s condition deteriorates, a practice that the IHI supports. The IHI also supports the widespread deployment of medication reconciliation plans at all transition points in care. These, and other commonsense ideas, have made an impact on the quality and safety of inpatient care.

The IHI developed a framework for optimizing health system performance called the Triple Aim initiative. The three aims, which remain a constant challenge, are to:

1. Improve the patient experience and satisfaction.
2. Improve the health of populations.
3. Reduce the cost of health care.

The IHI is working with volunteer organizations across the United States to implement these goals.

Sepsis, a serious, often deadly, medical condition characterized by an inflammatory state caused by severe infection, has been targeted by the IHI for improvements. Mortality rates for the approximately 750,000 new sepsis cases diagnosed each year is 25 percent, or 210,000 patients (Resar et al. 2012). The IHI is hoping to reduce this number by encouraging health care organizations to develop processes for early detection and to implement standardized evidence-based practices. To promote use of evidence-based practice guidelines, the IHI has developed the “Severe Sepsis Bundle,” which is a series of treatments, based on evidence, that when implemented as a group (or bundle) will improve outcomes.

The bundle concept was developed in 2001 (Resar et al. 2012) to improve intensive care unit care through enhancing teamwork and communication for multidisciplinary teams. Improvements were significant, and the bundle concept was adapted to other high-volume areas of concern.

Agency for Health Research and Quality

The mission of the AHRQ, which is part of the U.S. Department of Health and Human Services, is to improve the quality and safety of health care and the efficiency and effectiveness of health care services. Its charge covers a wide range of expertise, including gathering data on the cost and use of health care

services, acquiring information about the results of medical treatments, defining efforts to promote quality and safety, reducing medical errors, using information technology effectively, developing prevention initiatives, and educating patients about their health care options.

In 2004, the AHRQ began a series of reports called *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies* (Shojania, K. G., et al. 2004); these reports evaluate quality strategies related to chronic conditions and practice areas. Examples of topics the reports include information about bundled payments, health disparities, effectiveness of medication adherence interventions, and improving palliative care, among many others. Quality measures are developed, based on these reports, as are educational materials and tools and guidelines for care. The CMS adopted the Patient Safety and Quality Indicators developed by the AHRQ that focus on preventable complications, such as unnecessary death and surgical wound infections, for inpatient hospitalizations for its report on hospital performance. The AHRQ is also concerned with prevention and has developed initiatives, such as the Patient-Centered Medical Home model of care (see Chapter 2), which focuses on coordinating primary care across the health care system and ensuring that the care is comprehensive and accessible to the population served.

The AHRQ supports various quality improvement and patient safety initiatives. Some of the safety initiatives sponsored by the AHRQ include the administration of the Patient Safety and Quality Improvement Act of 2005, which collects, analyzes, and provides feedback to providers about patient safety events. Quality indicators measure health care quality and track changes over time. The organization publishes an annual National Healthcare Quality Report that measures effectiveness, safety, timeliness and efficiency of care. Another initiative, **TeamSTEPPS** (Team Strategies and Tools to Enhance Performance and Patient Safety), is an evidenced-based system designed to improve communication and teamwork skills among health care providers. Another tool, a patient safety culture assessment tool, is used by hospitals, nursing homes, and medical offices to evaluate their patient safety culture and assess the impact of interventions to improve quality and safety.

The AHRQ also has a medical research component. By synthesizing scientific evidence for conditions that are high volume and important to the Medicare and Medicaid programs, this component provides evidence-based guidelines on treatments that have proven most effective. Patient-centered outcomes research compares drugs, surgeries, and different health care delivery options so that patients and their families can evaluate options and risks by going to the website: <http://www.ahrq.gov/health-care-information/topics/topic-patientcentered-outcomes-research>. Another program, the Centers for Education and Research on Therapeutics, conducts research about drugs and medical devices and provides education about them.

IT activities that improve decision making for health care providers and the quality and safety of medication management are also supported by the AHRQ. Other initiatives involve ensuring that there is value to health services. The Medical Expenditure Panel Survey (<http://meps.ahrq.gov/mepsweb/>) is the only national source of data about how Americans use services, how frequently, and at what cost.

National Quality Forum

In 1999, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry recommended that a forum for quality measurement and reporting be established as a combined effort of public and private sectors. The National Quality Forum (NQF), a nonprofit public service coalition of purchasers, providers, hospitals, and quality improvement organizations, was established in response to that recommendation and charged with developing a plan for implementing quality measurements, including data collection and reporting standards. The NQF would also endorse measures and ensure that these quality measurements and performance data were accessible to the public.

The NQF reviews and recommends standardized health care performance measures; the measures are used to evaluate organizational structure, processes and outcomes of care as well as patient perceptions about their care. The NQF recommends preferred practices that can lead to improved outcomes and develops frameworks for organizing practices. Data from performance measures are used for public reporting, such as for the CMS Hospital Compare. The data also support P4P initiatives, where excellent performance receives financial rewards and poor performance receives less reimbursement for certain conditions acquired during a patient's hospital stay. The NQF was instrumental in defining for the CMS which preventable errors should be considered never events and not reimbursed. In the future, the NQF will recommend quality measures for payment and accountability programs.

The Leapfrog Group

Established in 2000, the Leapfrog Group was formed as a response to the 1999 report *To Err Is Human*, which not only focused attention on the high death rate from preventable medical errors but also recommended that large employers use their enormous purchasing power to try to influence the quality, safety, and value of health care. Employers who spend billions of dollars on providing their employees with health care wanted some control—a way to assess whether

their investment was returning value. A group of large corporations, including General Motors, IBM, and Toyota, among others, joined forces to find a way to use their influence; they realized that “leaps” forward could be attained by rewarding hospitals that were able to implement significant safety and quality improvements. Today the Leapfrog Group is comprised of a coalition of 65 employers.

The group developed a survey to compare hospital performance on national standards of safety, quality, and efficiency. Through the transparent reporting of the results of the Leapfrog Hospital Quality and Safety Survey, vast numbers of employees—over 37 million—can evaluate the safety, quality, and efficiency of different hospitals and make informed choices about where to spend their health care dollars. Leapfrog recommends that employees choose hospitals that meet four criteria, proven to reduce error and promote quality and safety:

1. The use of computer physician order entry for medication orders to reduce prescribing errors
2. The use of evidence-based hospital referrals, which use scientific criteria, such as volume of procedures performed and outcome data
3. The use of intensivists, specially trained physicians, in intensive care units
4. A high Safe Practices Score reflecting adherence to procedures and practices recommended by the NQF and AHRQ

The Leapfrog Group believes that with these criteria, preventable medical mistakes will be significantly reduced.

The Leapfrog Group publicly reports Hospital Safety Scores based on CMS data and its own survey (<http://www.hospitalsafetyscore.org/>) that ranks hospitals on 26 measures of safety and uses incentives to reward hospitals that perform the best. The project, launched in 2012, assigns a letter grade to hospitals based on how well they protect patients from accidents, injuries, and errors. Over 2,600 hospitals across the country have been assigned a grade. The Hospital Safety Score is considered a standard measure of patient safety and has broad media approval, endorsed by the *Wall Street Journal*, *USA Today*, and the *AARP* magazine.

Data: The Foundation of Quality Management

The quality theorists, methodologies, and organizations reviewed in this chapter have all referred to data as the foundation of monitoring safety and quality of care. In this section, some of the fundamentals of quality data are introduced.

The quality theorist Edwards Deming is said to have quipped: “In God we trust. Everyone else has to use data.” The reason data are critical to evaluating care is that with data, there is some objective standardization, a way to quantify

and define the concept of “good” care or “quality” care. How else could an administrator or caregiver offer evidence that the delivery of care or the hospital services are excellent and responsive to patient expectations? Of course, a person could say “Trust me, I know my business,” but today’s health care customers are sophisticated enough to want more than paternalistic reassurance. By using data, the assessment of processes, services, outcomes and experience can be objective and effectively communicated.

Health care is awash in information, in numbers, and in data—about organizational processes, clinical processes, regulatory processes, financial information, patient information, staff information, organization-specific information, national information, and so on. But simply having data does not ensure a better understanding of processes or outcomes. The vast amount of data has to be organized and analyzed before it is meaningful and useful.

Case Example: Falls

Patient falls can be used as an example. Patient falls can result in fractures, surgery, or other problems; patients who fall often complain and sometimes institute lawsuits against the organization. Falls may also result in longer length of stay (LOS) which has financial implications to the health organization. Much information about falls is available. Professionals can retrieve data about prevalence of falls (how many people fall during a specified time period), outcomes of the falls (injuries), treatment that was required (surgery, medications), cost of the falls to the organization, and so on. Falls in one organization can be compared to falls in others. Information about the patients who fall, their ages, diagnoses, and risk factors, and about staffing ratios, times of day of falls, and medications associated with falls can be gathered and analyzed.

The issue is what to do with all this available information. When information is collected in a focused way with a question to answer (why are patients falling?) or a hypothesis to test (elderly patients on diuretics fall more than elderly patients not on diuretics), the data being gathered are quality data. The main reason to gather quality data is to evaluate whether improvements are necessary and what interventions might be effective to mitigate a problem. Those determinations cannot be made unless the causes, dimensions, and scope of the problem are known. There is a saying in quality circles: You can’t manage until you measure. Information is key to performance improvement, which requires data specifically focused on specific improvement goals. If data collection efforts are not tailored to specific issues, the result may be a great deal of information that clouds the issue rather than sheds light on it.

Once the problem is defined, the data collection efforts can be focused and finely tuned. If data show that 10 patients fall during a month on a specific unit, how should this result be interpreted? Is 10 an acceptable number, or is it an indication of a flawed process? In order to decide whether this number is acceptable, compare it to the total number of patients on the unit. If the

unit consists of 10 patients and 10 patients fall (100 percent), there is a serious problem. If the unit contains 100 patients and 10 fall (10 percent), that is less serious but perhaps still requires some investigation.

Quality Indicator

In other words, rather than a simple raw count of the number of falls, you need a percentage to better define the scope of the problem. Being a fraction, a percentage allows you to capture information about the incidence of the problem (how many people fall?) in the **numerator**, compared to the number of people who had the opportunity to fall (the number of [elderly] patients on the unit) in the **denominator**. This percentage is a quality indicator, indicating the scope of the problem. When you define, collect, and examine information with a specific purpose, you are developing a quality indicator.

The numerator and denominator of the quality indicator can be defined to examine or explore a problem very specifically. For example, if the improvement effort is focused on falls that resulted in hip fractures in patients who were 85 or older, that population would be the numerator. Or the number of patients over 85 who fell and had resulting hip fractures and who were on diuretics can be counted as the numerator. The specific population of interest defines the numerator; the general population from which the numerator comes is the denominator. In this case, the denominator represents those patients over 85 who had the opportunity to fall (see Figure 1.6).

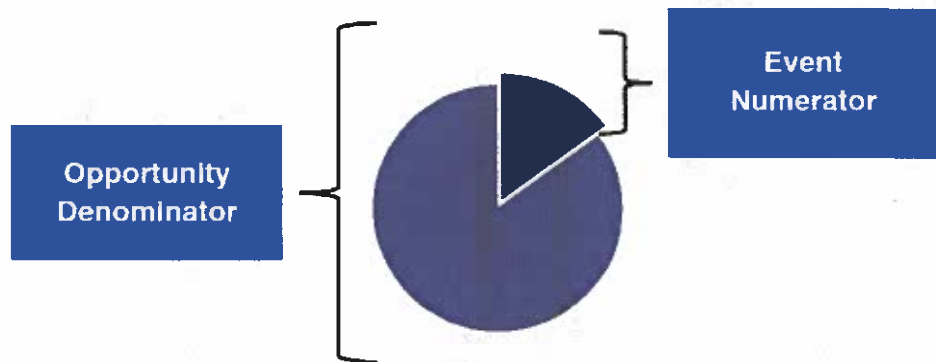
Barriers to Using Quality Data to Assess Care

Although it sounds eminently sensible to collect information using quality measures, it is a relatively new conceptualization of how to assess care. The move toward using objective information for decision making has been slow. Numbers that reveal poor outcomes are interpreted as failures rather than opportunities for improvement, and few professionals want to admit to failure. When faced with data that reveal poor outcomes, physicians often question the accuracy of the data, the competency of the coders, the appropriateness of the risk adjustment, and so on, rather than accept the numbers and try to improve the process and outcomes.

In decades past, physicians evaluated the delivery of care, discussing problems in mortality and morbidity (M&M) conferences. If a patient died, or if the mortality rate or any other problem was at a certain level, the medical literature was reviewed to see if that level was appropriate for a specific condition. Sometimes issues of competency may have been addressed; sometimes the mortality was accepted as part of the natural progression of the disease.

M&M methods do not readily result in quality management or performance improvement initiatives because there is little interest in analyzing the population with the high mortality, understanding the patient characteristics,

FIGURE 1.6. QUALITY INDICATOR



Numerator	The specific population that you are interested in; the Event (the number of patients over 85 who fell, had hip fracture, and were on diuretics)
Denominator	The entire population from which you are collecting information; the Opportunity (the number of patients over 85)
Quality Indicator	$\frac{\text{Event or Numerator}}{\text{Opportunity or Denominator}}$
Rate	$\frac{\text{Numerator}}{\text{Denominator}} \times 100$

reviewing the processes of care that might have led to the mortality, or developing measures in order to review the mortality rates over time. In terms of indicators, physicians may have discussed the numerator, but rarely would the denominator be discussed. Little effort was made to introduce, develop, and implement improvement processes. Patients were individuals who were cared for by individual physicians. Aggregating information about patient populations in order to improve patient safety is a recent development, an outgrowth of the 1999 IOM report on preventable medical errors.

Case Example: Cardiac Surgery Mortality

Often an organization is comfortable continuing its care practices and is not looking to change. However, if an external agency reviews the care provided and ranks it as poor, that shakes things up. For example, New York State was among the first to publish data about mortality rates for cardiac surgery. One of the flagship hospitals in the health care system in which we work was reported to have a higher mortality rate than comparable hospitals. Needless to say, such publicity is not good for business, and the governing board of trustees and the chief executive wanted to understand what was going on and then take steps to remediate the situation.

All rights reserved. May not be reproduced in any form without permission from the publisher, except fair uses permitted under U.S. or applicable copyright law.

When questioned about the high mortality rates, the medical staff gave the kinds of responses that they had been giving for years: Their patients were sicker than patients at other hospitals and therefore at higher risk for dying. The chief executive and the governing board weren't satisfied with that explanation and charged the quality management department with analyzing the situation.

The New York State mortality data introduced new ways of understanding data. The data were *risk-adjusted*, a very important concept. *Risk adjustment* refers to a complex statistical process that adjusts for variation among patients in order to account for differences in the patient population. Risk adjusting allows for fair and accurate comparisons of patient outcomes across organizations. By risk adjusting the cardiac mortality via a statewide cardiac advisory group, physicians could no longer assert that their patients were sicker than others as a reason for a higher mortality rate. By normalizing the population, new explanations for unexpected mortality could be formulated. As physicians became more comfortable looking at published data and learned to respect and trust the quality management department, performance improvement efforts could be undertaken to try to lower the high mortality rate.

Investigating the cause of the high mortality rate in the hospital and coupling the New York State data with available administrative data, the fact that many cardiac mortalities were associated with a secondary diagnosis of sternal wound infection or sepsis was uncovered. Patients who had had emergency surgery, had bleeding (when patients have planned surgery, often they stop taking blood thinners, but emergency patients had no warning and so remained on their blood-thinning medication), had prolonged hospital stays, and were often readmitted. Once the source of the problem was understood, solutions could be implemented to alleviate the problem: Clotting medication was administered to emergency surgery patients. Two years later the Department of Health reported that the hospital mortality rate was the lowest in the state. Administrators and physicians saw the tremendous value of using data to analyze patient outcomes.

Risk-adjusted data has made a difference in promoting changed practices. The government and private agencies dedicated to improving health care and patient safety have made a difference in spurring organizations to change. Quality management, quality metrics, and quality methodologies have become the foundation of performance improvements.

Summary

Quality management has evolved over time, with prominent health care and quality theorists contributing to improving patient safety and performance. Familiarity with the foundations of quality offers perspective on the changes being implemented in the reform environment. This chapter introduces:

- the contributions of quality theorists to quality management
- the basics of quality management methodologies
- the governmental, regulatory, and private organizations that are changing the way health care organizations monitor safety and improve care
- several examples of how quality data can be used to improve performance and encourage changed practices

Key Terms

bundle, control chart, denominator, end results, evidence-based medicine, numerator, outcomes measurements, Pareto principle, Plan-Do-Study-Act, quality data, risk-adjusted, Six Sigma, statistical quality control, TeamSTEPPS, transparency, zero defects

Quality Concepts in Action

The occurrence of never events in a hospital setting is a marker of poor care and poor processes and will have negative financial repercussions for the organization. As a hospital administrator or nurse manager, how would you react to reports of never events? Would you:

- challenge the data and defend the care as appropriate?
- implement new programs in the hope of improvement?
- focus on prevention to avoid the occurrence of never events?
- punish the offending staff members?
- hire new staff to combat never events?

Defend your position and explain what specific steps you would take and why.

References

- Batalden, P. B., and J. J. Mohr. 1999. "An Invitation from Florence Nightingale: Come Learn about Improving Health Care." In Joint Commission on Accreditation of Healthcare Organizations, *Florence Nightingale: Measuring Hospital Care Outcomes*. Oakbrook Terrace, IL: 11–16.
- Best, M., and D. Neuhauser. 2005. "W. Edwards Deming: Father of Quality Management, Patient and Composer." *Quality and Safety in Health Care* 14: 310–312.
- Best, M., and D. Neuhauser. 2006. "Joseph Juran: Overcoming Resistance to Organisational Change." *Quality and Safety in Health Care* 15 (5): 380–382.

- Codman, E. A. 1934. *The Shoulder: Rupture of the Supraspinatus Tendon and Other Lesions in or about the Subacromial Bursa*. Boston: Thomas Todd.
- Committee on Quality of Health Care in America, Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press.
- Creech, B. 1994. *The Five Pillars of TQM: How to Make Total Quality Management Work for You*. New York: Truman Talley Books.
- Crosby, P. 1979. *Quality Is Free*. New York: McGraw-Hill.
- Donabedian, A. 2005. "Evaluating the Quality of Medical Care." *Milbank Quarterly* 83 (4): 691–729.
- Health Policy Brief. 2012, December 13. "Reducing Waste in Health Care." *Health Affairs*.
- Holusha, John. 1993, December 21. "W. Edwards Deming, Expert on Business Management, Dies at 93." *New York Times*.
- Institute of Medicine of the National Academies. 2006. *Preventing Medication Errors: Quality Chasm Series*. <http://www.nationalacademies.org/hmd/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx>
- James, B. C. 1989. *Quality Management for Health Care Delivery*. Chicago: Hospital Research and Educational Trust of the American Hospital Association.
- James, J. 2013. "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care." *Journal of Patient Safety* 9 (3): 122–128.
- Joint Commission on Accreditation of Healthcare Organizations. 1999. *Florence Nightingale: Measuring Hospital Care Outcomes*. Oakbrook Terrace, IL: Author.
- Keating, S. 2016. "Presurgical Tobacco Cessation Counseling." *American Journal of Nursing* 116 (3): 11.
- Kohn, K. T., J. M. Corrigan, and M. S. Donaldson, eds. 1999. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press.
- Lohr, K. N., ed. 1990. *Medicare: A Strategy for Quality Assurance*, Vol. 1. Washington, DC: National Academies Press.
- Mead, M. 1955. *Cultural Patterns and Technical Change*. Geneva: UNESCO.
- Mullan, F. 2001. "A Founder of Quality Assessment Encounters a Troubled System First-hand." *Health Affairs* 20: 137–141.
- Resar, R., F. A. Griffin, C. Haraden, and T. W. Nolan. 2012. *Using Care Bundles to Improve Health Care Quality*. IIII Innovation Series White Paper. Cambridge, MA: Institute for Healthcare Improvement.
- Shojania, K. G., K. M. McDonald, R. M. Wachter, and D. K. Owens. 2004. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies Vol. 1. Series Overview and Methodology*. Rockville, MD: Agency for Healthcare Research and Quality.

Suggestions for Further Reading

- Berwick, D. M. 1991. "Controlling Variation in Health Care: A Consultation from Walter Shewhart." *Medical Care* 29 (12): 1212–1225 [abstract].

- Campbell, S. M., M. O. Roland, and S. A. Buetow. 2000. "Defining Quality of Care." *Social Science & Medicine* 51 (11): 1611–1625.
- Codman, E. A. (1918) 2013. "A Study in Hospital Efficiency: As Demonstrated by the Case Report of the First Five Years of a Private Hospital." *Clinical Orthopaedics and Related Research* 471 (6): 1778–1783.
- Deming, W. E. 1967. "Walter A. Shewhart, 1891–1967." *American Statistician* 21: 39–40.
- Deming, W. E. (1993) 2000. *The New Economics for Industry, Government, Education*, 2nd ed. Cambridge, MA: MIT Press.
- Deming, W. E. 1986. *Out of the Crisis*. Cambridge, MA: MIT Press.
- Dlugacz, Y. D., A. Restifo, and A. Greenwood. 2004. *The Quality Handbook for Health Care Organizations: A Manager's Guide to Tools and Programs*. San Francisco: Jossey-Bass.
- Dlugacz, Y. D. 2006. *Measuring Health Care: Using Quality Data for Operational, Financial, and Clinical Improvement*. San Francisco: Jossey-Bass.
- Donabedian, A. 1980. *Explorations in Quality Assessment and Monitoring: The Definition of Quality and Approaches to Its Assessment*. Ann Arbor, MI: Health Administration Press.
- Donabedian A. 1989. "The End Results of Health Care: Ernest Codman's Contribution to Quality Assessment and Beyond." *Milbank Quarterly* 67 (2): 233–256.
- Fenter, T. C., and S. I. Lewis. 2008. "Pay-for-Performance Initiatives." *Journal of Managed Care Pharmacy* 14 (6): S12–S15.
- Jha, A. K., E. J. Orav, A. B. Ridgway, J. Zheng, and A. M. Epstein. 2008. "Does the Leapfrog Program Help Identify High-Quality Hospitals?" *Joint Commission Journal on Quality and Patient Safety* 34 (6): 318–325.
- Juran, J. 1988. *Quality Control Handbook*, 4th ed. N.P.: McGraw-Hill.
- Juran, J. 2004. *Architect of Quality: The Autobiography of Dr. Joseph M. Juran*. New York: McGraw-Hill.
- Mallon, W. J. E. 2007. "Amory Codman Considered Father of Evidence-Based Medicine." 9 (3). <http://www.aaos.org/news/bulletin/janfeb07/research1.asp>
- Mallon, W. 2000. *Ernest Amory Codman: The End Result of a Life in Medicine*. Philadelphia: WB Saunders.
- "Medical Errors in the USA: Human or Systemic?" 2011. *Lancet* 377 (9774): 1289.
- Pelletier, L. R., and C. Beaudin. 2008. *Q Solutions: Essential Resources for the Healthcare Quality Professional*, 2nd ed. Glenview, IL: National Association for Healthcare Quality.
- Roberts, J. S., J. G. Coale, and R. R. Redman. 1987. "A History of the Joint Commission on Accreditation of Hospitals." *JAMA* 258 (7): 936–940.

Useful Websites

<http://www.ahrq.gov/>

<http://www.ahrq.gov/health-care-information/topics/topic-patientcentered-outcomes-research.html>