

CHAPTER 1

The Global Evolution of Continuous Quality Improvement: From Japanese Manufacturing to Global Health Services

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We are here to make another world.

—**W. Edwards Deming**

Continuous quality improvement (CQI) comes in a variety of shapes, colors, and sizes and has been referred to by many names. It is an example of the evolutionary process that started with industrial applications, primarily in Japan, and has now spread throughout the world, affecting many economic sectors, including health care. In this introductory chapter, we define CQI, trace its history and adaptation to health care, and consider its ongoing evolution. References to subsequent chapters and a previously published volume of case studies (McLaughlin, Johnson, & Sollecito,

2012) provide greater detail and illustrations of CQI approaches and successes as applied to health care.

Despite the evolution and significant progress in the adoption of CQI theory, methods, and applications, the need for greater efforts in quality improvement in health care continues unabated. For example, a major study from 2010 encompassing more than 2,300 admissions in 10 North Carolina hospitals demonstrated that much more needs to be done to improve the quality and safety in U.S. hospitals, and it may have implications for health care globally. It found that “patient harms,” including preventable medical errors and other patient safety measures, remained common with little evidence of improvement during the 6-year study period

from 2002 to 2007 (Landrigan et al., 2010). In recent years, there has been substantial progress in the greater diffusion of CQI in health care in certain sectors. For example, there has been broader institutionalization of CQI in public health in the United States, much of which can be attributed to the broader application of accreditation requirements; this is described in Chapters 11 and 12. Great progress has also been seen in the broader adoption of CQI in resource-poor countries, as documented in Chapter 13. However, with greater complexity in health care comes greater challenges; for example, greater uses of technology bring benefits and risks, as described in Chapter 4, and more widespread applications of evidence-based interventions do not necessarily provide improved outcomes (Wandersman, Alia, Cook, Hsu, & Ramaswamy, 2016). As a result, the challenge of how to cross the quality chasm (Institute of Medicine [IOM], 2001) in health care clearly remains, and our goal in this text is to help to shed light on the scope of the problem and potential solutions.

► Definitions

Quality in Health Care

The exact definition of quality in health care varies somewhat for the various sectors of health care. The World Health Organization (WHO) provides a broad-based definition that encompasses global health care as:

“the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be safe, effective, timely, efficient, equitable and people-centered.”

Safe. Delivering health care that minimizes risks and harm to service users, including avoiding preventable injuries and reducing medical errors.

Effective. Providing services based on scientific knowledge and evidence-based guidelines.

Timely. Reducing delays in providing and receiving health care.

Efficient. Delivering health care in a manner that maximizes resource use and avoids waste.

Equitable. Delivering health care that does not differ in quality according to personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status.

People-centered. Providing care that takes into account the preferences and aspirations of individual service users and the culture of their community (World Health Organization, 2017).

Quality Assurance

Quality assurance (QA) is closely related to, and sometimes confused with, CQI. QA focuses on conformance quality, which is defined as “conforming to specifications; having a product or service that meets predefined standards” (McLaughlin & Kaluzny, 2006, p. 37). QA is sometimes the primary goal of accreditation processes, for example in the 1980s and 90s hospital accreditation by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) now known as The Joint Commission (TJC) was primarily focused on meeting predefined standards (i.e., QA). More recently, especially in public health, accreditation is intended to promote CQI (see Chapters 11 and 12). QA is sometimes included in broader CQI initiatives as a way of defining baseline care, as an interim goal or as part of the process definition, but CQI is much broader in its goals than QA.

A related concept that should be mentioned briefly is quality control (QC), which was widely used in the early development of

procedures to ensure industrial product quality. Various definitions can be found for this term (Spath & Kelly, 2017), and in some cases, QC is confused with QA. It is our experience that QC is synonymous with inspection of products or other process outputs with the goal of determining which products should be rejected and/or reworked, often accompanied by counting the number of “defects.” The role and weaknesses of inspection (in comparison to CQI) are further discussed by Ross (2014) as part of the evolutionary development of CQI.

Continuous Quality Improvement (CQI)

A succinct but accurate definition of CQI in health care is: “the combined efforts of everyone—health care professionals, patients and their families, researchers, payers, planners and educators—to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)” (Batalden & Davidoff, 2007, p. 2).

To expand on that definition, for example to include public health, and describe how this term has led to a broad movement, we provide a bit of history. What was originally called *total quality management* (TQM) in the manufacturing industry evolved into CQI as it was applied to health care administrative and clinical processes. Over time, the term continued to evolve, and now the same concepts and activities are referred to as *quality improvement* or *quality management*, or even sometimes simply as *improvement*, as in the Model for Improvement (Langley et al., 2009). Except when we refer to specific historical examples, the terms CQI and QI will be used primarily throughout this text.

In health care, a broader definition of CQI and its components is this: *CQI is a structured organizational process for involving personnel in planning and executing a continuous flow of improvements to provide quality health care that meets or exceeds expectations.*

CQI usually involves a common set of characteristics, which include the following:

- A link to key elements of the organization’s strategic plan
- A quality council made up of the institution’s top leadership
- Training programs for personnel
- Mechanisms for selecting improvement opportunities
- Formation of process improvement teams
- Staff support for process analysis and redesign
- Personnel policies that motivate and support staff participation in process improvement
- Application of the most current and rigorous techniques of the scientific method and statistical process control

Institutional Improvement

Under its various labels, CQI is both an approach or perspective and a set of activities applied at various times to one or more of the four broad types of performance improvement initiatives undertaken within a given institution:

1. Localized improvement efforts
2. Organizational learning
3. Process reengineering
4. Evidence-based practice and management

Localized improvement occurs when an ad hoc team is developed to look at a specific process problem or opportunity. *Organizational learning* occurs when this process is documented and results in the development of policies and procedures, which are then implemented. Examples include the development of protocols, procedures, clinical pathways, and so on. *Process reengineering* occurs when a major investment blends internal and external resources to make changes, often including the development of information systems, which radically impact key organizational processes. *Evidence-based practice and management* involve the selection of

best health and management practices; these are determined by examination of the professional literature and consideration of internal experience, and more recently, especially in public health, accreditation requirements. The lines of demarcation between these four initiatives are not clear because performance improvement can occur across a continuum of project size, impact, content, external consultant involvement, and departure from existing norms.

Societal Learning

In recent years, the emphasis on quality has increased at the societal level. The Institute of Medicine (IOM) (now called the U.S. National Academy of Medicine) has issued a number of reports critical of the quality of care and the variability of both quality and cost across the country (IOM, 2000, 2001). This concern has increased with mounting evidence of the societal cost of poor-quality care in both lives and dollars (Brennan et al., 2004). It builds on the pioneering work of Phillip Crosby (1979), who provided a focus on the role of cost in quality initiatives that is quite relevant today. Crosby's writings emphasize developing an estimate of the *cost of nonconformance*, also called the *cost of quality*. Developing this estimate involves identifying and assigning values to all of the unnecessary costs associated with waste and wasted effort when work is not done correctly the first time. This includes the costs of identifying errors, correcting them, and making up for the customer dissatisfaction that results. Estimates of the cost of poor quality range from 20–40% of the total costs of the industry, a range widely accepted by hospital administrators and other health care experts.

This view leads naturally to a broadening of the definition of quality by introducing the concept of *adding value*, in addition to ensuring the highest quality of care, implying greater accountability and a cost benefit to

enhance the decision-making and evaluation aspects of CQI initiatives. This concept has seen a resurgence in recent years as national health plans, for example in the United States and the United Kingdom, look to minimize cost and increase value while providing the highest quality of care. For example, several leading experts propose refocusing on quality and accountability simultaneously, noting that “improving the U.S. health care system requires simultaneous pursuit of three aims: improving the experience of care, improving the health of populations, and reducing per capita costs of health care” (Berwick, Nolan, & Whittington, 2008, p. 759). These same sentiments are echoed by Robert Brook of the RAND Corporation, who proposes that the future of CQI in health care requires a focus on the concept of *value*, with consideration of both cost and quality (Brook, 2010).

Most recently, a large-scale reinforcement of these concepts in the United States is found in the goals of the Affordable Care Act (ACA), which jointly emphasizes improvements to access, quality of care, and cost reduction. Although some progress can be attributed to the ACA for example, in regard to lowering hospital acquired infections and readmissions—achievement of its long-term goals is still a work in progress (Blumenthal, Abrams, & Nuzum, 2015; Somander, 2015). These concepts are discussed in greater detail throughout this book, particularly in the final chapter (Chapter 14). Concerns about linking quality and value are not limited to the United States; similar evidence and concerns have been reported from the United Kingdom, Canada, Australia, and New Zealand (Baker et al., 2004; Davis et al., 2002; Kable, Gibbard, & Spigelman, 2002). This emphasis has played out in studies, commissions, and reports as well as the efforts of regulatory organizations to institutionalize quality through their standards and certification processes. As you will see throughout this book, concern for quality and cost is a matter of public policy.

Professional Responsibility

Health care as a whole is often likened to a cottage industry with overtones of a medieval craft guild, with a bias toward treatment rather than prevention and a monopoly of access to and implementation of technical knowledge. This system reached its zenith in the mid-20th century and has been under pressure ever since (McLaughlin & Kaluzny, 2002; Rastegar, 2004; Schlesinger, 2002; Starr, 1982). It is reinforced by the concept of *professionalism*, by which service providers are assumed to have exclusive access to knowledge and competence and, therefore, take full responsibility for self-regulation and for quality. However, much of the public policy debate has centered on the weaknesses of the professional system in improving quality of care. Critics point to excessive professional autonomy; protectionist guild practices, such as secrecy, restricted entry, and scapegoating; lack of capital accumulation for modernization; and economic self-interest as major problems. As we will see, all of these issues impinge on the search for improved quality. However, we cannot ignore the role of professional development as a potential engine of quality improvement, despite the popular emphasis on institutional improvement and societal learning. This, too, will be addressed in subsequent chapters.

► Rationale and Distinguishing Characteristics

As health care organizations and professions develop their own performance improvement approaches, their management must lead them through a decision process in which activities are initiated, adapted, and then institutionalized. Organizations embark on CQI for a variety of reasons, including accreditation requirements, cost control, competition

for customers, and pressure from employers and payers. Linder (1991), for example, suggests that there are three basic CQI strategies: true process improvement, competitive advantage, and conformance to requirements. Some institutions genuinely desire to maximize their quality of care as defined in both technical and customer preference terms. Others wish simply to increase their share of the local health care market. Still others wish to do whatever is necessary to maintain their accreditation status with bodies such as TJC, National Committee on Quality Assurance (NCQA), and others, after which they will return to business as usual. As you might imagine, this book is written for the first group—those who truly wish to improve their processes and excel in the competitive health care market by giving their customers the quality care that they deserve.

Although CQI comes in a variety of forms and is initiated for a variety of reasons, it does have distinguishing characteristics and functions. These characteristics and functions are often defined as the essence of good management and leadership. They include: (1) understanding and adapting to the external environment; (2) empowering clinicians and managers to analyze and improve processes; (3) adopting a norm that the term *customer* includes both patients and providers and that customer preferences are important determinants of quality in the process; (4) developing a multidisciplinary approach that goes beyond conventional departmental and professional lines; (5) adopting a planned, articulated philosophy of ongoing change and adaptation; (6) setting up mechanisms to ensure implementation of best practices through planned organizational learning; (7) providing the motivation for a rational, data-based, cooperative approach to process analysis and change; and (8) developing a culture that promotes all of the above (see Chapter 2).

The most radical departure from past health care improvement efforts is a willingness

to examine existing health care processes and rework these processes collaboratively using state-of-the-art scientific and administrative knowledge and relevant data-gathering and analysis methodologies. Many health care processes developed and expanded in a complex, political, and authoritarian environment, acquiring the patina of science. The application of data-based management and scientific principles to the clinical and administrative processes that produce patient care is what CQI is all about. Even with all the public concern about medical errors and patient safety, improvement cannot occur without both institutional will and professional leadership (Millenson, 2003).

CQI is simultaneously two things: a management philosophy and a management method. It is distinguished by the recognition that customer requirements are the key to customer quality and that customer requirements ultimately will change over time because of changes in evidence-based practices and associated changes in education, economics, technology, and culture. Such changes, in turn, require continuous improvements in the administrative and clinical methods that affect the quality of patient care and population health. This dynamic between changing expectations and continuous efforts to meet these expectations is captured in the Japanese word *kaizen*, translated as “continuous improvement” (Imai, 1986). Change is fundamental to the health care environment, and the organization’s systems must have both the will and the way to master such change effectively.

Customer Focus

The use of the term *customer* presents a special challenge to many health professionals (Haupt, Gilkey, & Ehringhaus, 2015). For many, it is a term that runs contrary to the professional model of health services and the idea that “the doctor knows best.” Some health professionals would prefer terms that connote the more dependent roles of *client* or *patient*. In some

cases, it is professional pride about caring for patients and their families that causes disdain for the term customer. In CQI terms, *customer* is a generic term referring to the end user of a group’s output or product. The customer can be external or internal to the system—a patient, a payer, a colleague, or someone from another department. User satisfaction then becomes one ultimate test of process and product quality. Consequently, new efforts and new resources must be devoted to ascertaining what the customer wants through the use of consumer surveys, focus groups, interviews, and various other ways of gathering information on customer preferences, expectations, and perceived experiences. Chapter 4 addresses some of the issues surrounding current methods for “surveying” customers to measure satisfaction, and Chapter 7 discusses the role of the patient in quality and safety.

System Focus

CQI is further distinguished by its emphasis on avoiding personal blame. The focus is on managerial and professional processes associated with a specific outcome—that is, the entire production system. The initial assumption is that the process needs to be changed and the persons already involved in that process are needed to help identify how to approach a given problem or opportunity.

Therefore, CQI moves beyond the ideas of participative management and decentralized organizations. It is, however, participative in that it encourages the involvement of all personnel associated with a particular work process to provide relevant information and become part of the solution. CQI is also decentralized in that it places responsibility for ownership of each process in the hands of its implementers, those most directly involved with it. Yet this level of participation and decentralization does not absolve management of its fundamental responsibility; in fact, it places additional burdens on management. In situations where the problem is within

the system (usually the case), management is responsible for change. CQI calls for significant amounts of managerial thought, oversight, flexibility, and responsibility.

CQI inherently increases the dignity of the employees involved because it not only recognizes the important role belonging to each member of the process improvement team, but it also involves them as partners and even leaders in the redesign of the process. In some cases, professionals can also serve as consultants to other teams as well as to management. Not surprisingly, organizations using CQI often experience improvements in morale (intrinsic motivation) and higher levels of engagement. When the level of quality is being measured, workers can rightly take pride in the quality of the work they are producing. The importance of motivation and engagement to CQI efforts is discussed in greater detail in Chapter 2.

Another important aspect of having a systems focus is the recognition that health care systems are dynamically complex and can include many organizations, both large (macro-) systems and small (micro-) systems (see Chapters 6 and 9). An important part of a systems focus is the understanding that improving quality and safety of complex systems requires systems thinking (see Chapter 2), a management discipline that “acknowledges the large number of parts in a system, the infinite number of ways in which the parts interact and the nature of the interactions” (Spath & Kelly, 2017, p. 44). See Ross (2014) for further description of the components of systems thinking.

Measurement and Decision Making

Another distinguishing feature of CQI is the rigorous belief in fact-based learning and decision making, captured by Deming’s saying, “In God we trust. All others bring data.” Facts do include perceptions, and decisions cannot all be

delayed to await the results of scientifically correct, double-blind studies. However, everyone involved in CQI activities is expected to study the multiple causes of events and to explore a wide array of system-wide solutions. The primary purpose of data and measurement in CQI is learning—how to make system improvements and what the impact of each change that we have already made has had on the overall system. Measurement is not intended to be used for selection, reward, or punishment (Berwick, 1996). It is surprising and rewarding to see a team move away from the table-pounding “I’m right and you’re stupid” position (with which so many meetings in health care start) by gathering data, both qualitative and quantitative data, to see what is actually happening and why. Multiple causation is assumed, and the search for answers starts with trying to identify the full set of factors contributing to less-than-optimal system performance.

The inherent barriers that accompany CQI implementation include the tension between the professionals’ need for autonomy and control and the objectives of organizational learning and conformance to best practices. Organizations can also oversimplify their environment, as sometimes happens with clinical pathways. Seriously ill patients or patients with multiple chronic conditions do not fit the simple diagnoses often assumed when developing such pathways; a traditional disease-management approach may not suffice, and a broader chronic-care model that incorporates a personalized approach may be necessary (See Chapter 7). There may also be a related tendency to try to over control processes. Health care is not like manufacturing, and it is necessary to understand that patients (anatomy, physiology, psyche, and family setting), providers, and diagnostic categories are highly variable—and that variance reduction can only go so far. One must develop systems that properly handle the inherent variability (called *common-cause variability*) after unnecessary variability (called *special-cause variability*) has been removed (McLaughlin, 1996).

► Elements of CQI

Together with these distinguishing characteristics, CQI in health care is usually composed of a number of elements, including:

- Philosophical elements, which for the most part mirror the distinguishing characteristics cited previously
- Structural elements, which are usually associated with both industrial and professional quality improvement programs
- Health specific elements, which add the specialized knowledge of health care and public health to the generic CQI approach

Philosophical Elements

The philosophical elements are those aspects of CQI that, at a minimum, must be present in order to constitute a CQI effort. They include:

1. Strategic focus—Emphasis on having a vision/mission, values, and objectives that performance improvement processes are designed, prioritized, and implemented to support
2. Customer focus—Emphasis on both customer (patient, provider, payer) satisfaction and health outcomes as performance measures
3. Systems view—Emphasis on analysis of the whole system providing a service or influencing an outcome and practicing systems thinking
4. Data-driven (evidence-based) analysis—Emphasis on gathering and using objective data on system operation and system performance
5. Implementer involvement—Emphasis on involving the owners of all components of the system in seeking a common understanding of its delivery process
6. Multiple causation—Emphasis on identifying the multiple root causes of a set of system phenomena

7. Solution identification—Emphasis on seeking a set of solutions that enhance overall system performance through simultaneous improvements in a number of normally independent functions
8. Process optimization—Emphasis on optimizing a delivery process to meet customer needs regardless of existing precedents and on implementing the system changes regardless of existing territories and fiefdoms
9. Continuing improvement—Emphasis on continuing the systems analysis even when a satisfactory solution to the presenting problem is obtained
10. Organizational learning—Emphasis on organizational learning so that the capacity of the organization to generate process improvement and foster personal growth is enhanced

Structural Elements

Beyond the philosophical elements just cited, a number of useful structural elements can be used to structure, organize, and support the continuous improvement process. Almost all CQI initiatives make intensive use of these structural elements, which reflect the operational aspects of CQI and include:

1. Process improvement teams—Emphasis on forming and empowering teams of employees to deal with existing problems and opportunities (see Chapter 6)
2. CQI tools—Use of one or more of the CQI tools so frequently cited in the industrial and health-quality literature: flowcharts, checklists, cause-and-effect diagrams, frequency and Pareto charts, run charts, and control charts (see Chapter 4)

3. Parallel organization—Development of a separate management structure to set priorities for and monitor CQI strategy and implementation, usually referred to as a quality council
4. Organizational leadership—Leadership, at the top levels and throughout the organization, to make the process effective and foster its integration into the institutional fabric of the organization (see Chapter 2)
5. Statistical thinking and analysis—Use of statistics, including statistical process control, to identify common vs. special causes of variation in processes and practices (see Chapter 4)
6. Customer satisfaction measures—Understanding the importance of measuring customer satisfaction, but also the strengths and weaknesses of available sources of data and survey methodologies in current use (see Chapter 4)
7. Benchmarking—Use of benchmarking to identify best practices in related and unrelated settings to emulate as processes or use as performance targets
8. Redesign of processes from scratch—Making sure that the end product conforms to customer requirements by using techniques of quality function deployment and/or process reengineering

Health Care–Specific Elements

The use of CQI in health care is often described as a major management innovation, but it also resonates with past and ongoing efforts within the health services research community. The health care quality movement has its own history, with its own leadership and values that must be understood and respected. Thus, there are a number of additional approaches and

techniques in health care that health managers and professionals have successfully added to the philosophical and structural elements associated with CQI, including:

1. Epidemiological and clinical studies, coupled with insurance payment and medical records data, often referred to as the basis of evidence-based practice
2. Involvement of the medical staff governance process, including quality assurance, tissue committees, pharmacy and therapeutics committees, and peer review
3. Use of risk-adjusted outcome measures
4. Use of cost-effectiveness analysis
5. Use of quality assurance data and techniques and risk management data

► Evolution of the Quality Movement

If you would understand anything, observe its beginning and its development.

—Aristotle

To fully understand the foundation of the CQI approaches that have developed over the years and the reasons for their successful implementation, it is important to understand the underlying philosophies of the founders of this “movement” and the way in which these methodologies that have been adapted to health care evolved from industry. The application of quality-improvement techniques has reached unprecedented levels throughout the world and especially in health care. What started as a “business solution” to address major weaknesses, including a reputation for poor quality, that Japan faced in its manufacturing after World War II has spread beyond

manufacturing to encompass both products and services. This proliferation includes multiple industries across the world and, most notably, all sectors of health care. W. Edwards Deming described what happened in Japan as a “miracle that started off with a concussion in 1950.” This miracle was the beginning of an evolutionary process whereby the Japanese military was transformed after the war and given a new goal: the reconstruction of Japan. As a result, “Japanese quality and dependability turned upward in 1950 and by 1954 had captured markets the world over” (Deming, 1986, p. 486). Built upon the expertise of Japanese leaders from industry, science, and the military, and with the guidance of Deming, using his own ideas and those of his colleague, Walter Shewhart, this miracle would transform industry not only in Japan, but also in many other countries around the world.

Although Deming and Shewhart both had been advocating a statistical approach to quality for some time, the Japanese were the first to implement these ideas widely. In Japan, the use of these techniques quickly spread to both product and service organizations. Outside Japan, despite slow adoption at first, this movement spread to the United States and Europe in the 1960s and 1970s. But its large-scale adoption did not occur until the 1980s in manufacturing, most notably due to competition from the Japanese automobile industry. In fact, the U.S. industry was perceived to be in a state of crisis when these methods began to receive wider acceptance. As Deming surmised, this crisis was due to poor quality that could be traced primarily to the incorrect belief that quality and productivity were incompatible. Deming demonstrated the fallacy of this notion in his landmark book, *Out of the Crisis*, first published in 1982 (Deming, 1986), thus forming the basis of what is now known as continuous quality improvement.

From this foundation, CQI has evolved exponentially—over time, across the world, and from industrial manufacturing to the provision of services. The beginning of the quality

revolution occurred in America in 1980, when Deming was featured on an NBC television documentary, “If Japan Can, Why Can’t We?” and a later PBS program, “Quality or Else,” both of which had a major impact on bringing quality issues into the U.S. public’s awareness (AmStat News, 1993).

Over many years, Deming made enormous contributions to the development of CQI, but he is perhaps best known for the 14-point program of recommendations that he devised for management to improve quality (see **BOX 1.1**). His focus was always on processes (rather than organizational structures), on the ever-continuous cycle of improvement, and on the rigorous statistical analysis of objective data. Deming believed that management has the final responsibility for quality because employees work in the system and management deals with the system itself. He also felt that most quality problems are management-controlled rather than worker-controlled. These beliefs were the basis for his requirement that CQI be based on an organization-wide commitment, including the important role and example of senior leaders.

The quality evolution later crossed fields as diverse as computer science, education, and health care—and within health care, it has evolved to encompass multiple levels and segments of health care delivery. As discussed earlier, this evolution has taken many forms and names over the years, encompassing and subsuming quality control, quality assurance, quality management, and quality improvement. Like the field itself, its name has evolved from total quality management (TQM) to continuous quality improvement (CQI), or simply quality improvement (QI).

From TQM to CQI

The evolution from TQM to CQI was more than a simple change in terminology; it represents a fundamental change in how organizations have come to recognize the importance of ensuring that changes are improvements

BOX 1.1 Deming's 14-Point Program

1. Create and publish to all employees a statement of the aims and purposes of the company or other organization. The management must demonstrate constantly their commitment to this statement.
2. Learn the new philosophy, top management and everybody.
3. Understand the purpose of inspection, for improvement of processes and reduction of cost.
4. End the practice of awarding business on the basis of price tag alone.
5. Improve constantly and forever the system of production and service.
6. Institute training.
7. Teach and institute leadership.
8. Drive out fear. Create trust. Create a climate for innovation.
9. Optimize toward the aims and purposes of the company the efforts of teams, groups, staff areas.
10. Eliminate exhortations for the work force.
11.
 - a. Eliminate numerical quotas for production. Instead, learn and institute methods for improvement.
 - b. Eliminate management by objective.
12. Remove barriers that rob people of pride of workmanship.
13. Encourage education and self-improvement for everyone.
14. Take action to accomplish the transformation.

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and that the improvement processes are ongoing, requiring learning and involvement in the process at all levels, from the individual to the organization level. CQI has been directly linked to management and leadership competencies and philosophies that embrace change and innovation as the keys to a vision of value-driven growth. The fundamentals of TQM are based on the scientific management movement developed in the early 20th century. Emphasis was given to “management based on facts,” but with management assumed to be the master of the facts. It was believed to be the responsibility of management to specify one correct method of work for all workers and to see that personnel executed that method to ensure quality. Gradually, that perspective has been influenced by the human relations perspective and by the recognition of the importance and ability of the people in the organization. **FIGURE 1.1** illustrates the wide range of leaders who were involved in the quality evolution, with an emphasis on health care.

Some of the most notable contemporaries of Deming and Shewhart who were major contributors to the history of TQM, and later CQI, include Armand Feigenbaum, Joseph Juran, and Philip Crosby. Their contributions have been widely documented in the literature, as well as through organizations that continue to promote their ideas, such as the Juran Institute. They are included, along with many others, in websites that profile these gurus of quality improvement and their individual ideas and techniques that form the basis of modern CQI.

Ongoing Evolution in Japan

While the quality concepts originally applied in Japan were evolving across other countries, they continued to develop and evolve within Japan as well, with numerous original contributions to CQI thinking, tools, and techniques, especially since the 1960s. The most famous of the Japanese experts are Genichi Taguchi and Kaoru Ishikawa.

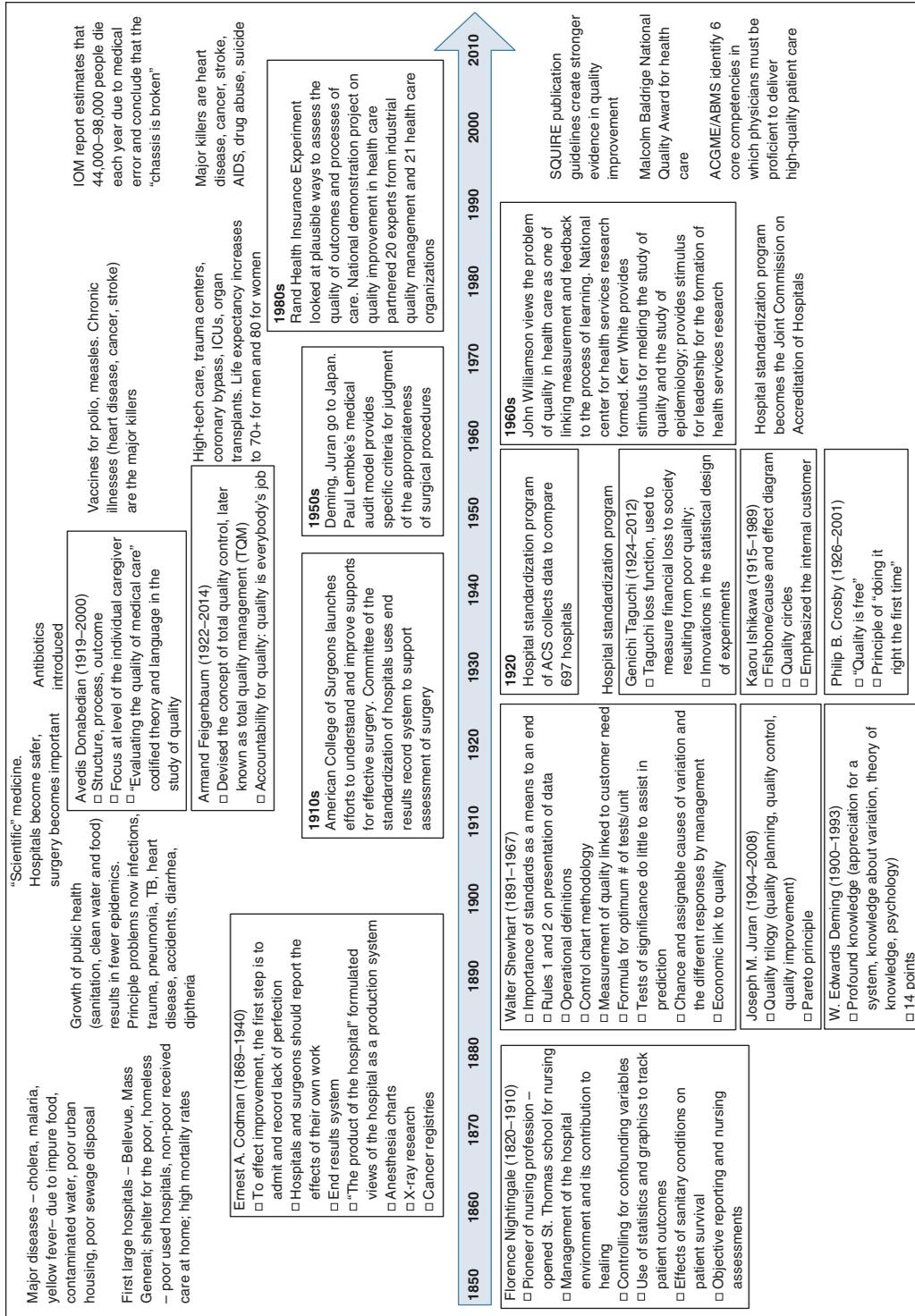


FIGURE 1.1 Some of the Evolutionary Context of Quality in Health Care

BOX 1.2 Recent Contributions of Japanese Quality Engineers

1. Total participation is required of all members of an organization (quality must be company-wide).
2. The next step of a process is its “customer,” just as the preceding step is its “supplier.”
3. Communicating with both customer and supplier is necessary (promoting feedback and creating channels of communication throughout the system).
4. Emphasis is placed on participative teams, starting with “quality circles.”
5. Emphasis is placed on education and training.
6. Instituted the Deming Prize to recognize quality improvement.
7. Statistics are used rigorously.
8. Instituted “just in time” processes.

Taguchi was a Japanese quality expert who emphasized using statistical techniques developed for the design of experiments to quickly identify problematic variations in a service or product; he also advocated a focus on what he called a “robust” (forgiving) design. He emphasized evaluating quality from both an end-user and a process approach. Ishikawa is well known for developing one of the classic CQI tools, the fishbone (or Ishikawa) cause-and-effect diagram (see Chapter 4). Along with other Japanese quality engineers, Ishikawa also refined the application of the foundations of CQI and added the concepts described in **BOX 1.2**.

Cross-Disciplinary Thinking

More than a historical business trend or a movement, the growth of quality improvement represents an evolution of both the philosophies and processes that have been studied and improved over the years, through application, review, feedback, and then broader application. There has been a fair amount of scrutiny, and these approaches have not only stood the test of time but have evolved to address criticisms and have been adapted to meet specialized needs that are unique in some segments, especially in health care. This phenomenon has occurred naturally as a result of cross-disciplinary strategic thinking

processes, where learning occurs by focusing not on what makes industries and disciplines different from each other, but rather on what they share in common (Brown, 1999). A good example of this commonality is a focus on adding value to products and services for customers, be they automobile buyers, airline passengers, or hospital patients. This notion can be directly extended to quality improvement (see **FIGURE 1.2**) by noting that industries—for example, automobile manufacturing vs. health care—may differ in terms of specific mission, goals, and outcomes but may share strategies to add value, including the philosophy, process, and tools of CQI. As a result, the common strategic elements of CQI have been adopted from diverse industrial applications and then customized to meet the special needs of health care.



FIGURE 1.2 Cross-Disciplinary Strategic Thinking

Comparing Industrial and Health Care Quality

Cross-disciplinary learning between industry and health care was spurred during the 1990s and contributed to this evolutionary process. A comparison of quality from an industrial perspective vs. quality from a health care perspective reveals that the two are surprisingly similar and that both have strengths and weaknesses (Donabedian, 1993). The industrial model is limited in that it (1) does not address the complexities, including the dynamic character and professional and cultural norms, of the patient–practitioner relationship; (2) downplays the knowledge, skills, motivation, and legal/ethical obligations of the practitioner; (3) treats quality as free, ignoring quality–cost trade-offs; (4) gives more attention to supportive activities and less to clinical ones; and (5) provides less emphasis on influencing professional performance via “education, retraining, supervision, encouragement, and censure” (Donabedian, 1993, pp. 1–4). On the other hand, Donabedian suggested that the professional health care model can learn the following from the industrial model:

1. New appreciation of the fundamental soundness of health care quality traditions
2. The need for even greater attention to consumer requirements, values, and expectations
3. The need for greater attention to the design of systems and processes as a means of quality assurance
4. The need to extend the self-monitoring, self-governing tradition of physicians to others in the organization
5. The need for a greater role by management in assuring the quality of clinical care
6. The need to develop appropriate applications of statistical control methods to health care monitoring
7. The need for greater education and training in quality monitoring and assurance for all concerned (1993, pp. 1–4)

In reality, there is a continuum of CQI activities, with manufacturing at one end of the continuum and professional services at the other (Hart, 1993). The CQI approach should be modified in accordance with its position along this continuum. Manufacturing processes have linear flows, repetitive cycle steps, standardized inputs, high analyzability, and low worker discretion. Professional services, on the other hand, involve multiple nonstandardized and variable inputs, nonrepetitive operations, unpredictable demand peaks, and high worker discretion. Many organizations, including health care organizations, have processes at different points along that continuum that should be analyzed accordingly. The hospital, for example, has laboratory and support operations that are like a factory and has preventive, diagnostic, and treatment activities that are professional services. The objective of factory-like operations is to drive out variability to conform to requirements and to produce near-zero defects. At the other end, the objectives of disease prevention, diagnosis, and treatment are to do whatever it takes to produce improved health and satisfaction and maintain the loyalty of customers—including both patients (external customers) and employees (internal customers).

An important contrast between traditional industry and health care is evidence of the pace of quality improvement initiatives in health care relative to the traditional industries that spawned CQI methods globally. As described by a former director of the McKinsey Global Institute, William Lewis, “For most industry the benefits from the various quality movements have been quite large but ... they are also largely in the past” with only incremental progress now being made, and he contrasts that development with health care, which is the “big exception” (Leonhardt, 2009, p. 11). So while

health care has learned from manufacturing and commercial industry, its evolution in CQI has led to acceleration in comparison to the slowdown, and even reversal, seen in manufacturing and commercial industry; for example, consider the quality issues faced in 2010 by Toyota—a manufacturing pioneer from which some of these approaches have evolved (Crawley, 2010; Dawson & Takahashi, 2011). (It should be noted that reports in the commercial media in recent years indicate that these issues have been resolved by a return to best practices and greater customer focus [Rechtin, 2014].)

This evolution, or cross-disciplinary translation, continues within a variety of health care settings, as will be illustrated throughout this text, with some tools and techniques being especially good examples of cross disciplinary adoption. Probably the best example is the Plan, Do, Study, Act (PDSA) cycle originally developed by Shewhart (1931) for industry. (Although the PDSA cycle is often attributed to Deming, he attributes it to Shewhart [Deming, 1986].) It is especially amenable to widespread use in health care and continues to find new applications to meet an ever-widening range of clinical and programmatic problems (see **FIGURE 1.3**).

One very interesting example of the cross-disciplinary/industry phenomenon, which has been given much attention both in scientific journals and in popular media, is the

adoption of surgical checklists to prevent errors. The checklist is a very simple but powerful project management and safety tool that has been used in various industries, but it is probably most well known for its effectiveness in the airline industry. A strong case has been made in scientific publications and in the popular media for greater adoption of checklists in surgery (Haynes et al., 2009) and other medical specialties (Gawande, 2009; Pronovost et al., 2006). Although its adoption in a wide range of settings has been seen in recent years, the effectiveness of this tool, used by itself, has been questioned by some (Bosk et al., 2009) and studied by many, with the goal of better understanding its role and improving its effectiveness (Avelling, McCulloch, & Dixon-Woods, 2013; de Vries et al., 2010; Wandersman et al., 2016). The use of checklists also provides a good illustration of some basic CQI principles that have broader implications. For example, checklist usage raises two key questions that are important in regard to a variety of CQI applications: (1) how much does the effectiveness of using checklists vary for different health care applications and settings? and (2) what is their specific role in improving health care safety and quality? One brief answer to these questions is that while the checklist is a simple tool, it is not a magic bullet—instead, it can be an effective means for helping ensure the application of other CQI principles in an overall

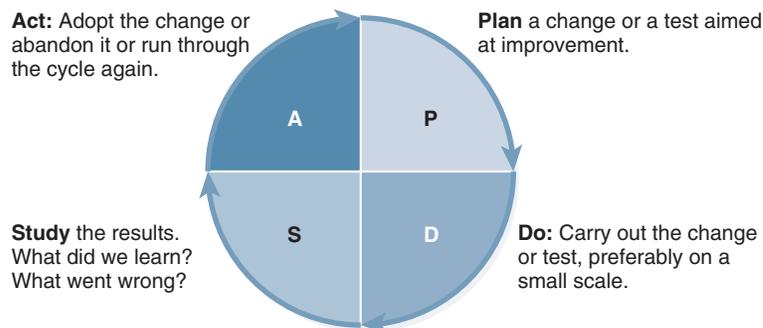


FIGURE 1.3 Shewhart (PDSA) Cycle

Reprinted from *The New Economics for Industry, Government, Education* by W. Edwards Deming by permission of MIT and W. Edwards Deming. Published by MIT, Center for Advanced Engineering Study, Cambridge, MA 02139. Copyright © 1993 by W. Edwards Deming.

program of quality assurance and improvement. For example, its use and effectiveness (or lack thereof) has broad implications about how health care teams communicate and share responsibilities; how leadership supports innovations and change—ultimately a cultural issue; and how to monitor and ensure compliance with CQI initiatives (Avelling, McCulloch, & Dixon-Woods, 2013; Dixon-Woods & Martin, 2016). Checklists provide an example of the importance of teamwork in CQI (see Chapter 6) and provide an example of a CQI tool (in Chapter 4) as well as an example of the broader issue of culture, leadership, and diffusion of CQI in health care (in Chapter 2). Checklists are also used as an example of the use of social marketing to increase compliance with CQI innovations and tools (in Chapter 8).

New approaches, refinements of older concepts, and different combinations of ideas are occurring almost daily in this ongoing evolutionary process. As more and more organizations adopt CQI, we are seeing increasing innovation and experimentation with CQI thinking and its applications. This is especially true of the health care arena, where virtually every organization has had to work hard to develop its own adaptation of CQI to the clinical process.

The Evolution Across Sectors of Health Care

The evolution in health care—which started in the most well-defined sector, hospitals—now includes all segments of the health care system and has become woven into the education of future practitioners, including not only administrators and physicians but also nurses, public health practitioners, and a wide array of other health professionals. It has spanned health care systems in many industrialized nations and now has become a way of meeting emerging crises, with widespread global health applications in resource-poor nations (see Chapter 13).

As illustrated in Figure 1.1, the health care evolution of CQI may be traced back to the

work of Florence Nightingale, who pioneered the use of statistical methods to analyze variation and propose areas for improvement. As one of many quality improvement initiatives, Florence Nightingale used descriptive statistics to demonstrate the link between unsanitary conditions and needless deaths during the Crimean War (Cohen, 1984). The evolutionary context of quality in health care, described in Figure 1.1, has occurred at many different levels, spanning history and geography, and has included a broadening of applications and a sharpening of tools and techniques. Both within and outside health care, probably the most dramatic part of this evolution has been the wide dispersion of knowledge about how to use these techniques, first starting with a small group of expert consultants and later expanding to a broad range of practitioners with a common goal to make improvements in a diverse set of products and services. Coupled with that “practice” goal have been educational efforts to develop and disseminate quality-improvement competencies by teaching these methods to an ever-widening range of health care professionals. For example, these efforts have included recent initiatives in nursing, the primary profession of Florence Nightingale (Sherwood & Jones, 2013).

In parallel with this broadening health care evolution over time and space, the same improvement processes were being applied to CQI tools and techniques, leading to improvements and greater precision relative to the measurement of outcomes and processes. The improvement processes also spawned international private- and public-sector organizations, which can be thought of as “health care quality czars,” that have applied and expanded these approaches. These organizations include the Institute for Healthcare Improvement (IHI) and both national and international regulatory agencies, such as the CMS in the United States, which, with the establishment of Quality Improvement Organizations (QIOs), uses data from the Medicare and Medicaid system to monitor quality of care and, more

importantly, to define improvement strategies (Schenck, McArdle, & Weiser, 2013). Similarly, local, national, and international accreditation agencies, such as TJC in the United States and its global counterparts (e.g., Joint Commission International [JCI]), have mandated the need for quality improvement in large health care systems (see Chapter 12). Ultimately, this has led to the emergence of quality leaders, with recognized achievements via a health care organization's eligibility to receive awards such as the Malcolm Baldrige National Quality Award (Hertz, Reimann, & Bostwick, 1994; McLaughlin & Kaluzny, 2006).

Around the mid-1980s, CQI was applied in several health care settings. Most notable was the early work done by three physicians following the principles outlined by Deming: Paul Batalden at Hospital Corporation of America (HCA), Donald Berwick at Harvard Community Health Center and IHI, and Brent James at Intermountain Health Care. Examples of their work and ideas will be illustrated throughout this chapter and this book.

Armed with the ideas of these creative quality leaders who elaborated on techniques, such as the PDSA cycle that were drawn originally from the pioneers of quality improvement, an acceleration marked by more widespread applications has occurred throughout all sectors of health care in the 21st century. That acceleration was spurred greatly by “a wake-up call” describing the crisis that health care quality was facing entering the new millennium.

► The Big Bang—The Quality Chasm

Quality under the rubric of patient safety suddenly came to dominate the scene following the two significant IOM reports, *To Err Is Human* (IOM, 2000) and *Crossing the Quality Chasm* (IOM, 2001). Virtually all those concerns about cost and benefits and professional autonomy

seemed swamped by the documentation of unacceptably high rates of medical errors. The recognition that needless human suffering, loss of life, and wasted resources were related to unnecessary variability in treatment and the lack of implementation of known best practices galvanized professional groups, regulators, and payers into action. Suddenly, quality improvement was acknowledged to be a professional responsibility, a quality-of-care issue rather than a managerial tactic. Current investment and involvement levels are high as evidence has mounted that the variability in clinical processes and the lack of conformance to evidence-based best practices has cost the public dearly. Many of the actors identified previously are demanding accountability for patient safety and for achieving acceptable levels of clinical performance and outcomes achievement. Adverse events are now undergoing extreme scrutiny, and a broad range of quality indicators are being reported, followed, and compared by payers and regulators (see Chapter 10).

One important change that called even greater attention to the seriousness of medical errors was that, effective October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) adopted a nonreimbursement policy for certain “never events,” which are defined as serious, preventable hospital-acquired conditions. The rationale is that hospitals cannot bill CMS for adverse events and complications that are considered never events *because* they are preventable; the goal is to motivate hospitals to accelerate improvement of patient safety. A list of never events can be found at the Agency for Healthcare Research and Quality (AHRQ) website, and a summary of how this step came about is offered by Michaels et al. (2007).

Local and regional variability in health care has long been known to exist, but the translation of that variability into missed opportunities for improved outcomes has been slow in coming. With that veil of secrecy about medical errors lifted, the demands for action and professional responsiveness have become extensive. This sea-change goes well

beyond concerns about malpractice insurance to issues of clinical governance, professional training, certification, and continuity of care.

For a while, financial questions seemed to have dissipated as the social costs took precedence. However, these cost issues have certainly been revisited and have grown in importance with the full implementation of the ACA in the United States and other health care reform initiatives in other locations around the world. Concerns about cost of care continue and need to be considered relative to CQI initiatives and the overall nature of the relationship of cost to quality and the role of value.

► From Industrialization to Personalization

Quality has been and continues to be a central issue in health care organizations and among health care providers. The classic works of Avedis Donabedian, Robert Brook, and Leonard Rosenfeld, to name a few, have made major contributions to the definition, measurement, and understanding of health care quality. However, the corporatization of health care in the United States (Starr, 1982) and other changes to the health care system have redefined, and will continue to redefine, how we manage quality. Given the increasing proportion of the gross national product allocated to health services and the redefinition of health care as an “economic good,” health care organizations are influenced to a growing extent by organizations in the industrial sector. As part of this process, health care organizations have become “corporations,” with expansion goals to create larger hospital systems. The long-held perception of health care as a cottage industry persisted into the 1960s and 1970s. In this view, health care was seen as a craft or art delivered by individual professionals who had learned by apprenticeship and who worked independently in a decentralized system. These practitioners tailored their craft

to each individual situation using processes that were neither recorded nor explicitly engineered, and they were personally accountable for the performance and financial outcomes of the care they provided.

The 1980s and 1990s witnessed a distinct change, which is often described as the “industrialization of health care” (Kongstvedt, 1997). This change affected almost all aspects of health care delivery, influencing how risks are allocated, how care is organized, and how professionals are motivated and incentivized. This industrialization process can be described utilizing the dynamic stability model of Boynton, Victor, and Pine (1993), which presents various industrial transformation strategies. These can be adapted to health care services to describe the transformation from craft to a more industrialized approach. For example, one strategy follows the traditional route of industrialization utilizing mass production to ensure high levels of process stability, as illustrated by the bundling of unique medical procedures into a few high-volume, specialized centers. However, most health care activities have followed an alternate route that is also described by this model, bypassing mass production due to the high variability in patient needs and using techniques of CQI and process reengineering.

The Victor & Boynton (1998) model for the organization suggests an appropriate path for organizational development and improvement. As presented in **FIGURE 1.4**, health care processes and product lines have begun to move from the craft stage to positions in all of the other three stages of that model. Each of the four stages requires its own approach to quality.

1. Craft requires that the individual improve with experience and use the tacit knowledge produced to develop a better individual reputation and group reputation. Craft activities can be leveraged to a limited extent by a community of cooperating and teaching crafts-persons.

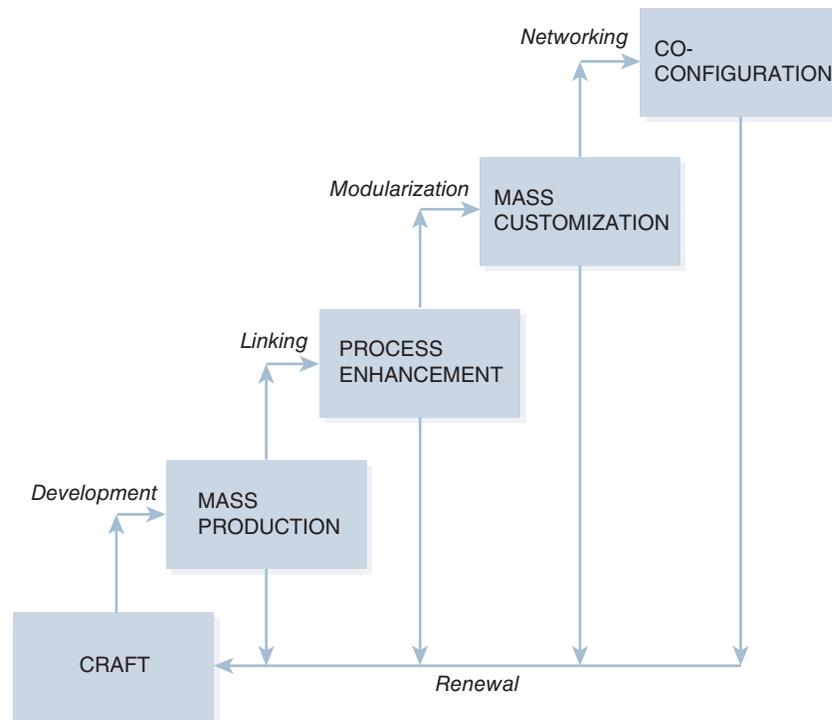


FIGURE 1.4 The Right Path Transformations Are Sequenced Along the Way

Reprinted with permission from Victor B., and Boynton, A.C. (1998). *Invented Here: Maximizing Your Organization's Internal Growth and Profitability*. Boston: Harvard Business School Press.

2. Mass production requires the discipline that produces conformance quality in high volume at low cost. Critics sometimes refer to this approach using terms such as *industrialization* or the *deskilling* of the profession and occasionally mention Henry Ford's assembly lines as a negative model.
3. Process enhancement requires that processes be analyzed and modified to develop a best-practice approach using worker feedback and process-owning teams within the organization.
4. Mass customization requires that the organization takes that best practice, modularizes and supports it independently, and then uses those modules to build efficient,

low-cost processes that are responsive to individual customer wants and needs.

Because health care is a complex, multi-product environment, various types of care can be found at each of the four stages, depending on the state of the technology and the strategy of the delivery unit. The correct place to be along that pathway depends on the current state of the technology. The revolution in health care organization is driven not only by economics, but also by the type of knowledge work that is being done. As described in Victor & Boynton (1998, p. 129):

Managers take the wrong path when they fail to account for the fact that (1) learning is always taking place, and (2) what learning is taking place

depends on the kind of work one is doing. The learning system we describe along the right path requires that managers leverage the learning from previous forms of work. ... If managers attempt to transform without understanding the learning taking place ..., then transformation efforts will be at best slightly off the mark and at worst futile. In addition, if managers misunderstand what type of work (craft, mass production, process enhancement, or mass customization) is taking place in a given process or activity when transformation starts, then they may use the wrong transformation steps (development, linking, modularization, or renewal).

These authors, however, were referring to a single, commercial firm with a relatively limited line of goods and services. In health care, a single organization such as a hospital might contain examples of multiple stages due to the variety of its products. There is a recognition that complexity is ever-increasing;

for example, one hears complaints that some traditional definitions apply to patients with only one diagnosis, whereas most very sick patients, especially the elderly, have multiple diagnoses. Therefore, the prevailing quality and performance enhancement systems have to be prepared with much greater levels of variability—in patient problem constellations, anatomy, physiology, and preferences, as well as in provider potentials and preferences (McLaughlin, 1996). Furthermore, increased availability of genetic information will further fractionate many disease categories, making the definitions of disease even more complex. Among other ideas, this has led to the concept of personalization of medicine and an associated concept, individualization of care, which will be discussed in greater detail in the next section.

FIGURE 1.5 suggests how this has and will occur in health care. As scientific information about a health care process accumulates, it shifts from the craft stage to the process enhancement stage. After the process is codified and developed further, it may shift into the mass production mode if the approach is sufficiently cut and dried, the volume is high,

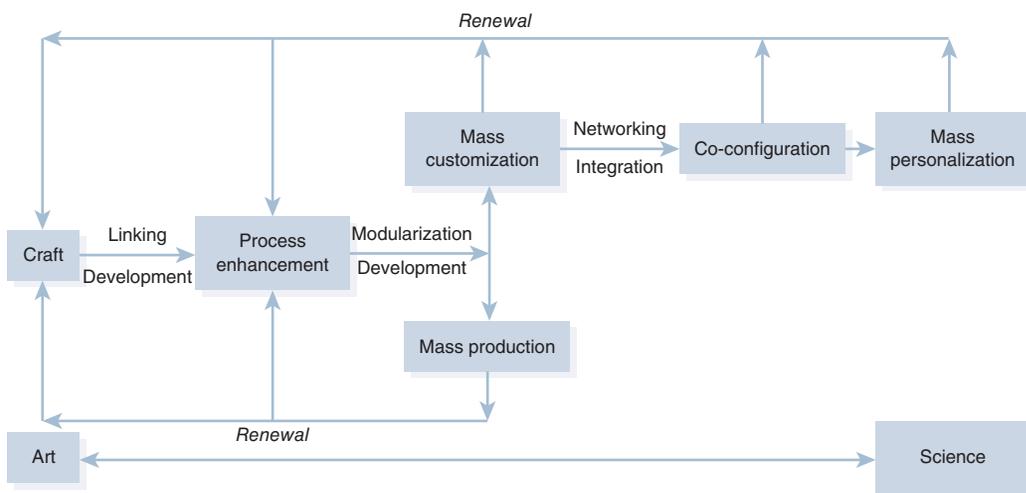


FIGURE 1.5 Revised Boynton & Victor Model for Health Care

and the patients will accept this impersonal mode of delivery. If there is still too much art or lack of science to justify codification, the enhanced process can be returned to the craft mode or moved into the mass customization and co-configuration pathway.

The craft mode contains multiple delivery alternatives. For example, if someone were to decide to commission an artist to make a custom work of art, that person has two ways to specify how it is to be controlled. The first is to say, “You are the artist. Do your thing, and I will pay whatever it costs.” This is *fee-for-service indemnity*. The other is to say, “You can decide what to do, but here is all that I can afford to pay.” This is *capitation*. In both cases, the grand design and the execution are still in the hands of the artist. However, that does not preclude the artist from learning by doing, obtaining suggestions from vendors of materials and equipment, or observing and collaborating with colleagues. Neither the artist nor the person commissioning the art commits to a single “best” way to do things, because neither is able to articulate or agree on the best way to reach the desired outcome.

The mass-customization pathway has long been thought of as the best way to produce satisfied health care customers at low or reasonable relative costs. The organization develops a series of modular approaches to prevention and treatment, highly articulated and well supported by information technology, so that they can be deployed efficiently in a variety of places and configurations to respond to customer needs. Clinical pathways represent one example of modularization. They represent best practices as known to the organization, and they are applied and configured by a configurator (the health care professional) to meet the needs of the individual patient. This requires an integrated information system that will give the health care professional, usually a generalist, access to specialized information and to full information about the patient’s background, medical history, and status; the system will

also allow the health care professional to synchronize the implementation of the modules of service being delivered. In a sense, mass customization represents a process that simulates craft but is highly science based, coordinated, integrated with other process flows, and efficient. How does this differ from the well-run modern hospital or clinic? As described by Victor & Boynton (1998, pp. 12–13):

The tightly linked process steps developed under process enhancement are now exploded, not into isolated parts, but into a dynamic web of interconnected modular units. Rather than the sequential assembly lines, ... work is now organized as a complex, reconfigurable product and service system.

Modularization breaks up the work into units that are interchangeable on demand from the customer. And everything has to happen fast. ... Modularization transforms work by creating a dynamic, robust network of units.

Within some of these units, ... there may still be active craft, mass production, or process enhancement work taking place, but all the possible interfaces among modules must be carefully designed so that they can rapidly, efficiently, and seamlessly regroup to meet customer needs.

Where does science come in? Victor and Boynton refer to architectural knowledge, a much deeper process understanding than that needed for earlier stages of their model. Also at a practical level, it takes hard science to legitimize the conformance by providers required to make such a system work.

The remaining stage of this model has been called “co-configuration”—a system in which the customer is linked into the network, and customer intelligence is accessed as readily as the providers’ knowledge. In a futuristic sense,

one should also be able to include the patient in the decision-making network to a high degree. The future has arrived in the form of what many authors call “mass personalization.” It represents an even more intense involvement of customers in product and service delivery choices; in health care, patient-specific needs and wants are being more directly addressed.

Mass Personalization

Personalization is an evolutionary concept that is not only having an impact on how industries deliver products and services but also on how organizations are structured, such as in learning organizations. It is an example of a business application that continues to evolve within the business world and is now beginning to evolve at its own pace within health care. In business, this evolution is especially apparent in service industries, where the morphing of mass customization into mass personalization has been fueled by the rapid growth of technology, especially the Internet, search engines, and personal media, to bring each customer’s wants and needs in direct contact with service providers.

This phase of evolution has happened quite rapidly, and its speed of growth is directly correlated with technological advances. “Two decades after its conception there is growing evidence that mass customization strategy is transforming into a mass personalization strategy” (Kumar, 2007, p. 533). It was not until 1987 that the term *mass customization* was first introduced; however, from 1987 to 2008, more than 1,100 articles on mass customization appeared in scholarly journals, with exponential growth in the 1990s (Kumar, 2007).

Personalization of products began in the 1950s, with affordability being the key component that led to its popularity and growth. As computer technologies have become more personalized, the concepts of mass customization and co-configuration have evolved into personalization, at an accelerated pace. As

Kumar explains, “Mass personalization strategy evolved from mass customization strategy as a result of strides in information and operational technologies” (2007, p. 536). Both strategies are in current use; while similar, they do have differences. As described by Tseng & Piller (2003, p. 7), who have written extensively on this trend:

Personalization must not be mixed up with customization. While customization relates to changing, assembling, or modifying product or service components according to customers’ needs and desires, personalization involves intense communication and interaction between two parties, namely customer and supplier. Personalization in general is about selecting or filtering information objects for an individual by using information about that individual (the customer profile) and then negotiating the selection with the individual. ... From a technical point of view, automatic personalization or recommendation means matching meta-information of products or information objects against meta-information of customers (stored in the customer profile).

This leads to strategies that are directed at what Kumar calls “a market of one” (Kumar, 2007, p. 533).

Health Care Applications of Personalization

That mass personalization is directly applicable to CQI is quite obvious due to their common focus on adding value and customer satisfaction and their common reliance on data and technology. What is a bit surprising is that personalization can be applied directly to CQI in health care, and how rapidly this

stage of evolution from business to health care is occurring. This concept is closely related to what Berwick calls “patient-centeredness,” a consumerist view of quality of care, which he describes as involving “disruptive shifts in control and power out of the hands of those who give care and into the hands of those who receive it” (Berwick, 2009, p. 555).

At first glance, the importance and reliance on evidence-based practice as part of CQI in health care might seem contradictory to personalization; however, as noted by Sackett and many others, the steps in applying evidence-based practice include evaluating the best data available but also using individual clinical judgment and patient input, including patient preferences, in making final treatment decisions (Sackett, 1996; Satterfield et al., 2009). The current definition of health care personalization encompasses the concepts of individualized care and shared decision making, in addition to personalized medicine (Barratt, 2008; Pfaff et al., 2010; Robinson, Callister, Berry, & Dearing, 2008). In all forms, these concepts lead to greater focus on patient characteristics, needs, and preferences in decision making about their care, and they are all closely associated with the customer focus concepts that are central to CQI. With greater availability of information, via the Internet and other more traditional sources, patients and their families are playing a greater role in health care decision making and quality of care. Sources of data and information abound in numerous easily accessible formats. For example, for many years the AHRQ has provided information to encourage patient participation in their medical care and the quality of the medical care they receive; one example is the AHRQ website “Questions to Ask Your Doctor” (AHRQ, 2012). Similar resources have long been provided by other organizations to support patients with specialty needs; for example, the National Cancer Institute’s Cancer Information Service was established in 1975 to help cancer patients find information

and treatment resources (NCI n.d.). What has contributed notably to the use of such information is that patients now have greater knowledge and access to technology, such as search engines to find medical information. This has led to input by patients and their families in their own health care decisions and in the quality of their care, which is discussed in greater detail in Chapter 7.

But the growth in health care personalization goes beyond patients having access to medical information; it relates directly to medical strategies and emerging science for providing higher quality, safer, more personalized treatments. This trend draws strength from a vision of personalized medicine primarily in terms of genomic medicine; it is a means of “focusing on the best ways to develop new therapies and optimize prescribing by steering patients to the right drug at the right dose at the right time” (Hamburg & Collins, 2010, p. 301). This vision includes partnerships among industry, academia, doctors, patients, and the public that will lead to a “national highway for personalized medicine.” One of the earliest signs of success relates to identifying the optimal dosage and combination of treatments for cancer patients (Spector & Blackwell, 2009).

As in the business community, the personalization concept in health care has evolved to include broader components of health care, in part because of advances in research and technology. In medical care, this includes recent breakthroughs in genomics (Spector & Blackwell, 2009) but also tools provided by computer technology, including greater use of electronic medical records. Individualized treatment strategies are further extensions of these concepts, going beyond genomics to include patients’ preferences and experiences in shared decision making with their providers, allowing greater patient participation in choice of drugs and dosages and administration; even more broadly, individualization leads to patients being more proactive in regard to prevention, screening, and early

treatment, through greater use of information technology, electronic medical records, and decision-making tools, such as patient decision support technologies (Pfaff et al., 2010).

Health care personalization can be thought of more broadly as an extension of Wagner's (1996) chronic care model, which focuses on the individual rather than the condition. This approach is especially useful when individuals have multiple chronic conditions.

The evolutionary path of CQI within health care is an important catalyst to personalization that is reflective of broader societal trends spanning a wide range of businesses. These trends are reflected in the concept of customer relationship management (CRM). As described by Kumar (2007), "CRM is the philosophy, policy, and coordinating strategy connecting different players within an organization so as to coordinate their efforts in creating an overall valuable series of experiences, products, and services for the customer." Kumar notes that CRM also requires that the customer be integrated into all aspects of product and process design and that "customer driven innovation has become a key source of strategic advantage." This relates not only to health care personalization but also to the traditional focus on customers in CQI and on methods of gathering customer feedback. This is reflected in many ways including the greater use (and some abuse) of patient satisfaction surveys as a way of evaluating quality of care (see Chapter 4).

With new opportunities come new challenges. The greater amount of information available and the increased role of "untrained" patients and their families in care decisions present the challenge of knowing how to evaluate the quality and appropriateness of treatment options. This has led to some level of conflict as the two extremes of standardization vs. personalization strain the boundaries and definitions of evidence-based medicine, with both extremes striving to achieve the highest quality of care. There is an ongoing broad discussion throughout health care, locally

and globally, about how to balance these concepts (Pfaff et al., 2010; Robinson et al., 2008; Satterfield et al., 2009; Wandersman et al., 2016). What is clear is that these patient-centered concepts are here to stay and will lead to the next stages of the evolution in health care and, as with the previous stages, will continue to grow exponentially.

Likewise, referring back to Berwick's (2009) notion of "patient-centeredness," patients are playing—and should play—a greater role in health care quality improvement. These patient-centered trends have had an impact on quality improvement education for health care professionals. For example, they are being incorporated into nursing education (Sherwood & Jones, 2013). Day and Smith (2007, pp. 139–140) describe this need:

Unfortunately there is wide variation in the quality of information provided by websites and no search engine screens for quality or accuracy. An important part of basic nursing education is helping students develop skills that enable them to evaluate web-based information, especially if that information is going to be passed on to a patient or family member or used as the basis for patient and family teaching.

Thus, as with other evolutionary stages in CQI, new challenges to quality management present themselves and will hopefully lead to new opportunities in an unending cycle of improvement.

► The Scientific Method of CQI

As CQI philosophies and processes have evolved within health care, a series of broad-based approaches have evolved and proven to be widely applicable across a range of health

care settings. These can be thought of as umbrella approaches under which specific change methods can be applied. At the foundation of these is the scientific method and the historically proven PDSA cycle, which has been particularly successful in health care as frameworks within which a variety of improvement methods have been applied to measure and further initiate improvement strategies.

Walter Shewhart at Bell Laboratories, was the first to introduce the Plan, Do, Study, Act (PDSA) cycle, which was presented earlier in Figure 1.3. It should also be noted that over time, the abbreviation PDSA was changed by some to PDCA, the “S” for study being changed to “C” for check, as in *checking* what impact an improvement has made on the process being changed. Today the terms are used interchangeably, as we will do throughout this book. Either way, Shewhart’s concept has become a very powerful and frequently used quality improvement methodology that has withstood the test of time.

Stated quite simply, PDSA cycles “provide a structure for iterative testing of changes to improve quality of systems. ... The pragmatic principles of PDSA cycles promote the use of a small scale iterative approach to test interventions, as this enables rapid assessment and provides flexibility to adapt the change according to feedback to ensure fit-for-purpose solutions are developed” (Taylor et al., 2014, pp. 290–291). The key features of any PDSA application are:

1. The use of repeated iterative cycles
2. Prediction-based test of change (developed in the plan stage)
3. Small-scale testing (build as confidence grows—adapting according to feedback and learning)
4. Use of data over time (to understand the impact of change)
5. Documentation (to support local learning and transferability to other settings) (Taylor et al., 2014, p. 293)

The two very successful and well-known applications of the PDCA/PDSA cycle that have evolved in health care are HCA’s FOCUS–PDCA model (Batalden & Stoltz, 1993) and the Model for Improvement (Langley et al., 2009). These encompass two frameworks that have been developed to use in conjunction with PDCA/PDSA cycles. In addition to these two major PDSA applications, numerous other CQI initiatives have centered around this basic improvement cycle.

The broad applicability of the PDSA cycle in health care can be traced directly to its roots as it was applied by Deming. One of Deming’s (1993) major premises was that management needs to undergo a transformation. In order to respond successfully to challenges to organizations and their environments, the way to accomplish that transformation, which must be deliberately learned and incorporated into management, is by pursuing what he called “profound knowledge.” The key elements of his system of profound knowledge are (1) appreciation for a system, (2) knowledge about variation, (3) theory of knowledge, and (4) psychology.

The Deming process is especially useful in health care because professionals already have knowledge of the subject matter as well as a set of values and disciplines that fit the Deming philosophy. Training in Deming methods adds knowledge of how to build a new theory using insights about systems, variation, and psychology, and it focuses on the answers given to the set of basic questions that center around knowing what is to be accomplished. Furthermore, it applies a cyclical process of testing and learning from data whether the change being made is an improvement and what improvements are needed in the future (Batalden & Stoltz, 1993). A Deming approach, as adopted by the HCA in Nashville, Tennessee, is illustrated in **FIGURE 1.6**. It was referred to by the HCA as FOCUS–PDCA and provided the firm’s health care workers with a common language and an orderly sequence for implementing the cycle

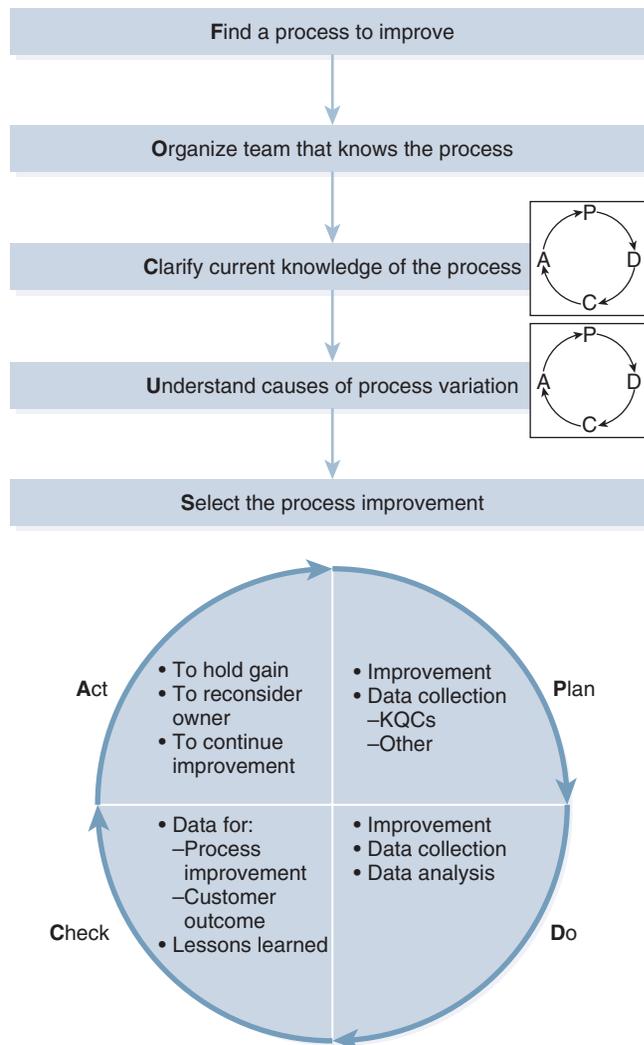


FIGURE 1.6 The FOCUS–PDCA Cycle

of continuous improvement. It focuses on the answers given to the following basic questions (Batalden & Stoltz, 1993):

1. What are we trying to accomplish?
2. How will we know when that change is an improvement?
3. What changes can we predict will make an improvement?
4. How shall we pilot test the predicted improvements?
5. What do we expect to learn from the test run?
6. As the data come in, what have we learned?
7. If we get positive results, how do we hold on to the gains?
8. If we get negative results, what needs to be done next?
9. When we review the experience, what can we learn about doing a better job in the future?

In parallel with the FOCUS–PDCA model was the introduction in 1992 of the Model for Improvement by Langley et al. (2009). It includes a PDSA cycle as its core approach, returning to the traditional “S,” emphasizing the importance of *studying* what has been accomplished before making further changes (FIGURE 1.7). Careful study and reflection are points of emphasis made by Berwick (1996), who describes this model as “inductive learning—the growth of knowledge through making changes and then reflecting on the consequences of those changes.”

Central to the Model for Improvement are three key questions:

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 an improvement?

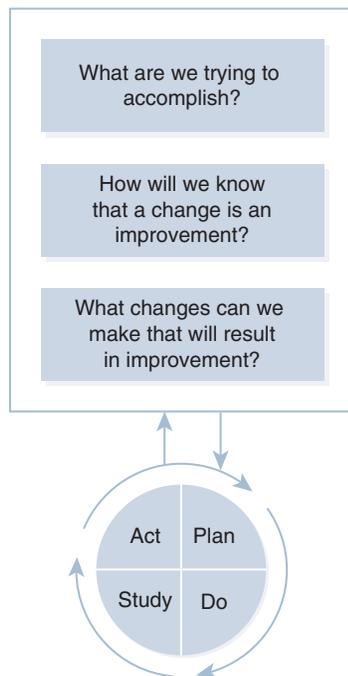


FIGURE 1.7 Model for Improvement

Reproduced from Langley, G.L., Nolan, K.M., Nolan, T.W., Norman, C.L. and Provost, L.P. (2009), *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*, 2nd ed., Jossey Bass, San Francisco.

The wide use of these approaches is due directly to the elegance and simplicity of the PDSA cycle. Likewise, the range of applications ties directly to the generalizability of the PDSA cycle. Recent applications have included public health (see Chapter 11), health care in resource-poor countries (see Chapter 13) and traditional medical care in industrialized settings, which are described throughout this book.

However, with the widespread use of PDSA, there have been some questions raised about how to assess validity and generalizability of specific applications before their results are transferred into clinical practice as new evidence-based methods (Speroff, James, Nelson, Headrick, & Brommels, 2004). These questions fall under the broad heading of how to apply critical appraisal criteria to PDSA, and other CQI initiatives, in a manner that is similar to appraisal of clinical research studies that are directed at efficacy and safety of new treatments or drugs. One approach to addressing these questions is to carefully review how well the key features of the PDSA methods (listed above) have been applied in a specific application; this approach is outlined by Taylor et al. (2014). Included in this approach is Berwick’s emphasis on careful study of findings at the “S” stage of each cycle, before acting on those findings (Berwick, 1996).

A useful set of guidelines for strengthening PDSA applications as well as other CQI initiatives, and which parallel the recommendations of Taylor et al. (2014), are presented by Speroff et al. (2004, p. 36) and start with four core questions:

1. Is the quality improvement study pertinent and relevant?
2. Are the results valid?
3. Are appropriate criteria used to interpret the results?
4. Will the study help you with your practice or organization of care?

These authors also present detailed recommendations for how to address each of these

four questions, including how to improve the causal inferences (internal validity) and generalizability (external validity) of PDSA studies (Speroff et al., 2004). Because of the simplicity and consequently the broad usage of PDSA, careful attention should be paid to the guidelines described above in order to ensure proper use and both internal and external validity of applications of the PDSA methodology.

Similar discussions have also been carried out recently in regard to improving the applicability of other well known CQI methods and specific results. Recommendations have been presented for greater emphasis on the fidelity of the applications and fuller understanding, and consideration of the context, in which project-specific results are obtained before broadly assuming the robustness of their findings. These recommendations help to explain why some CQI methods are not achieving the results that are expected and should be carried out before generalizing them to other settings, and we should always be cautious to not assume that a “magic bullet” has been found that will produce improvements in any situation, regardless of context (Dixon-Woods & Martin, 2016).

► Conclusions

The examples of how CQI has evolved in an exponential manner, especially since the advent of the new millennium, are many and varied. Whether this trend is due to greater customer awareness and demands, technology improvements, greater competition, or a combination of these factors, what is clear is that the trend is continuing on a global scale. While some traditional industries that had incorporated CQI are now “making only incremental progress” (Leonhardt, 2009) CQI in health care is leaping forward, using examples and lessons from outside as well as inside health care. National developments (e.g., the ACA in the United States) and international developments (e.g., applications of CQI in resource-poor

nations) have been both the result of and the source of global learning. This cycle of learning has led to innovations and paradigm shifts that will ensure further evolution in the future. The institutionalization of CQI in public health, which represents an extension of what has been learned in medical and hospital care, continues to grow due to various influences that mirror other health care sectors, such as national and local accreditation efforts.

The examples in this text of how CQI has spread and evolved are by no means exhaustive; improvements will continue to evolve at a pace that is difficult to capture in any snapshot in time. But the patterns of change that are described in this text provide a strong basis for future health improvement models and the challenges that come with these future models, as they address the questions of quality and cost and the issues of “value-added” care, leading to further learning and innovation to meet customer needs and improved health outcomes across the globe.

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