PART

1

Introduction

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 the companion casebook (McLaughlin et al., 2012) provide greater detail and illustrations of CQI approaches and successes as applied to health care.

It is clearly illustrated throughout this text that 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 be done in improving 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). The challenge of how to cross the quality chasm (Institute of Medicine [IOM], 2001) in health care clearly remains, and hopefully some of the material in this text and its companion case-book (McLaughlin et al., 2012) will help to shed light on the scope of the problem and potential solutions.

DEFINITION OF CONTINUOUS QUALITY IMPROVEMENT

What was originally called *total quality management* (TQM) in the manufacturing industry evolved into *continuous quality improvement* 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). In keeping with the previous editions and to focus on the unique challenges within health care, the term *CQI* will be used primarily throughout this text.

In health care, CQI is defined as 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

CQI, under its various labels, 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 medicine 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 medicine and management involve the selection of best clinical and management practices; these are determined by examination of the professional literature and consideration of internal experience. The lines of demarcation between these four initiatives are not clear because performance improvement can occur across a continuum of project size, impact, clinical 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 U.S. Institute of Medicine (IOM) has issued a number of reports critical of the quality of care and the variability of both quality and

cost across the country (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, which 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% to 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 et al., 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). These concepts are discussed in greater detail throughout this book, particularly in the final chapter (Chapter 20).

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 et al., 2002). This newer 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

As further explored in Chapter 2, 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 and 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 The Joint Commission (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. 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 customer preferences are important determinants of quality and that the term *customer* includes both patients and providers 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; and (7) providing the motivation for a rational, data-based, cooperative approach to process analysis and change.

What is perhaps most radical vis-à-vis 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 have 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 error 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 ultimately customer requirements will change over time because of 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. 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. 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 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 6 provides a more detailed discussion of how to measure customer 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 that 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. Where the problem is with the system (the usual 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. When the level of quality is being measured, workers can rightly take pride in the quality of the work they are producing.

Measurement and Decision Making

Another distinguishing feature of CQI is the rigorous belief in fact-based learning and decision making, captured by the saying, "In God we trust. All others send 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 traditional 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.

Subsequent chapters refer to some of the inherent barriers that accompany CQI implementation. These 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 (Seidman and Wallace, 2004). There may also be a related tendency to try to overcontrol 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 has to 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 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 care–specific elements, which add the specialized knowledge of health care 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 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

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. To quote Dr. Deming: "Management's job is to optimize the system."

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 (see Chapter 10)

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 4)

2. Seven CQI tools—Use of one or more of the seven CQI tools so frequently cited in the industrial and the health quality literature: flowcharts, cause-and-effect diagrams, histograms, Pareto charts, run charts, control charts, and regression analyses (see Chapter 3 for these and other tools)

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 analysis—Use of statistics, including statistical process control, to identify and reduce unnecessary variation in processes and practices (see Chapter 3)

6. Customer satisfaction measures—Introduction of market research instruments to monitor customer satisfaction at various levels (see Chapter 6)

7. Benchmarking—Use of benchmarking to identify best practices in related and unrelated settings to emulate as processes or use as performance targets (see Chapter 5)

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 (see Chapter 3)

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 in health care there are a number of additional approaches and techniques 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 medicine

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, which 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 TQM/CQI, but he is perhaps best known for the 14-point program of recommendations that he devised for management to improve quality (see **Table 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; 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 TQM/CQI be based on a top-down, organization-wide commitment.

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 to continuous quality improvement, or simply quality improvement.

TABLE 1–1 Deming's 14-Point Program

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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.
11a. Eliminate numerical quotas for production. Instead, learn and institute methods for improvement.
11b. 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.

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

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 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 (see http://www.juran.com/). They are included, along with many others, in Web sites that profile these gurus of quality improvement and their individual ideas and techniques that form the basis of modern CQI (see http://www.qualitygurus.com/gurus/).

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.

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 3). Along with other Japanese quality engineers, Ishikawa also refined the application of the foundations of CQI and added the concepts described in **Table 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

Timeline: 1850 | 1860 | 1870 | 1880 | 1890 | 1900 | 1910 | 1920 | 1930 | 1940 | 1950 | 1960 | 1970 | 1980 | 1990 | 2000 | 2010

Major diseases – cholera, malaria, yellow fever – due to impure food, contaminated water, poor urban housing, poor sewage disposal

First large hospitals – Bellevue, Mass General; shelter for the poor, homeless – poor used hospitals, non-poor received care at home; high mortality rates

Growth of public health (sanitation, clean water and food) results in fewer epidemics. Principle problems now infections, trauma, pneumonia, TB, heart disease, accidents, diarrhea, diphtheria

"Scientific" medicine. Hospitals become safer, surgery becomes important

Antibiotics introduced

Vaccines for polio, measles. Chronic illnesses (heart disease, cancer, stroke) are the major killers

High-tech care, trauma centers, coronary bypass, ICUs, organ transplants. Life expectancy increases to 70+ for men and 80 for women

Major killers are heart disease, cancer, stroke, AIDS, drug abuse, suicide

IOM report estimates that 44,000–98,000 people die each year due to medical error and conclude that the "chassis is broken"

Avedis Donabedian (1919–2000)
□ Structure, process, outcome
□ Focus at level of the individual caregiver
□ "Evaluating the quality of medical care" codified theory and language in the study of quality

Armand Feigenbaum (1922–)
□ Devised the concept of total quality control, later known as total quality management (TQM)
□ Accountability for quality: quality is everybody's job

1910s
American College of Surgeons launches efforts to understand and improve supports for effective surgery. Committee of the standardization of hospitals uses end results record system to support assessment of surgery

1950s
Deming, Juran go to Japan. Paul Lembke's medical audit model provides specific criteria for judgment of the appropriateness of surgical procedures

1986s
Rand Health Insurance Experiment looked at plausible ways to assess the quality of outcomes and processes of care. National demonstration project on quality improvement in health care partnered 20 experts from industrial quality management and 21 health care organizations

SQUIRE publication guidelines create stronger evidence in quality improvement

Malcolm Baldrige National Quality Award for health care

ACGME/ABMS identify 6 core competencies in which physicians must be proficient to deliver high-quality patient care

Ernest A. Codman (1869–1940)
□ To effect improvement, the first step is to admit and record lack of perfection
□ Hospitals and surgeons should report the effects of their own work
□ End results system
□ "The product of the hospital" formulated views of the hospital as a production system
□ Anesthesia charts
□ X-ray research
□ Cancer registries

Walter Shewhart (1891–1967)
□ Importance of standards as a means to an end
□ Rules 1 and 2 on presentation of data
□ Operational definitions
□ Control chart methodology
□ Measurement of quality linked to customer need
□ Formula for optimum # of tests/unit
□ Tests of significance do little to assist in prediction
□ Chance and assignable causes of variation and the different responses by management
□ Economic link to quality

1920
Hospital standardization program of ACS collects data to compare 697 hospitals

Hospital standardization program

Genichi Taguchi (1924–)
□ Taguchi loss function, used to measure financial loss to society resulting from poor quality;
□ Innovations in the statistical design of experiments

1960s
John Williamson views the problem of quality in health care as one of linking measurement and feedback to the process of learning. National center for health services research formed. Kerr White provides stimulus for melding the study of quality and the study of epidemiology; provides stimulus for leadership for the formation of health services research

Florence Nightingale (1820–1910)
□ Pioneer of nursing profession – opened St. Thomas school for nursing
□ Management of the hospital environment and its contribution to healing
□ Controlling for confounding variables
□ Use of statistics and graphics to track patient outcomes
□ Effects of sanitary conditions on patient survival
□ Objective reporting and nursing assessments

Joseph M. Juran (1904–2008)
□ Quality trilogy (quality planning, quality control, quality improvement
□ Pareto principle

Kaoru Ishikawa (1915–1989)
□ Fishbone/cause and effect diagram
□ Quality circles
□ Emphasized the internal customer

Hospital standardization program becomes the Joint Commission on Accreditation of Hospitals

Philip B. Crosby (1926–2001)
□ "Quality is free"
□ Principle of "doing it right the first time"

W. Edwards Deming (1900–1993)
□ Profound knowledge (appreciation for a system, knowledge about variation, theory of knowledge, psychology
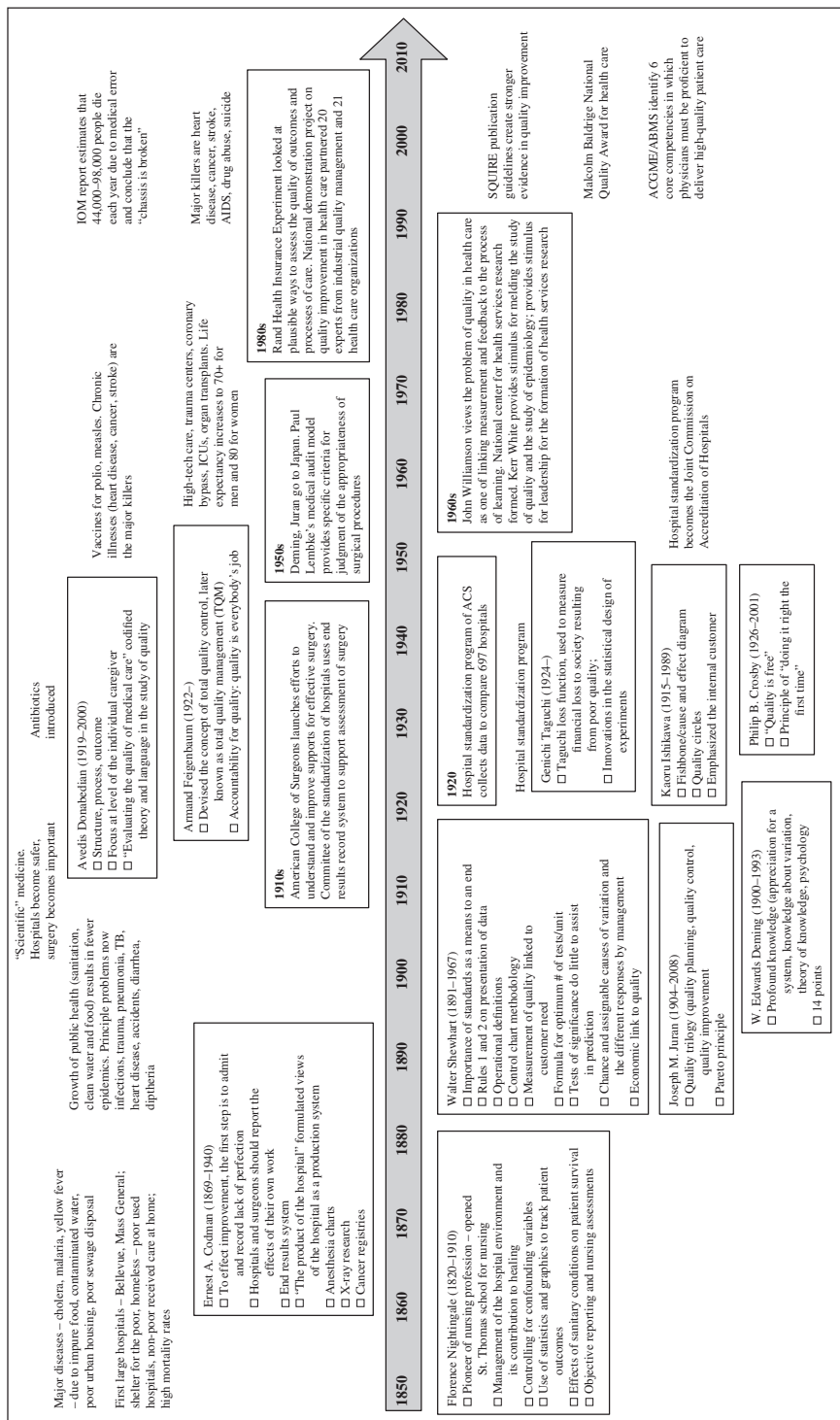□ 14 points

FIGURE 1–1 Some of the Evolutionary Context of Quality in Health Care

TABLE 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.

Source: Adapted from McLaughlin and Kaluzny, 2006.

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,

FIGURE 1–2 Cross-Disciplinary Strategic Thinking

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.

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) ignores 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 TQM/CQI activities, with manufacturing at one end of the continuum and professional services at the other (Hart, 1993). The TQM/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 by Toyota in 2010 (Crawley, 2010), a manufacturing pioneer from which these approaches have evolved.

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, such as the Plan, Do, Study, Act (PDSA) cycle originally developed by Shewhart (1931) for industry being especially amenable to widespread use and finding 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
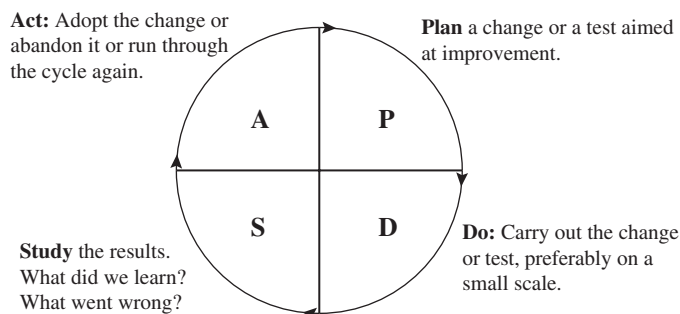
FIGURE 1–3 Shewhart (PDSA) Cycle

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

popular media circles in 2009–2010, including both print and television, is the adoption of surgical checklists to prevent errors. This is based on a very simple but powerful device—the checklist—which has been used in many industries and has been both a project management and a safety tool, 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 recently, the effectiveness of this tool, used by itself, has been questioned by some (Bosk et al., 2009). At the same time, practice-based research continues to explore its uses and to expand its applicability (de Vries et al., 2010). Checklists will be further discussed later in this text, both as an example of a quality improvement tool (in Chapter 3) and as an example of the broader issue of diffusion of CQI in health care (in Chapter 2); checklists are also the subject of an example in Chapter 8 and Case 9 in the companion casebook (McLaughlin et al., 2012).

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 area, 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—for example, to help address the worldwide AIDS epidemic (see Chapter 19).

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 (see Chapter 17).

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 that can be thought of as "health care quality czars," which 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 (see Chapter 15). 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 18). 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 et al., 1994; McLaughlin and Kaluzny, 2006) (see http://www.nist.gov/baldrige/) and other awards, such as the annual NCQA Health Quality Awards (see http://www.ncqa.org/tabid/1117/Default.aspx).

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 (see, for example, Chapter 13).

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* (2000) and *Crossing the Quality Chasm* (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 11). One important change that called even greater attention to the seriousness of medical errors was that effective October 1, 2008, the CMS adopted a non-reimbursement policy for certain "never events," which are defined as non-reimbursable serious hospital-acquired conditions. The goal is to motivate hospitals to accelerate improvement of patient safety. The rationale is that hospitals cannot bill CMS for adverse events and complications that are considered never events because they are preventable. A list of never events can be found at the AHRQ Web site (see http://psnet.ahrq.gov/primer.aspx?primerID=3), 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 as national health care reform initiatives undergo full implementation in the United States and other locations around the world, such as Australia and the United Kingdom, which is in the process of reviewing and reorganizing its National Health Service, largely to save money. 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.

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 health care change 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. **Figure 1–4** outlines this industrialization process utilizing the dynamic stability model of Boynton et al. (1993). One route, marked A, follows the traditional route of industrialization as illustrated by the bundling of cataract operations into a few high-volume, specialized centers. However, most health care activities have followed the B route, bypassing mass production due to the high variability in patient needs and using techniques of CQI and process reengineering.

The Victor and Boynton (1998) model for the organization suggests an appropriate path for organizational development and improvement. As presented in **Figure 1–5**, 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.
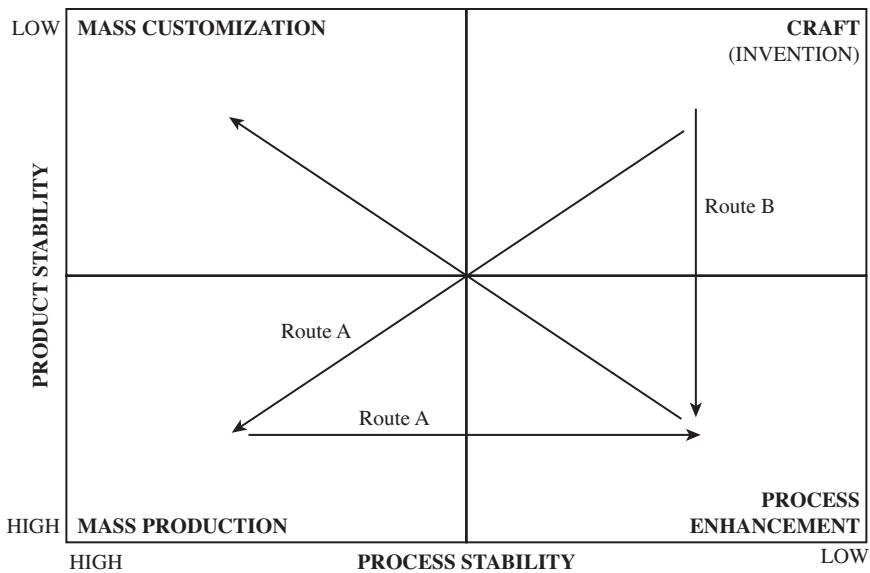
FIGURE 1–4 Adapting the Boynton-Victor-Pine Dynamic Stability Model to Health Care

Source: *OR/MS Today*, Vol. 25, No. 1. Reprinted with permission.

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 craftspersons.

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.
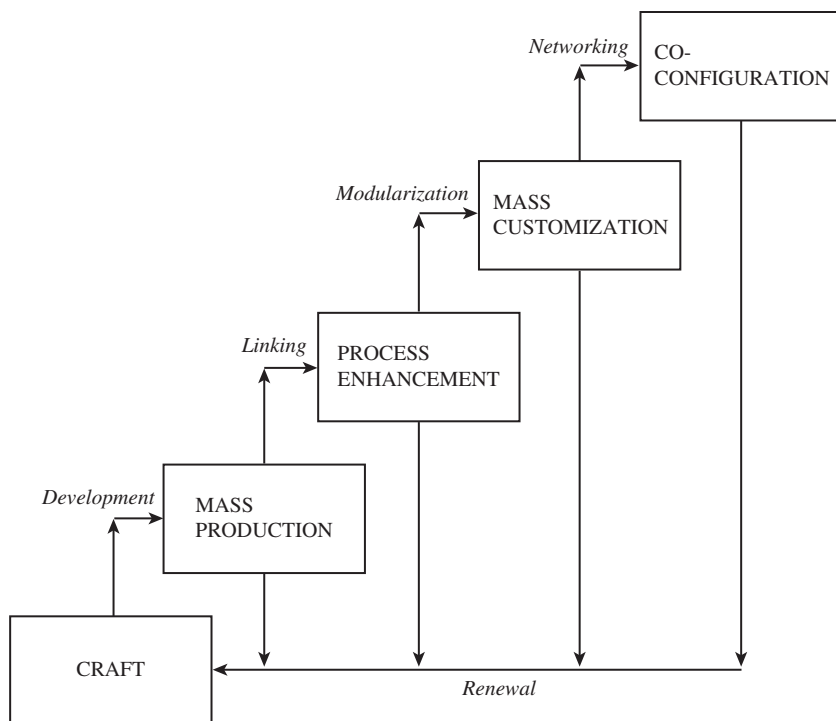
FIGURE 1–5 The Right Path Transformations Are Sequenced Along the Way

Source: 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.

Because health care is a complex, multiproduct 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 and Boynton:

> 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 customiza-
> tion) is taking place in a given process or activity when transformation
> starts, then they may use the wrong transformation steps (develop-
> ment, linking, modularization, or renewal). (1998, p. 129)

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 con-stellations, 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, that will be discussed in greater detail in the next section.

Figure 1–6 suggests how this has and will occur in health care. As sci-entific information about a health care process accumulates, it shifts from the craft stage to the process enhancement stage. After the process is codi-fied and developed further, it may shift into the mass production mode if the approach is sufficiently cut and dried, the volume is high, 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. If, for example, one were to decide to commission an artist to make a custom work of art, one 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.
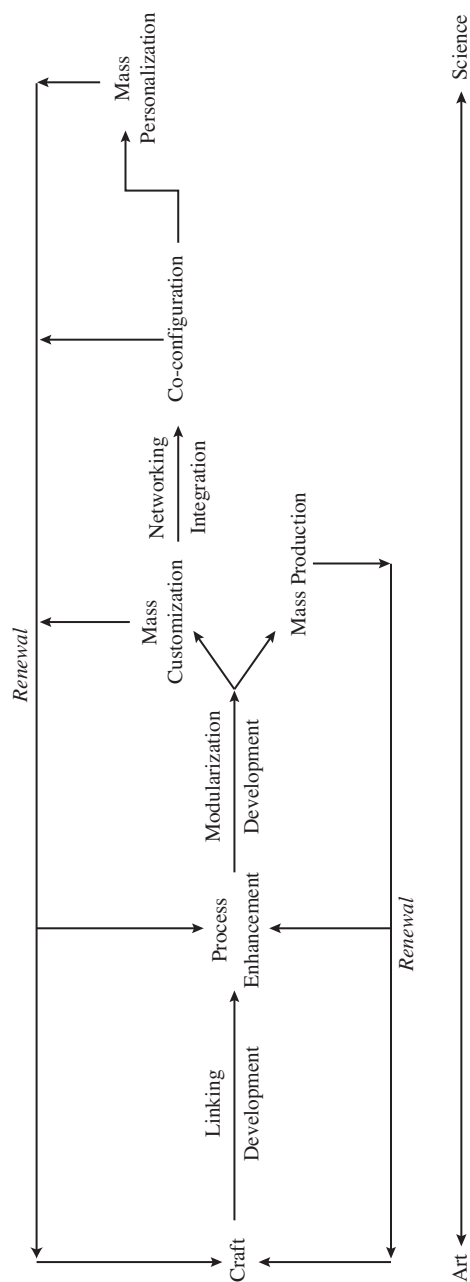
FIGURE 1–6 Revised Boynton and Victor Model for Health Care

Source: Adapted from McLaughlin and Kaluzny, 2006.

However, that does not preclude the artist from learning by doing or from vendors of materials and equipment or by observing and collaborating with colleagues. However, one does not commit to a one best way to do things, because one is not able to either articulate or agree on what is the best way.

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 practice as known to the organization, and they are applied by a configuror (the health care professional) to meet the needs of the individual patient. This requires an integrated information system that will give the configuror, 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 configuror 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 and Boynton:

> 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. (1998, pp. 12–13)

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'. 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 (see Chapter 10). 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 and Piller, 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). (2003, p. 7)

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" (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). 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 et al., 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 Agency for Healthcare Research and Quality (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 report "20 Tips to Help Prevent Medical Errors," which is available online (http://www.ahrq.gov/consumer/20tips.htm). 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 (http://www .cancer.gov/aboutnci/cis). 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 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. As described by Drs. Collins (Director of the U.S. National Institutes of Health) and Hamburg (Director of the U.S. Food and Drug Administration), we are now clearly on a path to personalized medicine (Hamburg and Collins, 2010). These distinguished health care leaders describe their 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" (p. 301). They go on to describe a partnership 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 and 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 not only recent breakthroughs in genomics 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).

Seidman and Wallace (2004) describe health care personalization more broadly as an extension of Wagner's chronic care model (1996), which focuses on the individual rather than the condition. This approach is especially useful when individuals have multiple chronic conditions leading to what these authors describe as "an evolution to mass personalized chronic condition care," encompassing both evidence-based medicine and self-management support, which relies on a collaborative approach between individuals and their physicians (Seidman and Wallace, 2004).

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, as described in Chapter 6.

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). 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, as described in Chapter 7, and referring back to Berwick's notion of "patient centeredness" (2009), 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, as described in Chapter 17. Day and Smith 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. (2007, pp. 139–140)

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.

BROAD-BASED APPROACHES/SUCCESSES

As CQI philosophies and processes have evolved within health care, a series of broad-based approaches have evolved and proven to be successful across a range of health care settings. These can be thought of as umbrella approaches under which specific change methods can be applied. The two most notable are the historically proven PDSA cycle and the quality improvement collaborative. These two broad approaches have proven to be particularly successful in health care as frameworks within which a variety of improvement methods have been applied to measure and further initiate improvement strategies.

The PDSA Cycle

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. Although the PDSA cycle is often attributed to Deming, he attributes it to Shewhart (Deming, 1986). 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.

The two very successful and well-known applications of the PDSA cycle that have evolved in health care are HCA's FOCUS–PDCA model (Batalden and Stoltz, 1993) and the Model for Improvement (Langley et al., 2009). 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 major premises (1993) 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 and Stoltz, 1993). A Deming approach, as adopted by the HCA, is illustrated in **Figure 1–7**. 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 of
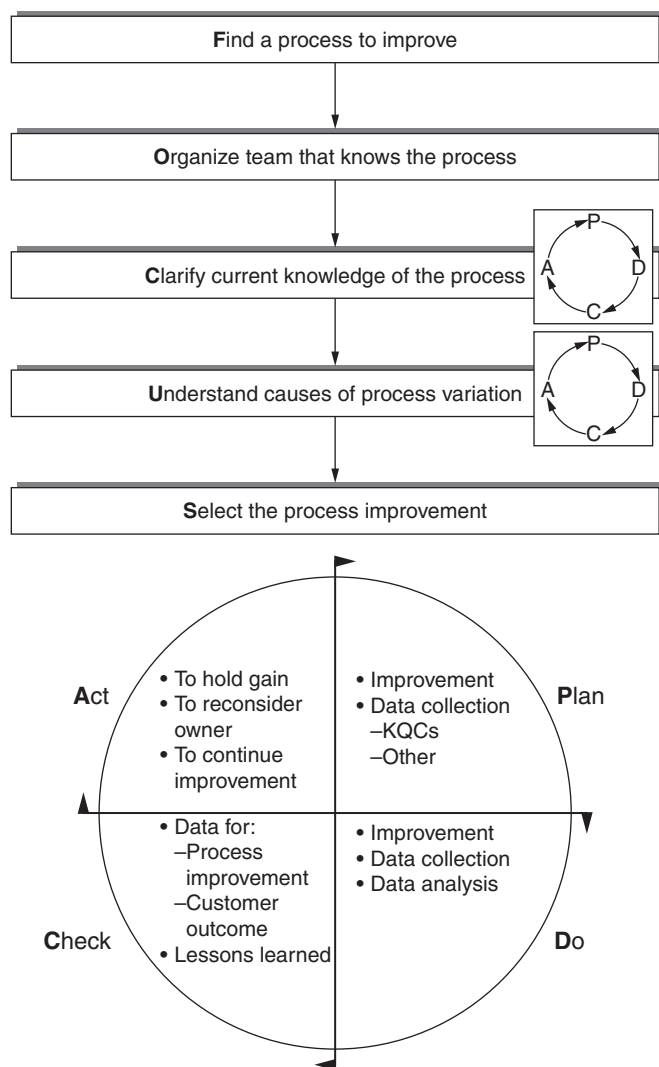
FIGURE 1–7 The FOCUS–PDCA Cycle

continuous improvement. It focuses on the answers given to the following basic questions (Batalden and 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 1–8**). Careful study and reflection are
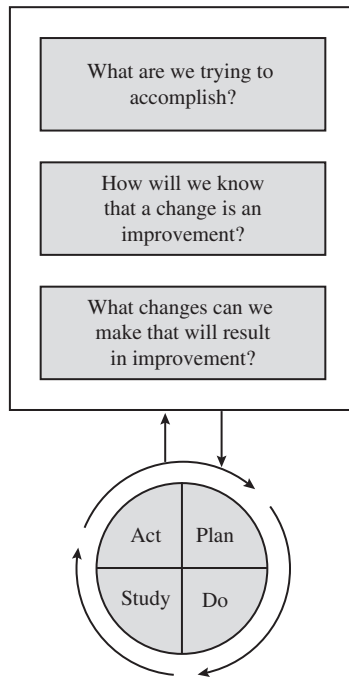
FIGURE 1–8 Model for Improvement

Source: The "Model for Improvement"—a systematic approach to rapid improvement of health processes (Langley et al., 2009).

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 this model 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?

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 16), health care in resource-poor countries (see Chapter 19) and traditional medical care in industrialized settings, which are described throughout this book.

Quality Improvement Collaboratives

Quality improvement collaboratives (QICs) are another example of a broad-based approach that exemplifies the evolution of CQI methods across geographic boundaries and areas of health care, with applications that range from primary care to public health. Although some authors feel that clear evidence of their effectiveness, in terms of improved outcomes, is lacking, their widespread adoption is well documented (Schouten et al., 2008). Simply defined, QICs consist of "multidisciplinary teams from various health care departments or organizations that join forces for several months to work in a structured way to improve their provision of care" (Schouten et al., 2008, p. 1491). They have been described as temporary learning organizations (Ovretveit et al., 2002) and have also been described in the context of diffusion of innovation; more specifically, in their comprehensive review of the literature on diffusion of innovation in health service organizations (2005), Greenhalgh et al. describe the goal of QICs as "spread of ideas." These authors formally describe QICs as multi-organizational structured improvement collaboratives and provide a succinct description of how they work:

> Participants in a quality collaborative work together over a number of months, sharing ideas and knowledge, setting specific goals, measuring progress, sharing techniques for organizational change and

> implementing rapid-cycle, iterative tests of change. Learning sessions
> are the major events of a Collaborative; these are 2-day events where
> members of the multi-disciplinary project teams from each health
> care organization gather to share experiences and learn from clinical
> and change experts and their colleagues. The time between learning
> sessions is called an action period in which participants work within
> their own organizations towards major, "breakthrough" improvement,
> focusing on their internal organizational agenda and priorities for
> changes and improvements whilst remaining in continuous contact
> with other Collaborative participants. (p. 163)

Introduced initially in the United States in the mid-1980s, QICs are
now used in many countries with varying health care financing systems,
including Canada, Australia, and European countries, where several
national health authorities support nationwide quality programs based on
this strategy. A similar approach has been used in the United Kingdom
through its National Health Service Modernization Agency; it is called
the Beacon Model and focuses on transfer of best practices, derived from
Beacon organizations "that have achieved a high standard of service
delivery and are regarded as centers of best practice" (Greenhalgh et al.,
2005, p. 168).

   QICs were initially developed and are still used in primary care. They
have now evolved to a broader number of settings, and their widespread
adoption in the United States has led to the formation of a national
organization, the Network for Regional Healthcare Improvement; this is
discussed in greater detail in Chapter 14 in relation to primary care.

   One of the first uses of QICs was the Northern New England
Cardiovascular Disease Study Group in 1986. Their continuing effec-
tive use within cardiovascular care is described in a systematic review of
the management of heart failure, published in 2006, 20 years after its
first introduction. This review concludes that the collaborative meth-
odology "has significant potential to improve the outcomes of patients,
particularly those with [heart failure] and chronic cardiovascular disease"
(Newton et al., 2006, p. 161). The success and widespread adoption of
QICs are directly related to the exchange and application of best practices
by experts and peers to carry out improvement initiatives.

   One notable contributor to the growth in use of QICs is the wide-
spread application known as the Breakthrough Series, developed by the
Institute for Healthcare Improvement in 1995 (Schouten et al., 2008).

Once again, QICs serve as an umbrella under which a broad array of specific methods can be used to carry out changes; these can also include the use of PDSA approaches, which have been a key feature of the collaborative methodology (Newton et al., 2006).

Referring to the work of Ovretveit et al. (2002), the reasons for the success of QICs can be grouped into four general categories: topics chosen for improvement, participant and team characteristics, skills of facilitator and expert advisers, and ensuring ways to maximize spread of ideas. Greenhalgh et al. explain that these success factors result from:

1. Clearly focused important topics that address clear gaps between current and best practice.

2. Highly motivated participants who clearly understand individual and corporate goals in a supportive organizational culture.

3. Effective teams and team leadership whose goals are in alignment with those of the organization.

4. Facilitation by credible experts, who provide adequate support outside as well as through the learning events.

5. Maximizing the spread of ideas through networking between teams and other mechanisms. (2005, p. 167)

Based on their systematic review of the literature, these authors conclude that QICs have been demonstrated to be successful and popular ways of implementing improvements in health service delivery; however, they also point out that two major criticisms are that they are expensive and that gains from them have been difficult to measure.

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) and some sectors of industry that were once leaders, such as the automotive industry in Japan, have experienced back stepping (Crawley, 2010), CQI in health care is leaping forward, using examples and lessons from outside as well as inside health care. National developments (e.g., health care reform 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, such as mass personalization, that will ensure further evolution in the future.

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 the chapters of this text provide a strong basis for future models of health care 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, improved health care, and outcomes on a global basis.

Cross-References to the Companion Casebook*

(McLaughlin, C. P., Johnson, J. K., and Sollecito, W. A. [Eds.]. 2012. *Implementing Continuous Quality Improvement in Health Care: A Global Casebook*. Sudbury, MA: Jones & Bartlett Learning.)

Case Study Number	Case Study Title	Case Study Authors
1	West Florida Regional Medical Center	*Curtis P. McLaughlin*
5	The Intermountain Way to Positively Impact Costs and Quality	*Lucy A. Savitz*
9	Forthright Medical Center: Social Marketing and the Surgical Checklist	*Carol E. Breland*
14	Continuing Improvement for the National Health Service Quality and Outcomes Framework	*Curtis P. McLaughlin*
17	Elk Hills Community Medical Center: Revisiting the Baldrige Award	*Curtis P. McLaughlin*

*Although there are other case studies that apply to this overview chapter, these are the cases with the most direct relevance to concepts presented in Chapter 1.

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