McLaughlin and Kaluzny's

Continuous Quality Improvement in Health Care

FIFTH EDITION

Julie K. Johnson William A. Sollecito

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To my home team—Paul, Harrison, Tore, and Elijah.

–JJ

To my family for their loving support always and especially to our newest addition, Mason, who represents the future, which is what this book is all about!

–WS

Contents

Acknowledgments

As we developed the fifth edition of *Continuous Quality Improvement in Health Care*, we were inspired once again by Drs. McLaughlin and Kaluzny. While we are very appreciative of their contribution of the Preface, their contribution has been so much greater through the years, as mentors and as colleagues.

We were also inspired by the thought provoking Foreword written by Dr. Paul Batalden where he outlined the model of CQI in improving quality, safety, and value and the model of coproduction in improving the "value of the health care service contribution to better health."

We have benefited greatly from the feedback of students who have provided insight and understanding of the importance of making this book a practical teaching tool that addresses the continuing challenges of improving quality and safety of health care in the future. We are most appreciative to our friends and colleagues around the globe who authored chapters. The coordination and integration of the contributing authors was a tremendous undertaking and we were privileged to work with excellent colleagues, who are truly expert practitioners of continuous quality improvement in health care.

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- Vaughn Upshaw and David Steffen—the importance of the learning organization concepts in CQI
- Anna Schenck, Jill McArdle, and Robert Weiser—the use of Medicare data in CQI and the real-world example of the Clemson Nursing Home Case Study
- Curt McLaughlin and David Kibbe—the importance of health information technology and understanding the strengths and weaknesses of various data sources used in CQI

Once again, as with CQI itself, the production of this book truly required teamwork and we appreciate and acknowledge the vital role of all of our fellow team members, not the least of which includes our families.

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Preface

The first edition of *Continuous Quality Improvement in Health Care* was published in 1994. Continuous quality improvement in health care was in its infancy. Paul Batalden had kindly educated us, and others, on his philosophy and groundbreaking efforts at Hospital Corporation of America. The Joint Commission had recently launched the *Agenda for Change*. Within the larger health care community there was interest as well as skepticism as to whether manufacturing techniques that were popular and successful were applicable to health care. The obvious need was to explain the basics and provide documentation to illustrate its applicability to health care organizations. The *First Edition* provided the basics along with a series of cases to illustrate its relevance to health care. A key chapter was "Does TQM/CQI Really Work in Health Care?"

By the *Second Edition* in 1999, the issues of quality in health care had come of age with the publication of the IOM report *Crossing the Quality Chasm*. Many issues of implementation had become evident and a new key chapter was "CQI, Transformation and the 'Learning' Organization." At the same time the importance of such efforts was recognized by the health care version of the National Malcolm Baldrige Quality Award, whose standards were included in the text.

The *Third Edition* in 2006 emphasized measurement, especially outcomes measurement, as the use of CQI concepts expanded. It also paid attention to information technology that had the power to enhance implementation and to disseminate results more widely. At the same time the barriers to widespread adoption of the knowledge produced were evident. The new cases on Intermountain Health Care and the American Board of Pediatrics efforts at organizational and professional learning were featured illustrations.

The *Fourth Edition* in 2013 was under the capable leadership of Bill Solliceto and Julie Johnson. Its publication aligned with the passage of the Affordable Care Act expanding the insurance coverage to 50 million people and the role of the CMS to assess different delivery models of care. It was a time of great expectations with emphasis on measurement and the movement of these efforts into a number of professional, governmental and international spheres. The CQI approach to quality and quality improvement had now achieved global prominence and led to the development of the companion volume, McLaughlin, Johnson, & Sollecito, *Implementing Continuous Quality Improvement in Health Care: A Global Casebook*.

As the *Fifth Edition* goes to press, basic elements of the ACA have been dismantled and, while quality improvement is a well-accepted management tool, issues of institutionalization, measurement, implementation and adaptation to environments remain challenging. One is tempted to conclude that not much has changed; major segments of the population are at risk of losing insurance coverage, interest in empirical evaluation of alternative care models and quality improvement efforts has slowed, and some evaluation studies on cost savings of quality improvement have not met expectations.

Over the past 25 years we have learned a lot about quality improvement, its implementation

and the challenges and opportunities of quality and quality improvement as a core function in health care. What has changed is the context within which health care is provided that must be accommodated within future quality improvement processes. Many of these contextual changes were un imaginable 25 years ago; the sequencing of the genome and its implication for genomic medicine, the commercialization of health care, the consolidation of heath care organizations on a massive scale, and the introduction of new forms of provider organizations, (e.g., ACOs, Walmart, and Humana), the deprofessionalization of health care providers, the basic demographics of the population, and the types of care that will be needed in the years ahead.

With these changes have come new issues involving quality improvement:

- Will the addition of ever more quality and "value" measures turn attention away from an overall culture of improvement? Will people focus in on what is measured? That is already one reason why health care is great at increasing revenue, but not at reducing waste.
- Can we overcome the gaps between professional points of view? Or will we continue to have an attending specialist see the story boards in the his unit as "something the nurses are doing?"
- Will the institutionalization and professionalization of quality in ever large and more complex institutions be relegated to the quality officer/office rather than a fundamental responsibility of all personnel?
- Will health care management recognize that their departments and institutions are part of a larger system of care? A system of care characterized by handoffs that transcend organizational boundaries involving an array of organizations and providers with different professional and organizational cultures yet critical to providing an integrated seamless care continuum from prevention to end of life.

These are not abstract academic issues. These are real issues, involving real people, of which we are all at risk. We know what it is like to observe specialists exhibit mutual hostility at the bedside because one didn't comprehend why the other demanded a prompt weekend consult, or wonder how a case manager can expect an emotionally exhausted family, following an extended and traumatic hospital stay, to select from a list of long term care facilities without any guidance or insight about the facilities. These experiences change your perspective on quality, quality improvement and the role of management in implementing organizational structures and mechanisms to assure interdisciplinary collaboration and training hospital personnel to effectively manage the transition points in the care continuum.

As we enter an era of an aging population and precision medicine supported by genomics and big data, the quality of care at the front end will rapidly improve leaving the greater challenges and the greater payoffs to society in chronic and end-of-life care. What Deming, a pioneer in quality improvement, stated 50 years ago remains relevant today—that the problems are with the system and the system belongs to management. Our methods of quality improvement must encompass these larger, increasingly relevant systems.

Curtis P. McLaughlin, DBA
Arnold D. Kaluzny, PhD
Chapel Hill, North Carolina

Foreword

…questions
that have no right
to go away (Whyte, 2007).

This book invites two questions that may "have no right to go away" in our journey toward better health:

1. If we make improving quality, safety, and value an "enterprise-wide effort," what do we need to know and do?
2. If we make improving the "value of the health care service contribution to better health" our focus, what do we need to know and do?

Enterprise-Wide Effort?

In response to this question, our attention has been directed at the ways and structures through which leaders lead organizations and the way(s) organizations and their people respond. In the last few decades, in addition to work "inside," we have been encouraged to look outside of the health care services sector to organization-wide efforts in automotive, computer, aerospace, and elsewhere, where great gains in quality, safety, and value have been made. We have learned a great deal about our own work: health care service as a system, process; system leadership; measurement of outcome; unwanted variation; system failure and unreliability; organization-wide contributions to better health; making improvement part of everyone's job; accountability for better performance and many other themes.

The *First Edition* of this book was published as we were deeply into these pursuits and learning (McLaughlin & Kaluzny, 1994). Several chapters in this edition of that book honor this question and help identify what might be known and done currently. Their content helps frame important contributions to leader development, selection, and performance assessment. In the short-term, following these chapters can offer today's leaders and organizations real substance in the performance of "leader and organization-wide work" for the improvement of health care service.

Value of Health Care Service Contribution to Better Health?

This question invites focus on the words "service," "value," and "contribution." It suggests that we recognize that we are mainly in the business of making services, that we are invited to attend to the economic value of our efforts and that we acknowledge that our services are best thought of as a contribution to health.

Service

Victor Fuchs in his early review of the emerging service economy noted that making a service was different from making a product (Fuchs, 1968). Services always required the active participation, insight from two parties: the professional and the beneficiary. Vincent and Elinor Ostrom were the first to call that

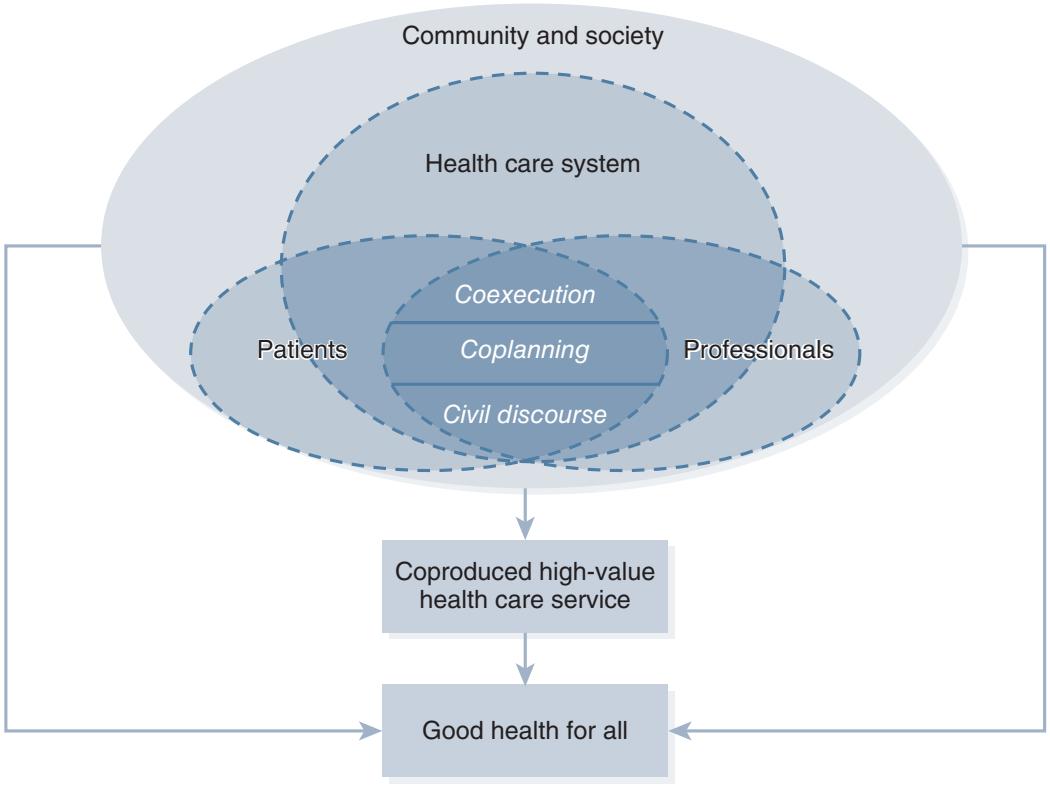

FIGURE 1 Conceptual Model of Health Care Services Coproduction

Reproduced from Batalden M. et al. *BMJ Qual Saf* 2016;25:509–517.

phenomenon "coproduction."[4] Building on the work of Lusch and Vargo (2014), Osborne, Radnor, and Nasi suggested that a "product-dominant logic" had overtaken a clearer view of the logic involved in making a service.[6] Building on these ideas of "service" and how "making a service" might be different from "making a product," Batalden and colleagues offered a description of the coproduction of health care service and a model for understanding and use, as illustrated in **FIGURE 1** (Batalden, Batalden, Margolis, et al., 2016).

The model invited attention to the interactions of patients and professionals. It suggested that a variety of interactions might be possible, ranging from "civil discourse" to "co-execution." It recognized that these interactions occurred partly within an openly bounded health care system and in the context of social and community systems. This variety of interaction depended in part on the knowledge, skill, habits and willingness to be vulnerable as the parties engaged in the relationships and actions that characterized a health care service.

These insights formed the basis of a clearer idea of the interdependent work of two groups of people, some of whom might be named "patients" and some named as "professionals"—though in reality they each brought different expertise to their shared interactions.

If we really mean that health care services are "coproduced," new tools that enable visualization and design that reflect the contribution of patients and professionals will be helpful. The measurement of process and result will need to reflect both the implementation and effect of the professional's science-informed practice (Greenhalgh, 2018) and

the methods of addressing and the degree of attainment of the patient's goal.

But not all health professional work seems to fit this service logic. Sometimes the health care work seems to better fit "making a product." Helping professionals know when to use which logic—service-making or product-making—will open new approaches to design, as well as professional education, development.

Value

Øystein Fjeldstad has suggested that multiple system architectures might be useful to create value in modern service-making. He includes the development of standardized responses to commonly occurring needs in linked processes (value chains), customized responses to particular needs (value shop), and flexible responses to emergent needs (value network) (Stabel & Fjeldstad, 1998; Fjeldstad, Snow, Miles, Lettl, 2012). Using this typology one can begin to imagine the opportunity to link them in ways that match need and system form. Much more development of these multiple ways of creating value seems likely.

Contribution

This word invites us to remember that a person's health is not easy to "outsource" to a professional. At best, the health professional's coproduced service makes a contribution to further another person's health. Recognizing that the shared work is a contribution to health, invites inquiry into patient need, patient assets, patient supports, patient knowledge & skill, patient's lived reality as part of the understanding for service coproduction design. A similar inventory of knowledge, skill, habits, capability and interest of professionals seems in order. Even the professional-patient relationship itself could be explored for its capability in contributing to the process of coproducing a service. Assessments of the role that other complementary resources & services, such as social services must become even more clear and reliable as we use and integrate them with health care services for "improved outcomes" (Bradley & Taylor, 2015).

With this edition, the editors point to the future of the second question and have opened this space for readers (Chapter 14).

In Summary

Both questions seem to have "patiently waited for us" in the poet's words (Whyte, 2007). They both invite strategic thinking and aligned professional action. Both recognize that "knowing" alone is not sufficient. Books like this can invite knowing and doing, but it is the reader who makes things happen. Enjoy the authors and editors' words in this book but enjoy their intent in the work of an informed, acting reader even more. Let me close with Mary Oliver's words (Oliver, 2005):

What I Have Learned So Far

> Meditation is old and honorable, so why should I not sit, every morning of my life, on the hillside, looking into the shining world? Because, properly attended to, delight, as well as havoc, is suggestion. Can one be passionate about the just, the ideal, the sublime, and the holy, and yet commit to no labor in its cause? I don't think so.
>
> All summations have a beginning, all effect has a story, all kindness begins with the sown seed. Thought buds toward radiance. The gospel of light is the crossroads of—indolence, or action.
>
> Be ignited, or be gone.

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CHAPTER 1

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

William A. Sollecito and Julie K. Johnson

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 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 (Houpt, 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