

QUALITY IN HEALTH CARE

Introduction

The most prolific serial killers in the United States are among the least known. While the Green River killer in Washington and the Killer Clown of Chicago are well known, serial killers in health care have been responsible for a higher number of deaths over extended periods of time. What does serial killing have to do with quality management in health care? The issue is, how can health care workers kill dozens of patients without being detected? More to the point, how can highly trained personnel working together to improve the health of their patients realize the worst possible outcome without unleashing an investigative process to identify and understand what was responsible for the deaths of their patients?

The most prolific serial killer in U.S. medical history may be Donald Harvey, who killed between 37 and 87 patients in two hospitals in Ohio and Kentucky over a 17-year period. Harvey was able to continue his murder spree by targeting critically ill patients and changing his method of killing. The death of critically ill patients is not unexpected, and there was no easy-to-identify pattern in Harvey's killings that would suggest something other than natural forces were at work. Harvey's unmasking was rapid when it finally occurred. He targeted a man whose condition was thought to be improving by his family and the hospital staff; his unexpected death sparked an investigation.

The authorities determined the death was a homicide and immediately began investigating the man's family. Satisfied that no member of his family was responsible, the police began investigating his medical providers. Shortly after beginning their investigation at Harvey's employer,

LEARNING OBJECTIVES

1. Set the context for the study of quality in health care
2. Understand the goals of quality management
3. Define quality and health care quality and understand their components
4. Recognize the contributions and challenges faced by health care quality pioneers
5. Understand the evolution of production and quality management processes
6. Apply system thinking to health care processes

they learned from multiple coworkers that Harvey was known as “the Angel of Death” due to his frequent presence when patients expired. Unfortunately, Harvey was no angel. He soon confessed to killing many patients.

Charles Cullen provides a second example. Unlike Harvey, Cullen worked in 10 health care institutions in New Jersey and Pennsylvania. Over 16 years Cullen murdered between 18 and 40 patients. Cullen killed many of his patients by administering overdoses of digoxin. Despite concerns over suspicious deaths, investigations were handled internally by his employers and failed to discover any wrongdoing. Cullen frequently changed jobs, and any concerns, if relayed, did not prevent him from finding continuous employment in the health care field. In the end it was only the dogged efforts of the family of one of his victims that resulted in his arrest for the death of their loved one and in the discovery of the other cases.

The issue for quality management is, how can the worst possible health care **outcome** occur repeatedly without signaling that there is a problem in the **system** that requires investigation? Walshe and Shortell in “When Things Go Wrong: How Health Care Organizations Deal with Major Failures” (2004) note that health care failures differ substantially from failures in other industries. Harvey’s case exemplifies the first of these differences: it is not uncommon for critically ill people to die, so questions are not raised when the expected happens. A second difference is that the cost of health care failure is borne almost entirely by patients and their families. Contrast a patient death with a plane crash. In a plane crash not only the passengers die; the flight crew also perishes and a multimillion-dollar aircraft is destroyed. A third difference is that health care is largely a self-governing profession that often works to conceal errors rather than have its shortcomings exposed to public scrutiny (Walshe and Shortell 2004).

The tendency in health care to restrict information and conceal error explains how a person like Cullen could continue to find health care employment despite patient safety concerns. Walshe and Shortell conclude that failures go unrecognized and uncorrected for several reasons: the culture of secrecy and protectionism prevalent in health care, fragmented information, self-deception and ad hoc rationalization, informal mechanisms to deal with problems, nondisclosure legal settlements, multiple investigative bodies, and the high cost of investigation (Walshe and Shortell 2004, 107–108). All these factors explain how malevolent workers can systematically harm patients over an extended period of time without attracting attention. In Cullen’s case, a primary factor that allowed him to continue killing patients was the unwillingness of prior employers to perform thorough internal investigations. Instead his employers seemed willing to barter his resignation from their organization for an unblemished personnel record.

outcome

the results of medical treatment

system

a set of interrelated elements assembled to achieve a goal

As Machiavelli noted long ago, “There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things” (Machiavelli [1532] 1992, 25). The question is: Will health care meet this challenge and implement a new order of things for the benefit of patients?

The Goal of Quality Management

The goal of quality management is to ensure that products and services meet customer expectations or generally accepted production standards, or both. If health care were meeting the highest quality standards, patients would be protected from the intentional acts of malevolent persons and the mistakes of well-meaning workers. The challenge facing health care is to improve patient outcomes by changing how care is delivered. While the elimination of harm is not possible, quality management seeks to design and control systems to minimize it to the extent possible.

Perpetrators take steps to avoid detection, so eliminating intentional acts can be difficult. But discovering mistakes is much easier and will improve patient care more than the elimination of intentional acts. The Institute of Medicine estimated in 1999 that medical error results in the death of between 44,000 and 98,000 patients per year (IOM 1999, 1). Many question the validity of this estimate, but even if it substantially overstates the number of deaths due to medical error, it highlights the enormous opportunity for improvement (Hayward and Hofer 2001; McDonald, Weiner, and Hui 2000).

This chapter, after defining quality, begins by demonstrating that the pioneers in quality improvement in health care were those trained in medical science and eager to apply an analytical approach to patient populations (rather than simply review outcomes of individual patients) to achieve better results for their patients. These pioneers stepped beyond the individual patient-doctor relationship to view medical practice from a wider perspective. Interpretation of individual patient results is clouded by the patient’s behavior, environmental factors, and luck as well as medical intervention. Each of these factors can increase or decrease the probability of a successful outcome. When we are viewing a single patient, the role of medical intervention in a positive or negative outcome may be difficult to determine. Just as the effect of a medical intervention may be difficult to determine, the performance of a provider, a group of providers, or the health care system is also difficult to judge.

The goal of this text is to provide medical workers with an understanding of the history of quality improvement techniques in health care, improve

understanding of quality improvement tools, and review the current state of quality improvement applications. This chapter demonstrates that quality improvement is not new to health care and that those who pioneered the application of statistical tools to health care outcomes did so with the goal of improving outcomes for patients. It is hoped that by the end of the text the reader will understand the tools for assessing performance and be able to apply them for the betterment of patients.

Defining Quality

quality

a measure of the degree to which a good or service meets established standards or satisfies the customer

Quality is a measure of the degree to which a good or service meets established standards or satisfies the customer. Quality according to this measure is judged by two different groups. The first is the customer: is the customer satisfied with their purchase? If the customer is satisfied, a product or service fulfills their definition of quality. Producers, however, should strive for more than simple satisfaction; they should attempt to instill in their customers the belief they are getting the most value for their money. If satisfied customers believe they can get even greater value for their money, they will likely spend their funds elsewhere or on different products or services.

Walter Shewhart noted that quality management should be concerned with *qualities* rather than *quality*. He stated that “every conceptual ‘something’ is really a group of conceptions more elementary in form” ([1931] 1981, 38). Customers value several elements of a purchase, including the product or service purchased, service (how the product or service is delivered), timing, environment, selection, and price. To flesh out these characteristics, think of yourself in a restaurant (or buying a car, attending an entertainment event, or receiving medical care). Goetsch and Davis (2010) discussed the restaurant industry as one that is easy to evaluate because most people have had multiple interactions with it. The first concern of a consumer is typically whether the **product** meets generally accepted standards: is the meal fresh, tasty, and the right temperature, and does it have an appealing appearance? The portion size also affects satisfaction and provides an example of the interpersonal subjectivity of satisfaction. Many individuals desire large portions and are disappointed if they leave a restaurant hungry, while others are upset with contemporary portions, believing they encourage overconsumption and waste. Although portion size is not a determining factor in everyone’s restaurant choices, restaurants consider this factor along with many other characteristics of the meal to determine how receptive the public will be to their product and whether people are likely to go back to their restaurant.

product

something produced to satisfy a human need or desire

A second key factor that affects satisfaction is whether the **service** was acceptable: was the server knowledgeable and competent and did he or she treat the customer with the appropriate amount of respect? Servers walk a fine line between being on-the-spot and overbearing, and they must correctly determine the amount of attention each patron desires so they can provide customers with a satisfying dining experience. Because there is no one-size-fits-all solution, producers must customize their products to the individual tastes and preferences of their customers.

A third factor is **timeliness**: was the meal delivered quickly enough or was there substantial wait between when you arrived and when you were seated, when you were seated and when your order was taken, when your order was taken and when your food arrived, and between finishing your meal and the arrival of the bill? Delays at any point diminish the satisfaction the diner may have gotten from a good meal and good service.

Interpersonal subjectivity of satisfaction was discussed regarding the product, but satisfaction may also vary systematically based on gender, age, and other characteristics. The fourth factor, **environment**, often raises different expectations in the minds of females and males. For example, females often prefer a dining atmosphere that can be called romantic, cozy, or stylish. On the other hand, males may prefer rustic or hole-in-the-wall type establishments (especially if they serve large portions). Anyone who works with other people knows the temperature in the workplace can never be set to please everyone. While environmental factors cannot be adapted on a customer-by-customer basis, producers need to be sensitive to the desires of their customers and provide a setting—furniture, color, lighting, temperature—that will appeal to the largest pool of potential customers.

The fifth component is **selection**. Restaurants of all types recognize the need to offer variety: different meats, vegetarian offerings, senior meals, and children's menus. Health care is moving toward capitalizing on the importance of choice by increasingly involving patients in the decision-making process. Research consistently shows higher satisfaction among customers who actively participate in their consumption choices.

Price is the final factor that affects satisfaction. There is an obvious relationship between price and **value**, but when customers receive the same product for a lower price, their satisfaction usually goes up. Most people enjoy a bargain. However, even here we see the impact of the subjectivity of interpersonal satisfaction. Some consumers enjoy a purchase more if it has a price that others cannot afford.

Consumer-driven evaluations of quality assume the customer is capable of evaluating the good or service. Customers do not need to be chefs to evaluate the quality of food they consume; nor do they have to be mechanics

service

(1) what is provided to a customer, for example, health care treatment, haircut, and so on or (2) how a customer is treated in a transaction with a producer

timeliness

an action performed within a time frame that renders it effective or satisfies a customer

environment

the social and physical factors surrounding an individual

selection

the set of options from which a customer can choose

price

the amount of money that must be given to obtain a good or service

value

the interpersonal satisfaction a person receives from consuming a good or service

to judge the performance of their cars. The interesting aspect of a consumer-driven evaluation of quality is that each customer may place different weights on the six measures listed previously, and the weights they place on each measure may change over time. Quality is a dynamic concept, and producers must be sensitive to the differences between consumers and to changes in consumer preferences.

The second evaluator of quality is the producer. Like consumers, producers assess quality by determining whether the product is free from defect or meets generally accepted standards. Some restaurants expect wait staff to greet patrons within two minutes of their being seated and monitor food temperatures to ensure hot and cold foods are stored and served at the appropriate temperature. Producer assessment has been the standard used in health care. Physicians have determined what good or bad care is based on accepted standards of medical practice. The problem with consumer-driven evaluations of health care quality is that patients often lack the training and knowledge to evaluate medical treatment. Moreover, a large part of medical care occurs when the patient is unconscious, anesthetized, in pain, or in a state of high anxiety and is thus incapable of objectively assessing care.

To help patients assess the quality of health care providers, many health care organizations use their Web sites to provide consumers with information about providers' credentials, experience, range of services, participation in research and education, and overall patient satisfaction and outcomes. Credentials address where the provider was educated and trained. Experience addresses how many times the provider has performed a particular operation or type of treatment. Most people believe that practice makes perfect, and evidence suggests that providers who routinely perform care have better outcomes than those who provide a service only on a sporadic basis.

Range of services speaks to the selection of services offered, but in health care it also applies to the ability to handle unexpected complications that may arise. Participation in research and education addresses the idea that organizations engaged in research are on the cutting edge of medicine and will be able to offer their patients the newest and best medical options. Similarly, reporting on participation in medical education seeks to capitalize on the idea that the best provider of care is the one who trains other providers.

Finally, patient satisfaction and outcome return to our original definition of quality: Was the patient satisfied with the care he or she received? As we have seen, satisfaction is a multidimensional concept, and patients' satisfaction with their experiences may be driven by a combination of factors: the interpersonal skills of their care givers, the environment, the wait

and recovery time, the cost, and the expected outcome of care. Outcome addresses the results of care—how do the results compare with those of other providers, and with the patients' own expectations? While superior outcomes may lead patients to choose one provider over another or may provide the basis for higher reimbursement, superior average outcomes give little comfort to a patient or their family when an adverse event arises. The elevation of patient expectations may ironically make people less tolerant of adverse outcomes regardless of their source.

The greater knowledge of medical practitioners combined with the lack of consumer ability to evaluate care has led to a system in which providers define and police quality. The problem with any producer-driven system is that producers may place their interests above those of the consumers. Reports of 98,000 preventable deaths lead many people to conclude that producer interests too often supersede patient interests and contribute to the high rate of patient injury.

Defining Health Care Quality

Health care quality is optimal care from the appropriate provider in the most appropriate setting in the most appropriate manner for the patient's unique circumstances (Nash, Coombs, and Leider 1999). There are five aspects to this definition. The first is optimal care, which harkens back to meeting generally accepted standards of medical practice. The definition adds that optimal care should be delivered by the appropriate provider. This requirement simultaneously excludes the untrained and overqualified. Health care systems fail when undereducated or underskilled personnel provide care, but they also fail if rudimentary tasks are performed by highly skilled individuals. In the first case we have the potential for bad care. Through practice such a worker may be able to competently perform routine care, but would the employee be able to respond to an emergency requiring knowledge and skill beyond their experience? In the second case, the patient may receive exceptional care from an overqualified provider, but the service might be overpriced and a poor use of the person's skills.

The most appropriate setting parallels the most appropriate provider. Care should be delivered in the setting that maximizes the effectiveness of care, minimizes risk to the patient, and effectively uses resources. Particular types of care require hospitalization; other care can be performed more effectively in outpatient settings, physicians' offices, or the patient's home. Quality care requires that the best setting be identified and used to deliver care.

health care quality
optimal care from the
appropriate provider
in the most appropri-
ate setting in the most
appropriate manner
for the patient's unique
circumstances

“In the most appropriate manner” recognizes that patients expect to be treated with respect, and providers must recognize their need to be a part of the medical decision-making process or their desire to delegate decision making to the provider. Finally, the patient’s unique situation recognizes that provider fears of “cookbook medicine” are often overstated; the role of the physician will always be to navigate between the standards of medical practice and the unique set of medical conditions a patient has and their preferences for a particular type of treatment.

This definition recognizes that health care quality is a process, but it is less clear on how quality should be measured. The **five Ds of health care quality**—death, disability, disease, discomfort, and dissatisfaction—specify the outcomes that can and should be measured. *Death*, measured by mortality rates, recognizes that given a choice between two providers treating identical patients, the better physician is the one with the lower **mortality rate**. The assumption of identical patients will seldom be met and later chapters will discuss the difficulty of comparing mortality rates, but at this point we will conclude that lower mortality rates are preferred to higher rates.

Disability, or **morbidity**, measures the degree of impairment a patient has after receiving treatment. Again, the idea is straightforward: providers having lower rates of disability or higher rates of functionality should be preferred to those who have higher rates of disability. *Disease*, a different aspect of morbidity, refers to the presence of disease after treatment. Providers achieving higher clearance rates should be preferred to those with lower rates.

Discomfort addresses the process of care rather than the outcome. Did the provider adequately manage treatment to minimize the patient’s discomfort or pain? Finally, *dissatisfaction* (or, more accurately, patient satisfaction) is one of the most widely measured factors. Payers and accreditors require organizations to regularly measure patient satisfaction as a key component of their quality programs. Many medical providers are rightly concerned about the use of patient satisfaction scores since patients may not be the best evaluators of medical care. Patients have numerous disadvantages as evaluators of the appropriateness or quality of care due to their lack of medical training, lack of consciousness during major events, physical pain, or emotional distress arising from the uncertainty of illness. In spite of these drawbacks, patients will ultimately decide which providers they patronize, and their voices need to be recognized.

In health care it seems easier to identify poor quality—the death of a young person with no history of medical problems, or the oft-cited reference to 98,000 preventable deaths—than systemic weaknesses, but as we will see, the self-evident may tell only part of the story, and the truth may be very different from what we believe. The single tragic event or the 98,000 preventable deaths statistic have a disproportionate impact on our perception

five Ds of health care quality

death, disability, disease, discomfort, and dissatisfaction

mortality rate

the number of deaths in a population

morbidity

the presence of illness or degree of dysfunction

of the performance of the health care industry. The unfortunate result is that too much attention is given to rare events and too little to unsafe practices that may eventually produce a tragic outcome. The goal of this text is to improve health care by making the reader a more sophisticated user of data so that unsafe practices can be identified.

The central idea of the text is:

No Measurement → No Management → No Mission

Measurement provides the foundation for managerial action, and effective management ensures the success of an organization. This causal chain recognizes that without objective measures of performance, an organization cannot know where it stands or whether changes are required, and if so, when they should be implemented. The actions of managers can only be random in the absence of measurement and information. A manager operating without information will not know if a system requires correction or what changes to undertake. In the absence of performance measures, it is also impossible to determine if a change improves system performance since there is no basis for comparison.

We know that what gets measured gets attention. Managers must be certain the critical elements of a system are monitored after measurement is undertaken. When employees know that certain elements of their job will be measured and evaluated and their job security or pay may be determined by their performance, they pay extra attention to these tasks. The downside of this enhanced focus could be that other necessary but less rigorously reviewed operations will be slighted. The challenge to management is to improve elements of a system without creating problems in other parts of the organization. Managers must evaluate and act on information generated from all the vital operations of the organization and should not let themselves fall victim to tunnel vision. The organization could perfect performance in one area (such as timeliness) but lose customers as higher valued activities (such as effectiveness) languish.

The mission of an organization is its reason for being. An organization's mission should state who is to be served and how they will be served. Organizations without direction or purposeful action will be unable to compete with organizations that target the same customers, know how they are performing, and have informed management that can capitalize on the strong points of the organization and minimize or eliminate their weaknesses. A lack of effective management will lead to the production of goods and services that will be less desirable than the offerings of more capable competitors. In the long run, the ability to measure and manage performance will determine which organizations thrive and which will wither and die.

Quality Pioneers in Health Care

Ignaz Semmelweis (1818–1865)

Throughout history physicians and medical workers have been concerned about the quality of care and the well-being of their patients. However, concern and control were left up to the individual provider and there was little formal comparison of results. One of the first physicians to challenge this system was **Ignaz Semmelweis**. Semmelweis, a Hungarian working in Vienna, noticed a substantial difference between the mortality rates for two obstetric clinics operating within the same institution. Mortality rates record the number of patients dying as a percentage of total cases and are one measure of health care quality.

Ignaz Semmelweis
a Hungarian physician who championed anti-sepsis procedures and demonstrated lower mortality rates due to hand washing

Semmelweis observed that the mortality rate of the clinic staffed by physicians was 9.9% over a six-year period and death was frequently the result of puerperal fever, while the clinic staffed by midwives had a mortality rate of 3.3%. Table 1.1 shows the rate over six years, and Semmelweis noted that actual deaths in the physician-staffed clinic were *higher* than reported, as many dying patients were transferred from the clinic to the hospital and their deaths were not included in the clinic totals (Semmelweis [1860] 1983, 64). The difference of roughly one death in every 10 patients in the physician-staffed clinic versus one death in 25 patients for the patients treated by midwives led Semmelweis to ponder the cause of the radically different outcomes. The high mortality rate in the physician clinic was known among the general public, and Semmelweis stated that he witnessed expectant mothers begging to be treated in the midwife clinic ([1860] 1983, 70). Women also delayed their arrival to the physician clinic for treatment, preferring to give birth outside the hospital.

Table 1.1 Clinic Mortality Rates, 1841–1846

Year	PHYSICIAN CLINIC			MIDWIFE CLINIC		
	Births	Deaths	Rate	Births	Deaths	Rate
1841	3,036	237	7.8%	2,442	86	3.5%
1842	3,287	518	15.8%	2,659	202	7.6%
1843	3,060	274	9.0%	2,739	164	6.0%
1844	3,157	260	8.2%	2,956	68	2.3%
1845	3,492	241	6.9%	3,241	66	2.0%
1846	4,010	459	11.4%	3,754	105	2.8%
Total	20,042	1,989	9.9%	17,791	691	3.9%

Source: I Semmelweis, [1860] 1983, *The Etiology, Concept, and Prophylaxis of Childbed Fever*, The University of Wisconsin Press, Madison, WI, 64.

As in the midwife-staffed clinic, the rate of puerperal fever in patients delivering outside the hospital was considerably lower than in the physician-staffed clinic. The prevailing medical opinion was that these deaths were caused by atmospheric-cosmic-terrestrial factors that were beyond human control. Semmelweis demonstrated that these factors could not explain the higher mortality rates in the physician-staffed clinic compared to either the midwife-staffed clinic or street deliveries, as these births were subject to the same atmospheric-cosmic-terrestrial conditions. The different mortality rates, combined with the death of one of his colleagues who was cut with a scalpel during an autopsy and the fact that mortality rates increased when Semmelweis, who performed extensive autopsies, replaced a physician who did not place the same emphasis on postmortem study, led Semmelweis to attribute the higher mortality rates to physicians moving between tasks and patients without washing their hands (Carter and Carter 1994). Semmelweis's chief concern was moving from the autopsy room to delivering babies without washing.

In May 1847 Semmelweis instituted a policy of hand washing in chlorinated lime before delivering babies, and the mortality rate in the clinic staffed by physicians was reduced to 2.38%. This success was short-lived as the mortality rate increased after a new group of medical students was introduced to the hospital. Semmelweis, fearing that the new students were neglecting to wash their hands between tasks, began a program of publicly displaying the names of students and patients so those who neglected to wash could be identified by their higher mortality rates. Semmelweis's efforts again led to a reduction in the mortality rate (Carter and Carter 1994).

The medical community remained skeptical despite his better outcomes, and he was drawn into a power struggle in Vienna that culminated in him not being reappointed to his post. Semmelweis returned to Budapest and was appointed director of a small maternity facility that had recently had a rash of puerperal deaths; again he instituted a policy of washing in chlorinated lime, and mortality rates fell (Carter and Carter 1994). He later replicated his success at the University of Pest, where he was appointed professor of obstetrics. But success in three institutions did not sway the larger medical community (Carter and Carter 1994).

Many physicians were skeptical and dismissive of Semmelweis's conclusion that failure to wash as doctors moved from one medical procedure to another was connected to the higher mortality rates. Physicians were comfortable with their belief that they were doing everything in their power to assist their patients and that these deaths were beyond control. The failure of his colleagues to recognize the fact that the so-called uncontrollable

factors producing death had been controlled led Semmelweis to publicly attack his colleagues. His perceived erratic behavior resulted in his forced confinement to a mental institution in 1865. During a struggle with asylum guards he sustained internal injuries and a wound that became infected. He died August 13, 1865. The year of Semmelweis's discovery was 1847, before germ theory was posited. Joseph Lister would later give Semmelweis substantial credit for his development of germ theory, stating “without Semmelweis, my achievement would be nothing” (Lienhard).

Semmelweis's story points out some of the essential ingredients of quality improvement. The first is the ability to quantify outcomes. Semmelweis was trained in statistics, and his training led him to calculate mortality rates. The second is the ability to identify a problem (or opportunity for improvement). The opportunity to compare mortality rates across clinics led Semmelweis to conclude that outcomes were significantly different. After reaching this conclusion, his focus changed to identifying the cause of the difference and determining if outcomes could be improved. Given his hypothesis that it was the actions of the providers that were introducing puerperal fever to patients in the obstetric clinic, he needed only to explore means of avoiding this exposure. Armed with prior outcomes, an identified potential cause, and a remediation method, the next step was to test the hypothesis and avoidance mechanism to determine if the problem had been correctly specified. Unfortunately for thousands of patients, Semmelweis's superior performance was unable to move a medical profession that was not ready to accept that simple hand washing could lead to improved patient outcomes.

Florence Nightingale (1820–1910)

Although Semmelweis's contributions were not fully recognized, others began to take a similar approach to medical care. Among the most famous is **Florence Nightingale**. Nightingale noted in the Crimean War the high mortality rate among soldiers brought to the field hospital. However, her journey to the field hospital merits attention. Nightingale was born into an upper-class English family in 1820 and as a young woman struggled against both her family's and society's expectation of the role of a young woman. Her choice of nursing was universally denounced in her family, as hospitals were known as dirty and deadly places and nurses were often characterized as drunken and promiscuous.

Due to her drive, by 1854 Nightingale had established herself as one of the foremost experts in England on hospital construction and operation. She was selected to supervise female nurses in the Crimean War after a

Florence Nightingale
an English nurse known for improving medical services of the British Army, improving conditions of workhouse infirmaries, and formalizing nursing education

series of articles in *The Times* on the treatment of British wounded led to a public outcry. By 1855, Nightingale had cut hospital deaths from 32 percent to 2 percent by improving the food, water, and clothing provided to patients, reducing overcrowding, and ventilating the wards (Winkelstein 2009). Others estimate that deaths fell from 42.7 percent to 2.2 percent (Neuhauser 2003).

One of Nightingale's biographers described the health system of the British army as one that "killed energy and efficiency, crushed initiative, removed responsibility and were the death of common sense" (Woodham-Smith 1951, 99). In this system, Nightingale was given the task of improving the health of the British soldier and the title of Superintendent of the Female Nursing Establishment in the English Military Hospitals in Turkey. This title, however, allowed the military bureaucracy to deny her authority to improve conditions in the Crimea since her authority was limited to Turkey. After the war, Nightingale continued to be impeded by active and passive resistance from policy makers, and even after government officials were replaced with persons sympathetic to her goals, she continued to face resistance from the military bureaucracy.

Like Semmelweis, Nightingale found that the path to improved health care required stirring up vested interests. Nightingale subsequently attempted, with Dr. William Farr, to improve health care service in all English hospitals by publishing mortality rates. In a book published in 1871 Nightingale, like Semmelweis, published mortality rates in maternity wards. She noted that mortality appeared related to the number of patients housed in the same room: 8.0 deaths per 1,000 when there were eight beds per room, 3.4 per 1,000 when four per room. She also documented 193.7 deaths per 1,000 in a hospital in Paris that housed maternity patients with medical and surgical cases (Woodham-Smith 1951, 305).

Nightingale was active in improving sanitary conditions in India, upgrading the conditions in workhouse infirmaries in England, and establishing a nursing school to enhance the skills and status of nurses. Reform in each case struggled against the established order. Hospitals, the military, the infirmaries, and the Indian authorities, who were all used to being accountable only to themselves, did not appreciate seeing their outcomes published for the rest of the world to view. The release of data was met with the only-too-common criticism that the numbers were wrong and the statistical methods were unsound. Fortunately, the attempts of opponents to change the debate from the quality of medical care to the soundness of the statistics were not successful.

While Nightingale often expressed frustration over the pace and extent of improvement, it was clear that her efforts brought great improvements

for the often overlooked members of society. Nightingale’s work stressed the need to collect data; her work followed the requirements of quality improvement in that she observed conditions and speculated on what would improve outcomes. She wrote, “The most important practical lesson that can be given to nurses is to teach them what to observe—how to observe—what symptoms indicate improvement—what the reverse—which are of importance—which are of none—which are the evidence of neglect—and of what kind of neglect” (Nightingale [1859] 1992, 105). A second lesson that can be drawn from Nightingale’s work with the British army is the need to reform the administrative system before quality issues can be addressed.

As in Europe, medicine and medical school training was undergoing a transformation in the United States in the mid-19th century. The rise of science was pushing medical schools to lengthen their degree programs and supplement their basic science requirements (Starr 1982). In 1876 the Association of American Medical Colleges was formed with the goal of standardizing medical education. Restructuring of American medical education reached a threshold in 1893, at **Johns Hopkins**. Hopkins that year required four years of training and an undergraduate degree for admission to its medical school. These changes, combined with licensing changes, put downward pressure on the number of U.S. medical schools. Table 1.2 demonstrates that the number of medical schools continued to increase until 1906 and contracted thereafter.

Johns Hopkins

an American school of medicine credited with establishing rigorous training standards for physicians

Table 1.2 Number of U.S. Medical Schools

1850	42
1870	75
1890	133
1906	160
1910	131
1915	95

Source: P Starr, 1982, *The Social Transformation of American Medicine*, Basic Books, New York, 42, 112, 118, 120.

No discussion of the evolution of American medicine is complete without mentioning **Abraham Flexner’s** report titled “Bulletin Number Four” (1910). Flexner, funded by the Carnegie Foundation, issued a scathing report on the quality of medical skills. An earlier AMA report concluded that of the 160 schools existing in 1906, 82 were rated A, 46 B, imperfect but redeemable, and 32 C, beyond salvage (Starr 1982, 118). The AMA report was not published, due to professional ethics, but led to the Flexner report,

Abraham Flexner

educator who reformed medical education in the United States

which judged medical schools more severely. Although this study continues to be heralded as the point of change in American medicine, one can see reform had begun in the 19th century and the number of U.S. medical schools had peaked prior to the release of Flexner's report.

Ernest Codman (1869–1940)

The evolution of medical education introduced into the medical system a new breed of physician who wanted to apply scientific principles to medicine. At the forefront of this group was **Ernest Codman**. Codman graduated from Harvard Medical School in 1895 and immediately began to systematize how he practiced medicine. Codman recorded the number of deaths occurring during anesthesia and believed medical practice could be improved by examining these deaths. To his dismay the primary reaction to these deaths among the surgeons he worked with was that death was an accepted, perhaps inevitable, part of treatment. Undeterred and unwilling to accept operating room deaths as inevitable, Codman began to chart anesthesia deaths and work toward reducing mortality rates. In 1914 he claimed there were no anesthesia deaths at his End Result Hospital (Codman [1914] 1996, 139).

His **End Result Idea** became the compelling passion of his life. The End Result Idea was that all patients should be followed long enough to determine the outcome of medical care. In his initial work with anesthesiology, Codman was not satisfied with the conclusion that treatment was unsuccessful; instead, he wanted to know why the patient died and what could be done to prevent future deaths. The End Result Idea required long-term follow-up to determine not simply whether the treatment was successful but also whether the patient's life improved as a result of treatment. Unfortunately, health care has focused on the easier-to-measure treatments than on impacts, and this choice has undermined the drive for health care improvement.

The End Result Idea, in addition to requiring postdischarge patient tracking, included peer comparisons and the public release of results. Peer comparison would allow physicians to understand how their outcomes stood in comparison to other practitioners. Codman hoped peer comparison would lead providers with substandard results to discover the source of outcomes and undertake improvement. Public release of results was advocated to enable patients to make more informed choices when selecting a provider, spurring further improvement. Obviously public release of medical outcomes threatened individual physicians as well as the medical profession as a whole. While Codman is often heralded as the father of outcomes management, none of Codman's ideas was widely accepted by the medical

Ernest Codman

an American physician known for championing long-term follow-up of patients, peer comparison, and public release of medical results

End Result Idea

belief that all patients should be tracked for at least one year to determine the outcome of care

establishment, and he found himself at odds with the generally accepted way of doing things. Codman believed that objective evidence was the only way to evaluate performance and that subjective factors that constituted most performance evaluation systems were merely the outdated remnants of a system that science had rendered obsolete.

Codman's opposition to promotion based on seniority rather than competency led him to quit his job at Mass General; he reapplied based on the superior outcomes he had achieved and was rejected. Undeterred, he opened his End Result Hospital in 1911 in Boston and issued annual reports each year documenting his successes and failures. His hospital closed in 1917 after the Halifax Harbor disaster, which killed roughly 2,000 people, when he chose to go to Canada with his staff to provide medical care to the injured.

Codman never reopened his hospital due to his commissioning in the U.S. Army during World War I. After the war, he would go on to establish himself as an expert in bone sarcoma and publish the definitive study on the shoulder (published in 1934). By the time of his death he was widely recognized for his efforts toward improving health care, and his fame has grown with time. The idea that patients should be tracked after treatment to determine the long-term effectiveness of treatment remains underutilized, however. Codman was concerned that given the emphasis on short-term results, a "physician might dupe a patient with kind words and unnecessary operations without worrying about the ultimate outcomes" (Crenner 2001, 228).

One can see Codman's foresight in reports of the mortality rate of bariatric surgery. Consider the commonly reported bariatric mortality rate of 0.5 percent. When the mortality rate is measured at one year, the rate for men between the ages of 65 and 74 is 12.9 percent, and 51.0 percent for men over 75 (Flum et al. 2005). John Wennberg cites similar statistics in prostatectomy: in-hospital mortality rates are 1.2 percent, 4.0 percent after three months, and 40.0 percent for one subgroup (Wennberg 1984).

These statistics demonstrate that the questions we do not ask often have a significant effect on the information we receive and use. Recent government attempts to publish the outcomes of cardiac surgery were also met by fierce medical opposition, which convinced New York to end its reporting efforts. One can see that the efforts and ideas of Semmelweis, Nightingale, and Codman have been incorporated into routine medical practice and benefited patients, but in a larger sense their ultimate objectives have yet to be fully realized. The ideas of establishing a firm scientific basis for medical practice, standardizing practice, and establishing accountability remain works in process.

Codman is the direct forerunner of the Joint Commission, which accredits many health care organizations. In 1912 the Clinical College of Surgeons of North America formed two committees. The first was to organize the American College of Surgeons. Codman was named chair of the second, to form a Committee of Standardization of Hospitals. The committee was formed to evaluate the quality of medical care and was eventually subsumed by the American College of Surgeons. In 1951, the Hospital Standardization Program merged with groups from the American Hospital Association, American Medical Association, and others to form the Joint Commission on Accreditation of Healthcare Organizations (Mallon 2000), whose standards will be discussed in upcoming chapters. In 2007, the organization shortened its name to the Joint Commission.

Requisite Skills for Improving Health Care

There are two skills required to improve health care delivery. The first is medical. Health care cannot be delivered by those who are unfamiliar with medical science (anatomy, biology, chemistry, and physics) and medical technology (equipment and pharmaceuticals). Health care deals with systems, bodily and medical, and practitioners must understand each. The second set of skills is analytical, which deals with determining how a system should work by examining its performance over time or relative to other systems. Practitioners must be concerned with the processes and systems that are established to perform work and achieve goals. Analytical skill requires the ability to organize data to discover commonalities and to develop plans to improve the performance of systems.

The ability to quantify results derived from groups of patients is essential for evaluation and improvement of care. The first duty of physicians, nurses, and other providers is the care of individual patients, so it is fitting that their education devotes the majority of time to building medical skills. However, it is clear that medical education should devote more time to dealing with patient populations and systems as society demands greater accountability and as insurers and payers increasingly apply quantitative techniques to evaluate patient care. Given the entry of insurers and payers into medical decision making, it is imperative that health care workers become knowledgeable of analytical techniques and capable of applying these techniques to their work. Providers who fear that third-party involvement in medical decision making will detract from individual care must understand that the emerging population perspective is designed to improve the health of patients. Population-based analysis is not a threat to the patient-physician relationship but rather a means of ensuring that

patients and physicians have access to the best medical information. Dr. Codman noted that some physicians trust their individual experience more than the history of mankind. Codman, on the other hand, recognized that the basis for knowledge is not a single case but rather accumulated experience (Codman [1914] 1996).

Table 1.3 Essential Ingredients for Quality Improvement

1.	Data collection
2.	Data comparison (benchmarking)
3.	Hypothesis
4.	Testing

cottage industry

a production system in which workers use their own tools; production may take place in workers' homes, there is limited capital investment, each product is unique, and workers provide their own direction

mass production

a production system designed to produce large volumes of standardized products using standardized and capital-intensive processes

process improvement

a production system designed to improve products by identifying and eliminating errors and defects

mass customization

a production system aimed at producing unique, low-cost, and high-quality products for customers

output

the products produced or the services rendered by a system

The essentials for quality improvement shown in Table 1.3 parallel the elements of the scientific method: observation, hypothesis, prediction, and testing. The scientific method begins with the observation of phenomena and with curiosity; that is, after observing phenomena the viewer asks what accounts for the outcomes observed. Hypothesis arises from curiosity and from attempts to explain the phenomena by building a plausible model of factors that could produce the outcome observed. After a tentative explanation is determined, the third step is to predict future events. If the explanation is valid, it should be able to predict future outcomes; in health care if treatment is effective, future outcomes should improve. The fourth and final step is to build an experiment to test the hypothesis. To improve health care quality, we must implement similar systems to ensure that predicted interventions can be tested to determine if they actually improve patient outcomes.

Evolution of Production Processes

The modern scientific method was developed by the 17th century, coinciding with the rapid transformation of production processes. Understanding this transformation helps us understand the current state of health care and where it may be headed. Four distinct stages have been identified for production processes since the 17th century: **cottage industry**, **mass production**, **process improvement**, and **mass customization** (see Figure 1.1). In a cottage industry workers use their own tools, production takes place in workers' homes, there is limited capital investment, each product is unique, and workers provide their own direction. This system had significant drawbacks including high cost, low **output**, and poor quality.

The 18th century saw a shift away from home production in many industries. Home production was replaced by factories that were built with large capital investment and that relied on new sources of power (for example,

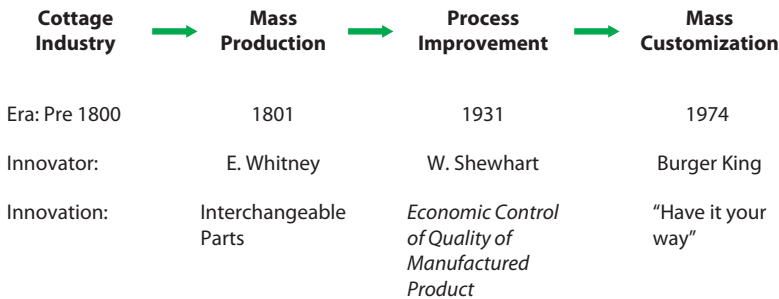


Figure 1.1 Evolution of Production Processes

steam and hydraulic). More important than these physical changes was the shift to **accountability**, **authority**, and **standardization**. Workers could no longer set their own hours, determine what they would do, or evaluate their own performance. Integrated mass production systems required work to be performed at certain times. Workers were given a limited set of tasks to perform, and their performance was judged by a third party. Mass production reached its high point with Henry Ford's invention of the assembly line. Mass production greatly expanded output and provided consumers with higher-quality goods and services at lower prices.

As output and quality improved with mass production, the increasing wealth of the United States made consumers more quality conscious. That, combined with Japan's drive to improve the competitiveness of their products on world markets after World War II, led productive processes into a third era: process improvement. The emphasis in process improvement is on improving the performance, durability, and reliability of products. Process improvement shifted producer focus from providing low-cost products to those with both low cost and high quality by instituting processes to identify and eliminate errors and, later, by improving systems to reduce the probability of errors. With the energy shocks of the 1970s, Japanese automobiles began their rapid infiltration into U.S. markets since they were more fuel efficient, had fewer defects per vehicle, and outlasted American-made autos. U.S. manufacturers began to see that their position on world markets was not guaranteed, and they instituted a series of programs—**continuous quality improvement (CQI)**, **total quality management (TQM)**, and Six Sigma among others—to enhance the desirability of their products.

Some producers have evolved from process improvement to mass customization. In mass customization the goal is **efficient** and **effective** customization of products and services that incorporate the features desired by individual buyers and that can be produced at a low cost while meeting quality standards. Customization harks back to cottage industries,

accountability
the obligation to explain one's actions and decisions

authority
the power to make decisions, judge performance, and initiate action

standardization
(1) in products, the production of nearly identical products with interchangeable parts; (2) in processes, the establishment of designated operations

continuous quality improvement (CQI)
a quality philosophy that emphasizes ongoing incremental changes to an organization's products and processes to increase customer satisfaction

total quality management (TQM)
a quality philosophy recognizing customer satisfaction requires superior performance from all aspects of an organization and thus management and improvement efforts must focus on and control the entire range of operations

efficient
utilizing the minimum amount of inputs to produce an output

effective
producing the desired outcome

in which workers would produce a unique product for a particular purchaser. This flexibility, however, came at a high cost in terms of price, ease of repair, and quality. Mass production, with its labor specialization, mechanization, and standardization of components, allowed cost to be driven down dramatically, thus expanding access to products to millions of families, but it was often seen as a one-size-fits-all mentality. Henry Ford famously summed up this attitude by stating that car buyers could have any color they wanted as long as it was black. In his case, the desire to keep Model T costs low trumped the desire of consumers to purchase cars of different colors.

Mass customization combines the best of unique, cottage-industry products with the advantages of mass production to produce custom products for a purchaser at a low cost with consistently high quality. Mass customization allows customers to select the features of the product they wish to purchase. For example, BMW advertises that a customer can select from 10 million options, and the Mars company allows purchasers to imprint M&M candies with their own sayings. The key to success in mass customization is the ability to modify a production process so it can produce high-quality custom products quickly and efficiently.

Where does health care lie along this continuum? Because health care relies extensively on the judgment of physicians, many aspects of health care reflect a cottage-industry model, especially in that medical practice is a profession that establishes its own standards and monitors its own performance. With the rise of medical science in the 19th century and the rapid increase in technology, some aspects of health care shifted to hospital settings, where specialization of labor is practiced and providers use vast amounts of capital in treating patients. The current emphasis on quality improvement in health care grew out of the work of Avedis Donabedian in the 1960s. Donabedian's work (1988) is discussed in Chapter Two. Thus, health care today incorporates aspects of cottage industry, mass production, process improvement, and mass customization. However, I place health care into the cottage industry category. I believe, like Codman, that improvement cannot occur until authority is spread beyond physicians; self-policing does not and cannot work. Mass production requires that someone other than the producer of a good or service evaluate the product. Codman noted that the reported outcomes of medical practice cannot be the sole domain of medical practitioners and suggested that a third party (Codman recommended a lay member of the hospital board) is required to validate the accuracy of these reports.

Quality Control in Industry

Walter Shewhart (1891–1967)

Semmelweis, Nightingale, and Codman highlight the two essential ingredients required to improve quality in health care: the ability to use statistics to identify an area for improvement and medical knowledge to discover solutions. The towering figure in applying analytical skills to quality improvement in industry is **Walter Shewhart**. Shewhart joined Western Electric in 1918 and worked on improving the reliability of their manufacturing processes.

Shewhart realized that all processes are subject to two types of **variance**: natural and assignable. Natural variation is the result of normal fluctuation in performance while assignable variation is due to special causes and signaled a movement away from normal performance. Shewhart's innovation was the creation of a system that could be used by assembly-line employees, workers whose skills lie outside the field of statistics, to distinguish between the two types of variation. Shewhart's **statistical process control** (SPC) charts will be introduced in Chapters Six through Eight to demonstrate how his work can be used to monitor health care processes.

Shewhart demonstrated that performance improvement required workers in a system to be able to differentiate the two types of variance that affect output. Assignable variations—changes in performance away from historical experience that may arise from poor performance or a change in the system—had to be distinguished from natural variance, which is always present in a process. Recognizing assignable variation is essential to knowing when corrective action is required to restore historical performance. Assignable variation signals the operator to investigate why performance is changing and to rectify problems as they arise.

On the other hand, implementing corrections when a system is operating with only natural variance, that is, within the range of performance it has historically operated in, can interfere with performance and reduce quality. Shewhart's work was designed to identify when a system had changed or was moving in a direction that would degrade output. Prompt recognition of assignable variation gives workers a tool to respond quickly to changes that could degrade output and minimize or eliminate problems.

Shewhart also developed the **Plan-Do-Check-Act (PDCA) cycle**, which specifies a definitive approach to problem solving versus ad hoc and random methods (see Figure 1.2).

Plan: Study system, identify problems or opportunities for improvement, and formulate corrective actions for problems or enhancements for improvements.

Walter Shewhart

a pioneer in quality management who distinguished natural and assignable variation, developed statistical process control, and championed the PDCA cycle

variance

the distribution of a variable around its mean

statistical

process control

a method of identifying natural and assignable variation based on probability

Plan-Do-Check-Act (PDCA) cycle

a continuous process of examining systems, implementing changes, and evaluating the effect of the change

Do: Implement a small-scale test of proposed correction or enhancement.

Check: Review results of test.

Act: (A) If desired outcome is achieved, implement correction or enhancement across organization; return to Plan and investigate further improvement in same area or focus on new area.

(B) If desired outcome is not achieved, return to Plan: Why didn't the correction or enhancement work? What else can be tried?

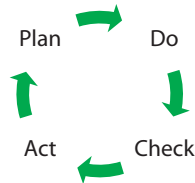


Figure 1.2 The PDCA Cycle

The PDCA cycle is a widely used tool for continuous quality improvement in health care, as workers always return to planning. If improvement or corrective efforts are successful, the PDCA cycle encourages workers to reexamine the system, including other parts of the system, to determine what other improvements can be achieved—improvements that will be valued by customers. If efforts are unsuccessful, a problem continues, or improvement is not achieved, the PDCA cycle encourages workers to return to the original issue and develop other plans to reach their goal.

W. Edwards Deming (1900–1993)

W. Edwards Deming perhaps the best-known champion of quality improvement, he popularized SPC and PDCA, and identified 14 principles to transform management and the seven deadly sins and numerous obstacles that could derail transformation

W. Edwards Deming is among the most recognized advocates, if not the father, of quality improvement. Deming brought Shewhart's SPC work into general use and is widely credited for the economic revival of Japan following World War II. His emphasis on quality led Japan away from inexpensive trinkets to establish it as a world-class producer of electronics and automobiles.

Deming is known for popularizing the PDCA cycle, a Shewhart innovation, and emphasizing the need for continuous improvement. He is also known for his specification of the seven deadly sins that lead to poor quality output. These sins include short-sightedness (focus on short-term profits, counterproductive employee evaluation techniques, and excessive staff turnover) and the lack of discipline or effort (inconstancy and overreliance on easily measured data), all of which inhibit quality work (Deming 1982).

To revive stagnant organizations and improve the quality of output they produce, Deming proposed 14 principles (Deming 1982). Among his principles he suggested moving away from **inspection** toward building quality into the product or service, thus eliminating inspection costs and incorporating

inspection

the process of using a second party to review the work of another to determine whether the work meets standards

everyone into ensuring quality (principles 3 and 14). Deming emphasized that complacency is the enemy; no organization can consider its products to be “good enough,” as competitors will perpetually seek advantage in the marketplace by improving products and recognizing changes in customer desires. Organizations must continuously improve to survive (principle 4). Improvement, however, can occur only if employees have the skill required to recognize and act on opportunity. Organizations must institute education programs that can provide the skills needed to maximize the contribution of workers (principles 5 and 13).

Deming suggested that a change in management is required. The function of management should be shifted from oversight to facilitation, and workers should not fear their superiors but see them as partners in the common task of creating the best product for customers (principles 7 and 8). Deming felt slogans should be eliminated; unfortunately the history of quality management has been replete with slogans (for example, “Zero defects”) that were unhelpful if not infantile (principle 10). Deming is well known for his assertion that 94 percent of all problems are due to management; that is, to a failure of management to control the system in which employees are working (Deming 1982).

Kaoru Ishikawa (1915–1989)

Kaoru Ishikawa, like Codman, recognized that quality improvement was “too important to be left in the hands of specialists” (Beckford, 1998). Ishikawa is known as the father of the **quality circle**. The quality circle required employees from different operations in an organization to meet to discuss problems. It was designed to break down the silos that develop within organizations, wherein employees are only concerned with what takes place in their area and do not consider the impact their work has on the work of other employees or on customers.

Ishikawa contributed to broadening the view of quality. Quality was not simply the immediate product or service but “after sale service, quality of management, the company itself, and the human being” (Beckford 1998). Like Shewhart and Deming, Ishikawa believed an educated workforce given timely data would be motivated to seek continuous improvement.

Ishikawa also developed **cause and effect diagrams** (also known as Ishikawa diagrams or fishbone charts). The cause and effect diagram is a tool for identifying the cause of problems. Organizations experiencing problems need to identify the problem (that is, the effect) and work backward to identify its cause. The cause and effect diagram guides the examination process and produces an easy-to-understand graphical representation of its conclusion.

Kaoru Ishikawa

quality improvement advocate known for quality circles, cause and effect diagrams, and the view that quality demanded more superior performance in all aspects of an organization and not simply superior goods and services

quality circle

teams of frontline employees assembled to identify production problems and improve operations

cause and effect diagram

a formal means of assembling, displaying, and evaluating the potential causes of a product defect or production problem

The ideas and tools developed by Shewhart, Deming, and Ishikawa are used repeatedly in this book, as the text focuses on the analytical techniques and medical applications that have been used to improve health care outcomes.

Evolution of Quality Management

Ever since people began trading goods and services, craftsmen have sought ways to distinguish themselves from others offering the same products. One way of besting competition is to provide superior quality products. Today we talk of “better, cheaper, faster,” but the same three elements of quality, price, and service have always formed the historical basis for competition.

Prior to the industrial revolution, quality was left up to individual craftsmen and customers. The craftsman determined the level of quality he would work to and suffered the consequences of failure if he did not reach the targeted level of quality or if his customers expected a higher level of performance. A more rigorous system to ensure quality was required as the industrial revolution advanced, labor specialization increased, and products became more complex. The production system had to ensure that the work of various personnel seamlessly fit together and that the final good or service met customer specifications.

Inspection was introduced to ensure quality and customer satisfaction (see Figure 1.3). Inspection required dedicated personnel to review the output of a process and determine which products were acceptable to sell and which should be rejected, to be either reworked or scrapped. While inspection is a first step, it has many flaws, the first of which is that accepting or rejecting the final product is very costly. Errors made early in the production process may require substantial reworking of acceptable work to correct the early error, or if the product is scrapped, the organization loses the cost of all resources and effort expended. A second drawback is that inspection is not a value-adding process; it produces nothing. The cost of inspection is part of the total cost of poor quality—this effort and its associated cost would not be required if things were done right. Third, inspection is not perfect; therefore many errors are not caught. Finally, making quality the job of a particular group of employees, the quality control department, often leads other employees to believe that quality is not their responsibility, and to act on that belief.

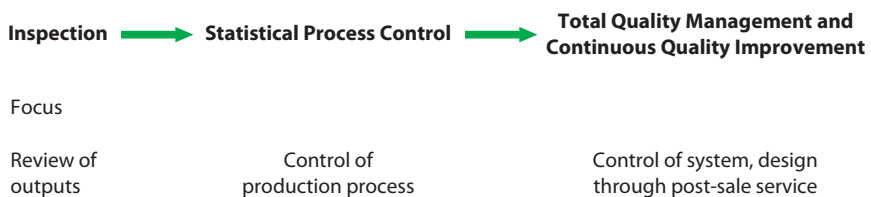


Figure 1.3 Evolution of Quality Control

In the 1920s, Shewhart realized the drawbacks of inspection and developed the more proactive statistical process control. *Process* is a key word, as Shewhart did not want to wait for the completion of a product before determining if it was acceptable or unacceptable. Shewhart's goal was to monitor the production system at various intermediate points to identify when a problem might be arising. If a potential problem is identified, adjustments can be made to the system earlier to ensure an acceptable product is produced and to reduce the number of incorrect outputs and the amount of rework needed to correct the problem. Shewhart's system was designed to be used by personnel on the assembly line. Workers would monitor the system, decide when changes were required, and take the necessary actions to ensure acceptable products were produced without the intervention of supervisory personnel.

Today, quality programs are commonly labeled *total quality management* and *continuous quality improvement*. Quality is now seen as encompassing all aspects of an organization's business, from sales through production and ending with billing and service (versus simply producing an acceptable product). The focus on all aspects of an operation reminds us that it is possible to produce great products and still lose customers. Customers demand more than a good product; they demand to be treated well and want their needs satisfied quickly. Poor service loses customers, and good products are insufficient to ensure success, because other organizations that produce similar products and provide exceptional service will win the battle of the marketplace.

A second major change is that the new quality systems are not content with maintaining quality but strive to continuously improve quality. Statistical process control emphasizes meeting specifications; the new emphasis is to improve products and services to meet changing customer expectations and counter improvements competitors are introducing. Continuous improvement requires an organization to understand its customers, processes, competitors, and evolving technology to ensure its goods and services offer the highest value in the marketplace.

System Thinking

Workers have a tendency to define their tasks narrowly, but quality management requires employees to understand how their performance affects the overall system and the satisfaction of customers. All work is a process, and only by understanding systems will we be able to implement real change—that is, be able to resolve the true causes of a problem rather than merely alleviate the symptoms of problems. This requires **system thinking**.

system thinking
a set of interrelated
elements assembled to
achieve a goal

input

what enters a system from the external environment; includes labor, supplies, and equipment

throughput

the process of how work is performed or how inputs are transformed into outputs

feedback

information on how a process is performing, which is relayed to the input, throughput, and output processes to improve their performance

Systems are composed of five elements: **input**, **throughput**, output, outcome, and **feedback**, and their performance is affected by what occurs within the organization and by the interaction of the organization with its external environment (see Figure 1.4). Inputs are what enter a system from outside; in health care this includes labor, supplies, equipment, and patients. Hospitals increase the probability of achieving their goals by controlling their purchased inputs (employees, supplies, and equipment) and by extending staff privileges to qualified physicians. Hospitals attempt to identify and use a set of inputs that is most likely to produce the desired outcome. Labor is screened to determine if individuals have the knowledge and skills to successfully complete the tasks they will be assigned. Similarly, supplies and equipment are assessed to determine if they are adequate for the tasks for which they will be used. Inputs that may fail to produce the desired outcome should be identified and eliminated *before* they enter the production system.

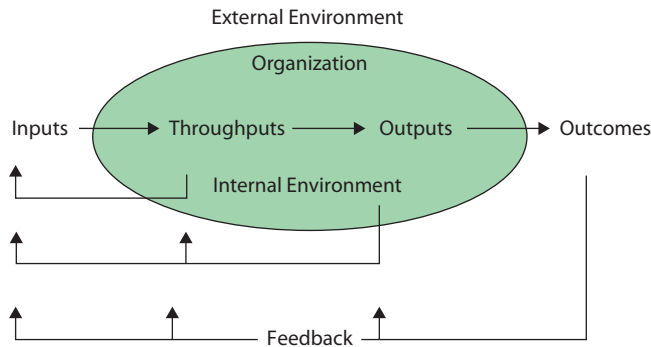


Figure 1.4 The System Model

Unlike labor, supplies, and equipment, a major variable in the production of health outcomes that is less subject to control is the patient. Patients present with a multitude of conditions that affect the probability of successful treatment, but this input and its variability cannot be eliminated. Health care organizations need to identify patient factors that must be incorporated into treatment plans to increase the probability of success. For example, patients allergic to penicillin need to be identified before penicillin is administered and an adverse reaction occurs, or patients admitted with preexisting infections in addition to their admitting diagnosis must be recognized and treated.

Input problems that could prevent the desired outcome from being reached include the use of inferior inputs such as less-skilled labor and low-cost materials or equipment. The use of the wrong inputs in a process may prevent the desired outcome from being achieved and produce harm. For example, in blood transfusions a patient must receive the correct or

universal blood type to avoid a hemolytic transfusion reaction, which could result in death. The employment of a spoiled, damaged, or impaired input may similarly have grave consequences. For example, the correct pharmaceutical may have been administered, but its effectiveness could be impaired if it is past its expiration date.

Throughput is the process of how work is performed, or the transformation of inputs into outputs. When a production process is unclear, it is described as a **black box**: an observer can see what enters and leaves the system (the inputs and outputs), but the specifics of the transformation process are unclear. Medicine and education are two black box processes. In medicine, patients enter the system in hopes that they will be released without the problems they had when they began treatment. The process by which a patient is treated is far from a deterministic process and includes dozens, if not hundreds, of tests and procedures. How physicians treat their patient is determined by where they were trained, where they practice, their schedule, the availability of equipment and supplies, the condition of the patient, and the desires of the patients and their families.

Similarly, students enter the education process with the expectation that they will graduate with more knowledge and new skills, but how knowledge and skills are gained is far from transparent. We see the educator, the textbook, assignments, and tests and student performance on standardized tests, but the process of how a student learns remains unclear. Was learning due to the lectures, reading the textbook, working the assignments, associating with fellow students, or other factors or a combination of factors? The problem in education is that we focus on inputs and outputs and give short shrift to what happens in the transformation process. The educational preoccupation with graduation rates fails to focus attention on what should be the outcome of education: ensuring that students gain the knowledge and skills necessary to be successful in life. This outcome requires educators to assess student postgraduation performance.

Something as seemingly simple as driving an automobile may be described as a black box. A driver may not know how an internal combustion engine works, but he or she knows how to steer, accelerate, and brake. Gas is the input and transport is the outcome, but the driver does not have to understand the working of the pistons or how the transmission operates to move from one place to another. On the other hand, auto production is a white (transparent) box. Each step in the creation of an automobile is sequenced, performance standards are detailed, and performance can be monitored and measured.

Throughput problems include poorly designed processes that may not be capable of producing the desired outcome if followed to the last detail

black box

a production system
whose internal operation
is unknown

or processes that are susceptible to error. Poorly designed systems increase the probability that employees working within the system will have slips or lapses or make mistakes (Reason 1990). Strong systems reduce the probability that workers will fail to undertake a desired activity, complete tasks, perform to standard, or use the correct process.

Organizations should monitor transformation processes to determine if they are operating in a manner likely to achieve the desired outcome. Monitoring a **white box** process is easier than a black box, as the steps are sequenced and performance standards are clear. In black box systems, such as health care, there is wide variability in how similar patients are treated. Because health care transformation processes vary based on who is operating the system and who is being treated, monitoring performance is a challenge. The difficulty of instituting effective monitoring increases with variability in the system.

Output refers to the products produced and services rendered, for example, tests, procedures, patient days, or discharges. Output is the result of the combination of inputs and how the inputs are manipulated (the transformation process). Potential output problems include bad design, such as that which occurs when the correct inputs are used and they are transformed as expected (the system functions to specifications) but the output fails to meet the use for which it was designed. The output either does not fit with subsequent processes or it is unsatisfying to the customer. A second problem would arise if the wrong output is produced, that is, if the wrong process is used.

Outputs are generally easy to measure and often become the end point in quality control processes. Measuring what is produced is easier than monitoring how it is produced. Health care billing systems generate on a daily basis the number of patients seen, the type and number of tests performed, the type and number of drugs dispensed, and so on, but these outputs do not tell us how many people were involved in the production process, how long production took, or the quality of the output. Did the physician identify and treat the patient's problem? Was the right test ordered and was it performed correctly? Was the right medication prescribed and delivered appropriately? The purpose of medical care is to improve patient health; the purpose is not the production of outputs.

Outcome refers to what is taken away from the system and is the proper measure of performance; for example, has the health status or function of a patient improved? Outcome is the performance of the outputs outside the production process. Did the set of products and services have the desired effect on the patient? When poor health outcomes arise, they may be the result of the care provided to the patient or the result of patient issues, such

white box

a production system whose internal operations are known and can be monitored

as an untreatable condition or a lack of patient compliance. In health care poor outcomes arise even if everything is performed according to generally accepted standards. Treatment may be flawless, yet a poor outcome may arise due to idiosyncrasies in how a patient responds.

A prime issue in assessing outcomes is the time frame used for evaluation. Codman pointed out that one year might be the minimum time frame to determine if treatment was successful. Unfortunately most health care organizations evaluate outcomes on much shorter and more arbitrary time frames, typically at discharge. A discharge focus allows providers to assess immediate outcomes but fails to determine if treatment improves a patient's long-term quality of life.

In a properly functioning system, acceptable inputs enter the production system and are effectively transformed into outputs that satisfy a human need or desire. When the desired outcome is not achieved, the problem may have arisen from poor inputs, a flawed transformation process, producing the wrong output or set of outputs, or a combination of these factors.

The fifth element, feedback, is designed to keep a system operating effectively and efficiently by monitoring performance and generating signals to alert those operating the process when the system is not performing as desired. Effectiveness is judged by whether goals are achieved, and efficiency measures whether excessive or unnecessary resources are consumed in the production process. The three feedback loops demonstrated in Figure 1.4 highlight the need for effective and timely feedback. While we would like to think all systems perform in the desired manner all the time (versus according to how they were actually designed and operated), the fact is that errors arise in all parts of a system.

We would like to think that all controllable inputs meet minimum standards, but experience shows that substandard inputs routinely enter systems. Before throughput begins, workers should evaluate the inputs to determine if they are appropriate for the task at hand. If an organization's resources are inadequate for the task, the feedback loop should be used to change the input function: what changes are required to ensure only acceptable inputs are allowed to enter the transformation process in the future?

The transformation process, however, may begin and finish before input deficiencies are recognized. In this case, the defect must be fixed or the product discarded, and a signal must be relayed to the intake process so similar problems are recognized and avoided in the future. The first feedback loop, between throughputs and inputs, is required when problems can be identified in the transformation process. Obviously the sooner a defect is recognized the better.

When problems arise due to inadequate inputs entering the system, the goal is to either screen out substandard inputs or, for those problems that cannot be eliminated, to accommodate them in the transformation process. Accommodation requires the transformation process to be altered to rectify the deficiencies in the incoming inputs. For example, when a patient is admitted with an infection in addition to the primary reason for the admission, additional pharmaceutical orders to treat the infection should be triggered, the patient may have to be placed in isolation, and universal precautions to prevent the spread of the infection to other patients should be implemented.

The second feedback loop connects output to throughputs and input. This feedback loop recognizes that problems may not be detectable until a product or service is produced. Early detection of problems may not be feasible. A physical product or a service may need to be created before problems can be identified, so operators must wait until the end of the production cycle to evaluate the process. In this case the error was not or could not be identified by those performing the work during the transformation process. For example, an x-ray technologist could shoot an x-ray and not recognize that the x-ray does not meet the requirements of the ordering physician or the radiologist. Since early detection is always more desirable, if the x-ray technologist recognizes the x-ray does not meet the required clarity standard, he or she can immediately reshoot the x-ray. If the error is discovered later, the patient must be retransported, the x-ray set up a second time, and a second reading of the x-ray must be performed by the radiologist. These costs can be avoided if the x-ray problem is discovered by the radiology technologist in the transformation process.

When a product or service is lacking or defective, the problem may have arisen from poor inputs, a faulty transformation process, or the production of the wrong output. We may assume that since substandard inputs were not detected during production, we should begin by examining the transformation process. But the question must be asked: Is the product defective as a result of an error made in combining inputs, or perhaps because the wrong output was produced? The problem could be due to any of the three causes, but at this stage the questions are: Why didn't the workers operating the process recognize and correct the defect before completing their work? Why was the process completed and the product passed forward even though there was a problem?

The third feedback loop connects the outcome produced—the ultimate goal of an organization—to all parts of the system. Poor outcomes may result from producing the wrong set of outputs, that is, from delivering the

wrong set of services. Errors may also still emanate from problems with throughputs or inputs that were not discoverable until the outcome could be observed. Discovery at the point of outcome raises the question of who discovered the defect: Was it an employee or a customer? When defects are discovered outside the organization, the organization risks alienating and losing customers, who may seek more reliable suppliers. The goal of system thinking is to discover problems as early as possible in the production process to initiate prompt corrective action, avoid poor outcomes, and prevent the problem from appearing in future cases.

The delineation of internal (within the organization) and external (outside the organization) environments emphasizes the fact that organizations should be able to exercise a high degree of control over activities that occur within their system: the intake of input, the transformation process, and the outputs produced. Failure to control these basic components is the basis of malpractice suits. Health care organizations cannot control the external environment, such as patients' behavior before and after they arrive for treatment (input and outcomes), however.

The challenge of controlling systems that function on a case-by-case basis, in which production decisions are made by individual physicians and patients, is substantially higher than those facing a production process in which large lots are produced at a scheduled time with detailed procedures, performance standards, and dedicated quality management staff. Effectiveness and efficiency require control of personnel, maintenance of equipment, availability of supplies, monitoring of output and outcomes, and initiation of corrective action as necessary. Health care has yet to fully incorporate system thinking into its operations, and this failure partially explains why the health care industry measures error rates per hundred while other industries expect rates of less than three errors per one million opportunities.

Summary

This chapter introduced the goals of quality management and how to define quality. Quality was conceptualized as a set of characteristics in which a deficiency in any element is sufficient to undermine the value of a good or service, demanding that producers recognize and control their entire production process. The pioneers in quality management in health care—Semmelweis, Nightingale, and Codman—demonstrated that data collection, data comparison, identifying causes, and developing and testing improvements are essential to improving patient care and showed that one of the largest obstacles to overcome is inertia.

Quality pioneers outside of health care have created multiple techniques to document and improve outcomes, and these advances have led to a rapid improvement in production processes and quality control in other industries. The bedrock of quality improvement in other industries is system theory, which is the ability to view processes as a set of inputs, throughputs, outputs, and outcomes controlled by effective feedback that always keeps in view the goal of the system. It is insufficient to focus on how parts of a system are operating; all parts of a system must be coordinated to achieve a desired outcome. Judgment of system performance should be based solely on how well a system serves its customers or patients. The chapter included a quote from Machiavelli pointing out that change occurs within the confines of existing systems and that change, however well intentioned, will be met with fierce resistance even by people who benefit from the system being challenged. Change will occur only if we can make a compelling case for it, identify what parts of a system need improvement, introduce improvements, and monitor the system to ensure that the new order of things is followed.

KEY TERMS

Accountability	Health care quality
Authority	Input
Black box	Inspection
Cause and effect diagram	Ishikawa, Kaoru
Codman, Ernest	Johns Hopkins
Continuous quality improvement (CQI)	Mass customization
Cottage industry	Mass production
Deming, W. Edwards	Morbidity
Effective	Mortality rate
Efficient	Nightingale, Florence
End Result Idea	Outcome
Environment	Plan-Do-Check-Act (PDCA) cycle
Feedback	Price
Five Ds of health care quality	Process Improvement
Flexner, Abraham	Product
	Quality

Quality circle	System thinking
Selection	Throughput
Semmelweis, Ignaz	Timeliness
Service	Total quality management
Shewhart, Walter	Value
Standardization	Variance
Statistical process control	White box
System	

REVIEW QUESTIONS

1. Define health care quality.
2. Describe the various components that may increase or decrease the quality of a good or service in the eyes of the consumer.
3. What were the common elements that characterize Semmelweis's, Nightingale's, and Codman's attempts to improve health care quality?
4. What two skills are required to improve health care quality?
5. At what point in the evolution of production processes does the health care industry reside? Explain your answer.
6. Explain the five components of a system.

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