ORIGINAL ARTICLES

From the International Society for Cardiovascular Surgery, North American Chapter

Presidential address: Sony, Porsche, and vascular surgery in the 21st century

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"It was the best of times; it was the worst of times"[1]
A Tale of Two Cities
Charles Dickens, 1859

To paraphrase Dickens, it is the best of times, it is the worst of times. Dickens, of course, was writing about the French Revolution of 1789. I am referring to the American, and to some extent worldwide, health care revolution of the 1990s. Never has the health care system been equipped with such extraordinary and exciting physical and intellectual resources and abilities to prevent and treat disease than it is now—surely the best of times. Yet, not in recent memory, and perhaps never has there been so much attention paid and action taken to control health care expenditures. The speed and magnitude of the changes have left most health care organizations and providers reeling, uncertain, and afraid—surely the worst of times in the opinion of many. It is beyond rational debate that health care costs have grown well beyond society's desire or ability to pay for them. U.S. health care costs were $949.4 billion in 1994 and have increased from 5% of the gross domestic product (GDP) in 1960 to nearly 14% of the GDP in 1994, and if the same rate of increase is sustained, it will reach 30% of the GDP by 2020. And yet, as profound as cost containment has been, health care expenditures have not declined. It is just the rate of increase in expenditures that has declined, from 12.9% in 1980, to 7% in 1993, to 6.4% in 1994. Nevertheless, Medicare spending increased 11.8% in 1994, compared with only a 4% increase for private health insurance plans. This is especially ominous for vascular surgeons who typically treat large numbers of Medicare beneficiaries.

One way or another, sooner or later, health care costs will have to be stabilized and controlled and at some arbitrary level, for example, a constant percent of the GDP. Efforts to produce continuous savings of the magnitude desired will require logistic and administrative efficiencies, as well as control of the intensity and volume of health services. It is not yet clear whether health care costs have been controlled, but it can be accepted that they will be controlled, and we will all be affected.

So far, most of the attention and effort in health care reform by administrators, payers, and government has focused on the issues of cost containment and access to care rather than on quality of care.[2] Chelimsky[3] reviewed and analyzed the number of articles in the *New York Times* that primarily addressed the factors of medical cost, access to health services, and quality of care from 1989 to 1993. She found 302 articles on cost, 58 on access, and only 11 on quality. For physicians, who have traditionally borne the responsibility for clinical quality, an integral element of the health care revolution is a genuine concern about the quality of care. How can physicians and other clinicians constantly achieve high-quality care while meeting mandated and sometimes draconian cost restraints? To answer this question, it is first necessary to examine the relationship between quality and cost in health care.

QUALITY IN HEALTH CARE

The relationship between quality and cost in health care is very complex and poorly understood.

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According to classic economic theory, there is a direct relationship between quality and cost—as quality goes up, costs go up. If it is assumed that this is true in health care, and I believe that most physicians do, then it follows that efforts to contain costs will threaten quality. Examples of cost-driven low-quality care are known to all of us. But if this assumption is wrong, if the relationship between cost and quality is negative or indirect, cost containment and quality improvement could be complementary, and it therefore might be possible to improve quality at the same time that costs are reduced.

Quality is a term widely used in many facets of contemporary life. It implies excellence, fineness, or superiority. For example, Sony is a company universally known and recognized for innovation and manufacturing excellent, that is, high-quality electronic products. What exactly is this quality? Each person probably has a different idea, depending on what products he or she has, what they are used for, and how they are expected to work. In business jargon, if a product satisfies one's expectations, it is said to possess quality. Thus quality is meeting or exceeding customers' expectations. But what is quality as it applies to health care? It is a multidimensional construct that is extremely hard to define, measure, and observe.[4] Surgeons instinctively think they know what quality is: low stroke rates after carotid endarterectomy; high graft patency and limb salvage rates after lower extremity bypass; high survival rates after aortic aneurysm repair. But these are results or outcomes, important to be sure, and a part of quality but not synonymous with a contemporary definition of health care quality. Outcomes describe the application of medical science, knowledge, and technology to the diagnosis and treatment of disease. In short, this refers to the difference between a patient's current and future health status attributed to the medical care provided. In this construct, health care quality has three components: interpersonal, amenities, and technical.

Briefly, the interpersonal component refers to the interactions between patient and provider and the perception by the patient and his or her family of the amount of responsiveness and attentiveness on the part of the provider. This is the "art" of medicine. Amenities of care include such things as the convenience and appeal of the health care facility. Managed care organizations are paying more and more attention to this aspect. The technical component is roughly equivalent to medical outcomes. Each of these three components can be assessed separately in terms of quality. Patients are not in a position to evaluate the technical aspects, but they are certainly capable of doing this for the other two components. Implicit in this concept is that of patient expectations. Just like the consumer expectations of Sony products discussed earlier, patients have expectations about the health care they receive and they make quality judgments about it.

Quality in health care can be looked at in another way, by considering it to consist of three different components: structure, process, and outcome.[5] Structure involves the relatively fixed characteristics of the medical delivery system, such as number, types and qualifications of health care providers, and facilities, including equipment (CT and MRI scanners, for example). The process component is what is actually done to or for the patient—the application of drugs, medical procedures, etc. It too can further be regarded as consisting of inputs leading to actions resulting in outputs (outcomes). Outcomes, as defined earlier, are the changes in a patient's health status that can be attributed to the antecedent medical care. If one then considers the practice of medicine as a process, or rather an infinite series of processes, each one of which results in an output, one can then consider the quality of these processes as well as the quality of the results or outputs they produce. This model of quality emphasizes that quality is not the output (results) alone.

Another way in which quality can be categorized and evaluated is in terms of content or delivery. Content quality describes the technical component of medical care and is roughly equivalent to medical outcomes, whereas delivery quality describes patients' satisfaction with their health care experiences. Quality then becomes an individual's personal judgment or evaluation of an output and the personal interactions that take place as the output(s) is (are) delivered to the individual. It is based on an individual's (or society's) value system. It is a relative term with no fixed unit of measurement, and therefore it cannot be described in static terms, such as good or bad, but only as better or worse over time. And because each individual's culture, past personal experiences, and prejudices create expectations, quality again can be seen to involve meeting expectations. Quality can be judged to be acceptable when positive expectations are met. When expectations are consistently exceeded, then quality is judged to be excellent. Because values and judgments are part of quality and because they can change over time (for example, through education), quality gets redefined each time there is an interaction between an individual and an item or process for which the term is evaluated.

Service quality or delivery of care is evaluated primarily by patients, but as a learned profession, medicine has reserved the right to judge its own content quality. Our profession sets its own expectations regarding medical outcomes using a variety of methods, including informal consensus, clinical trials and hypotheses, individual, institutional, and multi-institutional experiences, etc., as expressed in the medical literature or less formally. When discussions about quality of care occur, most physicians believe that the care they are providing and have always provided is of the highest or best quality. Both consumers, i.e., the public, and third party payers have become skeptical. Consequently, the profession's exclusive hold over medical quality content is being challenged and eroded as payers, patients, and others become more informed and begin to take a more active role in setting medical outcomes' expectations.

The preceding comments have demonstrated the complexity of the term quality as it is applied to health care. The current health care environment demands that we as physicians expand our concept of quality as it relates to both outcome and delivery. It is useful in this regard to accept the concept of patients as customers, even though this seems far too business-like to many physicians. Nevertheless, it is an undeniable fact that health care is becoming ever and ever more business-like and physicians must accept this and adapt to it.

QUALITY VERSUS COST

Quality, with its expanded definition, is related to costs in several ways. In manufacturing, process failures (low quality) result in error, rework, and waste. A bad outcome must either be fixed or thrown away. Health care differs from manufacturing in that there isn't the luxury of throwing bad outcomes away, for they represent loss of life or functional ability. When the output (results) of a health care process (intervention) fails and does not meet quality expectations, complications and death result and additional medical resources are expended in an attempt to correct the situation. But either way, throwing it out or fixing a bad outcome, increases costs. Thus diminished quality leads directly to higher costs. These additional costs and resources are referred to as quality waste and represent process failures in medical care just as they do in manufacturing.[6] When operations are performed for inappropriate indications, and there is abundant evidence that this is common, the resources used that do not contribute positively to patients' health status, plus those required to treat the complications that inevitably occur from any series of operations, both represent quality waste. Repeating laboratory tests and x-ray examinations whose results are lost are other common but simple examples of wasted resources in health care.

The second way quality relates to costs is through productivity or its corollary, inefficiency. There is considerable variation amongst physicians in practice patterns in terms of resources used to achieve the same clinical results. For example, some surgeons operate faster than others. When two surgeons get the same clinical results from an operation but one takes twice as long to perform the operation as the other, the increased costs of the slower surgeon represent low productivity. In the provider-at-risk environment that now exists, inefficient practice patterns are no longer acceptable. This has led to efforts by some management groups to introduce economic profiling of physicians for credentialling purposes.

When total health resources are limited, as they certainly are today, wasted resources are not available for the needs of other patients and therefore do positive quality harm. This concept has also been used by some managed care organizations as justification for denying certain treatments to high-risk or elderly patients. Anecdotally, quality waste and low productivity are very commonly present in both hospital management and patterns of care. It is estimated that quality waste accounts for 25% to 40% of all hospital operating costs![7] Quality waste is a useful concept because it provides a framework for seeking and eliminating waste and rework, thereby improving a process, which then leads to improved quality and lowered costs.

Quality and costs are also intertwined in other ways. One of the most widely discussed in health care is expressed in the concepts of cost effectiveness, which have been well described in recent publications and will not be dealt with herein.[8,9]

From the foregoing, it is obvious that quality is intimately related to cost. But costs do not control quality, instead, quality controls costs. This concept has enormous implications for health care providers because it provides a framework for making things better in health care in spite of the severe spending limitations that have recently been introduced.

QUALITY IMPROVEMENTS

Quality has become a critical issue in almost all segments of business, industry, and organizations. It is now recognized that error, waste, and duplication of work lead to higher costs and less customer satisfaction, that is, decreased quality. This is not good for business and it's not good for health care. Al-

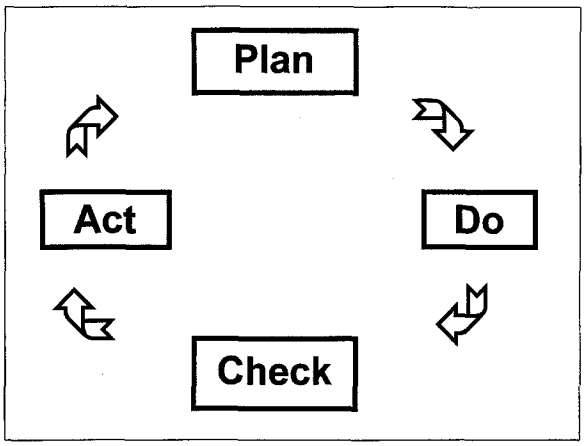

Fig. 1. The Quality Management or Shewhart Cycle, also known as PDCA (Plan, Do, Check, Act).

though some say that we should strive for perfection, this is an unrealistic objective and goal in health care. It will always be possible to improve quality. Surgeons have led the way for the medical profession through the traditional morbidity and mortality conferences that are an ingrained and integral component of surgical training and practice. Over the past 20 years, layered on top of this, has been an enormous and expensive effort, mandated and supported by organizations such as the Joint Commission on Accreditation of Health Care Organizations (JCAHO), collectively known as quality assurance. The customary approach to hospital quality assurance (QA) is to set standards; identify individual providers, clinicians, or hospitals that demonstrate unacceptable performance relative to those standards; and then take action to eliminate (i.e., improve) that performance.

It is not my purpose to debate the merits of QA programs, but only to point out that their focus has been on thresholds or standards, most of which are inherently arbitrary in nature and define acceptable or unacceptable levels of performance or compliance.[4] As such, they can become an artificial quality floor or ceiling. Hospital-based QA activities are designed to identify those activities (and practitioners) who are above or below these floors or ceilings, and then try to bring them into compliance with the standards. This approach uses thresholds to establish a statistical tail, then concentrates improvement efforts within that tail. It is analogous to industrial reliance on inspection as a means of improving manufactured products. It is what Berwick described as "the practice of finding the bad apple."[10] It embraces the philosophy of quality that is "good enough"

Table I. Quality Assurance versus Continuous Quality Improvement

	QA	*CQI*
Based on	Standards, thresholds	Specifications
Objective	Outcome	Process and outcome
Focus	Statistical tail	Whole group
Effect	Judgmental	Educational
Philosophy	Good enough	Best possible

rather than "the best possible." It is inherently a punitive system that elicits fear and resentment, and its effects on overall quality are far from optimum (Table I).

Another and better approach for improving quality, also borrowed from industry, encompasses the theory of continuous improvement. The concepts of this theory were formulated and espoused in the 1930s, most notably by Joseph M. Juran, Walter Shewhart, and W. Edwards Deming. Shewhart, an engineer at the Bell Laboratory and the father of industrial process control, introduced Deming, a mathematical physicist, to the use of statistical methods for quality control.[10,11] Shewhart was concerned with the application of his methods and techniques for controlling the quality of industrial production processes. He discovered that statistical information, i.e. data, was generated by all industrial processes and that this data could be used to describe the variation that exists in every industrial process. This became known as *statistical process control.*[12] He also described the quality management cycle, which consists of planning a new or improved process that will ultimately cause an improved outcome, implementing (doing) the process, measuring (checking) to see whether the process is having the expected outcomes, and then acting on the information (data) to reassess the plan or continue its implementation (Fig. 1).[10,12,13] Deming realized that Shewhart's methods, combined with other statistical aids, had great potential for the continuous improvement of production processes and the delivery of quality products. He developed a theory for management transformation that involved the application of 14 points, which he demonstrated to be equally applicable to banks, department stores, railways, and other service industries.[12] Deming introduced his ideas to U.S. industry early in World War II, and they had a profound effect on the quality and volume of war material production. After the war ended, American industry lost interest in his ideas as a result of the post-war economic boom. But he was invited to Japan to teach statistical methods for industry as part of Japan's

reconstruction efforts. He taught the Japanese how to use statistics to find out what any process would do, then design improvements to make the system yield the best results. His basic idea was that the more quality you build into anything, the less it costs. Deming's concepts and teachings contributed greatly to the post-war Japanese industrial revolution (Fig. 2).[14] The incredible success of Japanese corporations over the past three decades is a well-known story—television sets, videocassette recorders, compact disc players, steel, automobiles—to name a few. Japanese products, once derided as merely cheap copies of American or European designs, are now the standards of quality, and Japanese companies are similarly recognized around the world: Sony, Honda, Toyota, Mitsubishi, NEC, to name just a few. Unfortunately, it was not until the 1980s that American industry started to adopt the theory and practice of continuous quality improvement (CQI), which is what Deming's concepts have come to be called. For example, Ford Motor Company began consulting with Deming in 1981. Their well-known slogan, "Quality is Job 1," is more than just words. Ford is now building automobiles with fewer factory defects, and profits have increased. The Boeing company used similar methods, which they called "working together" and "design-build teams," in the design of its newest commercial jetliner, the 777, with remarkable success.[15]

A more recently publicized example from Europe involves the elite German automobile manufacturer, Porsche A.G.[16] Porsche was on the brink of bankruptcy in 1992 as a result of out-of-control manufacturing costs and slumping sales. Annual sales had fallen from 50,000 to 14,000, with only 3000 sold in the United States. In a bold and un-Teutonic action, Japanese engineers—mostly Toyota alumni—were hired to lead the reengineering of Porsche using Japanese CQI manufacturing principles and techniques. The results were dramatic. Manufacturing flaws have decreased 50%, large parts inventories have decreased 81%, manufacturing time has decreased by 40%, the number of workers has decreased by 19%, the number of managers by 31%, and factory space by 30%. Porsche is now making more cars, faster, by fewer people, and without decreases in its renowned technical sophistication and road performance. In 1995, the company reported its first profit in 4 years after $300 million in losses.

CQI, sometimes called industrial quality control, is an organized system that combines a set of methods and a management philosophy to continuously improve processes, outcomes, and services. According to CQI theory, real improvement in quality depends on understanding and continuously revising the production process on the basis of data generated by the process itself.[6,17,18] The focus throughout an organization, be it a factory, hospital, practice group, or HMO, is on continuous improvement through constant effort to reduce waste, rework, and inefficient processes. Sony embraces CQI using incremental product improvement as a corporate value, to the extent that its goals are to work to make its own products continuously better until they become obsolete.[19] The Japanese call this *kaizen*—doing things better, little by little, all the time.[20]

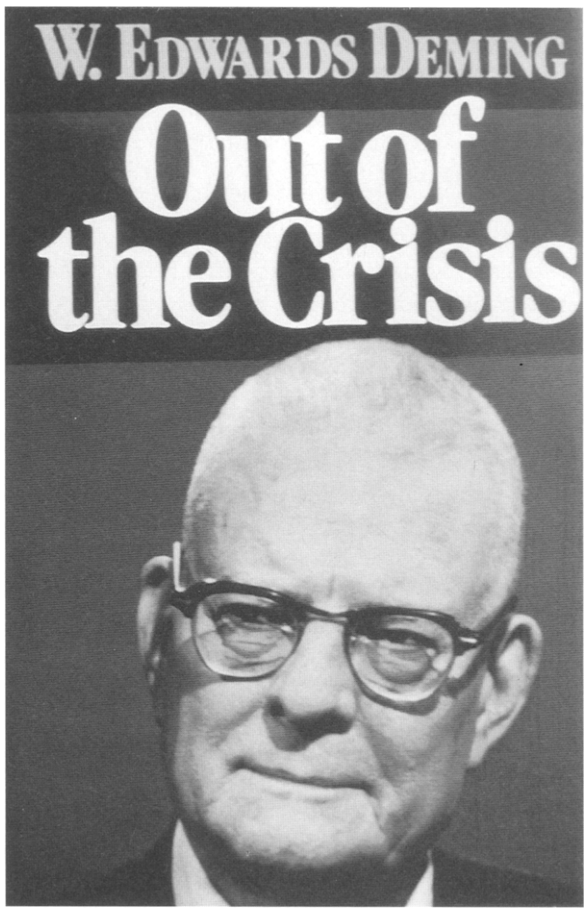

Fig. 2. W. Edwards Deming.

What have Sony, Porsche, Deming, and Shewhart got to do with American medicine in general and vascular surgery in particular?

As noted earlier, a process can be defined as a series of linked, often (but not necessarily) sequential steps that are designed to cause some set of outcomes to occur, to transform inputs into outputs, add value, and generate useful information. The practice of medicine can then be defined as a complicated series

of interrelated processes and subprocesses. Some are clinical procedures (i.e., operations), whereas others are nonclinical activities (admission to a hospital, billing, etc.). The use of this concept of process enables health care to be examined in a logical and insightful manner.

VARIATION

As Deming and Shewhart demonstrated, there is variation in every process, which is of two types: random and nonrandom. Random variation is that which is inherent in and a part of any real process. It represents the sum of many small variations, that is, background noise, and follows the laws of probability, behaving as a random function. It cannot be traced back to a root cause and therefore is considered as "appropriate," distinguishing it from "inappropriate" or nonrandom variation, which arises from a single cause that is not an inherent part of the process. Inappropriate variation can be traced, identified, and eliminated. Random variation is expected in any real care-delivery process as clinicians deal with differences in patient presentation, illness, and preferences. It is most easily seen, for example, in the ranges of normal values for standard laboratory tests or body temperature.

One of the two fundamental principles of CQI is the elimination of inappropriate or nonrandom variation. This is accomplished by using statistical process control to separate the random from the nonrandom variation. Only then is a process considered to be under control or stabilized, and only then can it be analyzed and improved in a scientific manner. The process can then become a research system within which the scientific method can be applied to test innovations or new ideas about how the process can be further changed to improve quality or increase productivity. Here is the Shewhart cycle in action, and in this system a clinical practice can become a true clinical laboratory.

VARIATION IN HEALTH CARE

Medical care is very complex, and variation is widespread in all areas of clinical practice. There are large variations in practice patterns even among physicians who work in the same health care system, as well as between physicians at different hospitals and in different communities. It is often assumed that because health care is a quintessentially human business, variation is inevitable, perhaps even desirable. Differences in patient attributes account for some differences in outcomes from similar treatment processes, but physicians vary in how they diagnose and treat similar patients beyond what can be explained by patient factors alone. Abundant data document that geographic variations in the use of medical and surgical procedures are common. In a study of carotid endarterectomy within 13 large geographic areas in the United States, the number of procedures varied from 5 per 10,000 to 23 per 10,000 Medicare enrollees, a ratio of 4.6.[21] When examined in a smaller area—23 adjacent counties—the rate of carotid endarterectomy still varied, from 5 per 10,000 to 41 per 10,000 Medicare enrollees, a ratio of 8.2. No statistically significant differences in the appropriateness of use of carotid endarterectomy were found, and the reasons for such a wide variation in use were largely unexplained.[22] Marked differences between institutions as well as between surgeons in incidence and mortality rates for coronary artery bypass grafting procedures (CABG) have been widely publicized in the lay press as well as the scientific press.[23,24] These observed differences in mortality rates were found to be independent of patient case mix. If differences in risk-adjusted mortality rates among hospitals are primarily a result of differences in specific care processes, modification of these processes should lead to improved outcome.

The Northern New England Cardiovascular Disease Study Group (NNECVDSG), which consisted of cardiac surgeons in all five cardiac surgery programs in Maine, New Hampshire, and Vermont, determined that the substantial variation in interinstitutional mortality rates within the same homogenous population was caused by actual differences in unknown aspects of patient care.[23] Stated differently, variations in processes were thought to be causing variations in outcomes.

Another example of variation is found in the way common patient care procedures are usually learned in teaching hospitals. Rarely is there a consistent way to do things, such as insert a central venous catheter, let alone a consistent way such procedures are taught to residents, interns, and medical students. Such methods are prone to be associated with wide variations in outcomes that can be traced back to inappropriate variations in the process. Because only 10% to 20% of medical practice is based on the type of scientifically sound knowledge that is derived from randomized clinical trials, it is not surprising that so much variation exists in the way we as physicians do just about everything. When asked to explain "why" a certain practice is used, most physicians can only state: "It's the way I was taught", or "It's the way I've always done it", or "It's always worked well for my patients." With so much variability in the pro-

cesses of health care, it is little wonder that there is so much variability in outcomes and quality. By studying a process using explicit measurable criteria (known as specifications), factual information can be gained and used to modify or eliminate the inappropriate variation.[25]

As noted earlier, common or random variation is expected in any real care-delivery process as clinicians react to differences in patient presentation, illness, and preferences. Any attempt to eliminate this kind of variation is merely tinkering and does not lead to quality improvement. Nonrandom or undesirable variation can arise from misinterpretation of random noise in clinical data, from unreliability in the performance of clinical and other systems intended to support care, from habitual differences in practice style that are not grounded in knowledge or reason, and from failure to integrate care across boundaries of components of the health care system. Each of these forms of variation can be eliminated with an expected improvement in quality and without insult to the professional autonomy, dignity, or purpose of physicians.

Some sources of variation in medical care cannot and should not be controlled. Treatment plans often must be customized to meet individual patients' needs and expectations. But quality experts suggest that substantial quality improvement can be achieved by eliminating unnecessary variation in the execution of the processes by which these treatment plans are implemented.[4] And although one patient's case is never exactly the same as another's, high-quality medical care may dictate that a specific procedure, such as a mammogram, or diabetic teaching, or aortic aneurysm repair, be done in a consistent manner to avoid omissions, errors, and nonrandom variation. By ensuring that resources are used in the most efficient manner possible, efforts to reduce this kind of variability will pay dividends in terms of patient outcomes and costs.

Variation in medical practice has also been attributed in part to professional uncertainty about available diagnostic and treatment strategies. There are many reasons for professional uncertainty, including lack of scientifically valid data on outcomes, delays in dissemination or acceptance of what valid data is available, human limitations in handling large volumes of complex information, differences in observation, measurement error, geographic differences in the type and availability of health care resources, in addition to the already mentioned differences in patient values, preferences, understanding, and communications.[25,26] The concept that unnecessary variation in clinical practice contributes to poor quality is an important justification for the development of consensus about "best practices" and the encouragement of adherence to these practices. These practice guidelines, discussed in more detail below, should be evidence-based, locally integrated, and updated as necessary.

CQI is itself a process that involves several steps.[11,25] First, a key process (a surgical procedure, for example) that needs quality improvement and cost control is identified. A team that possesses fundamental knowledge of the process documents the process, lists its outputs, identifies its customers, and measures their expectations of its outputs. The key process steps that causally determine whether an output will meet quality expectations (the desired output) must be explicitly documented, as must output and process specifications. Specifications define measurement variables and reflect both the goals that a process was created to achieve and the manner in which these goals are to be accomplished. The specifications can be updated as expectations change or as the process improves, and they thereby provide the basis for managing quality.[13] In fact, specifications define quality for a process. Then the improved process is implemented, eliminating inappropriate variation from the established standard of optimum care as defined by the specifications. Finally, the outcomes are measured, the improvement is documented, and new innovations are applied to the process, creating a loop of continuous improvement. This loop is, in simplest terms, the Shewhart cycle. This same approach in clinical medicine is called a clinical trial. Protocols for controlled clinical trials, by design, eliminate inappropriate variation from the treatment arms so that differences in outcomes can be attributed to differences in the treatments and not to differences (variation) in some other part of the process. In a less-sophisticated way, this is analogous to the way physicians have traditionally practiced, by examining the treatments they apply and the results they achieve and then using that experience to improve the care they provide to future patients. Unfortunately, individual physicians seldom possess sufficient objective data on which to consistently make scientifically sound judgments. It must be emphasized that CQI is a data-driven process—it cannot take place without objective data. Fortunately, modern computer and software technology allow sophisticated data handling to be available to nearly every physician at reasonable costs so such data can be collected even at the level of the individual practioner.

Many health care organizations have embraced CQI theory and applied it to improve both medical care and nonmedical or support services. For example, Classen et al.[27] used CQI techniques to examine deep postoperative wound infections. Their focus was a single process: the administration of perioperative prophylactic antibiotics. They prospectively studied 2847 patients who underwent clean or clean-contaminated surgical procedures at a large teaching hospital and found considerable variation in the timing of the administration of the antibiotics. The antibiotics were found to be most effective if administered within 2 hours before the surgical incision. In the first year of the study, only 40% of patients received prophylaxis within this optimal time, and there was a corresponding deep postoperative wound infection rate of 1.8%. Over the next 6 years, the percentage of patients who received their prophylactic antibiotics during the optimum time increased to 96%, and there was a corresponding reduction in infections to 0.4%. In addition to improving an important clinical outcome, there was a significant cost savings, estimated to be $714,000 (51 fewer infections at a cost of $14,000 each) in the last year of the study alone.

CQI methods have also been successfully applied in cardiac surgery. The aforementioned NNECVDSG combined clinical pathways and CQI methods on a regional level and documented a 24% decrease in in-hospital mortality rates for CABG.[28,29]

Hammermeister and colleagues[30] organized a Department of Veterans' Affairs program for continuous improvement in cardiac surgery that involved virtually all of the VA medical centers at which cardiac surgery was performed. Using a combination of CQI and traditional QA methods, a 14% decrease in the risk-adjusted operative mortality rate for the entire DVA cardiac surgical program was accomplished during the 4.5 years this program of continuous quality assessment and improvement were in effect.

A quality improvement project more directly applicable to vascular surgery was conducted by Brothers et al.,[31] who examined the process of carotid endarterectomy in a university hospital. They were particularly interested in developing strategies to reduce costs. After 1 year, average patient charges were reduced from $13,900 to $7700 as a result of a reduction in length of stay (2.2 vs 5.7 days) and reductions in charges for laboratory tests (77%), cardiac testing (53%), hospital room (60%), and radiology (78%). This reduction was accomplished with no deterioration in clinical outcomes, with a perioperative stroke/death rate of only 1%. Thus significant quality waste was eliminated, resulting in an overall improvement in quality associated with reduced costs. Muluk and associates[32] from the University of Pittsburgh have described their experience with aortic aneurysm repair in which the introduction and use of CQI methods resulted in a decreased mortality rate and decreased hospital costs. From these few examples, it is apparent that CQI works at all levels of health care—from individual offices to large hospitals to large systems of health care facilities.[33]

VASCULAR SURGERY IN THE 21ST CENTURY

The forces of change roaring throughout the health care industry will have a profound effect on what we as vascular surgeons will do and how we will do it in the 21st century, which is, after all, a mere 3 years from now. Cost containment and assessment, as well as managed care, managed competition, capitation, de-emphasis of specialty care, and financial control by administrators and payers, are fast becoming and are likely to remain facts of life in American medicine for the foreseeable future. For those who think that these are only temporary perturbations or just another California phenomenon that won't affect them, the magnitude and speed of change may be overwhelming. Health care expenditures will be controlled and health care will be rationed.

As physicians, we have less influence over the supply side of health economics, to wit, the amount of money the people of the United States are willing to pay for health care, but it is our responsibility and historical duty to determine and manage the quality side of the cost/quality relationship. The most effective way to improve quality is to develop systems that prevent quality failures before they happen—the quality is built in during the process, not added on at the end. Clinical practice guidelines have emerged as one of the most promising tools for doing this. The United States Congress created the Agency for Health Care Policy and Research (AHCPR) to study outcomes of care and to facilitate development of clinical practice guidelines, medical review criteria, performance measures, and standards of quality.[13] Implicit in this mandate are outcomes measurement and process measurement. Measurement from clinical guidelines is mostly process measurement. According to the AHPCR, Shewhart's quality management cycle is at the heart of quality improvement methods. Improving the quality of processes is one means of reducing costs while at the same time improving the quality of outcomes. Practice guidelines

apply the principles of CQI to clinical care. Evidence-based practice guidelines are ideal for managing complex clinical problems because they facilitate decisionmaking and are logical. Guidelines of this type improve quality and lower costs by reducing variation in the process of providing health care. Guidelines, or their close relative, critical pathways, define the process. Process management applied on an individual basis is case management.

Protocols define specifications in clinical practice. Guidelines become protocols when sufficient detail and definition are added to allow specific practice recommendations and measurements to be made.

Our two societies, the International Society for Cardiovascular Surgery–North American Chapter and the Society for Vascular Surgery, should take the lead in the development of evidence-based practice guidelines for the most important and common conditions treated by vascular surgeons. Although guidelines developed at a national level are usually not specific enough to be effectively used at the community level, experience has shown that they can usually be modified to encompass local factors. Development of practice guidelines is the planning phase of improving care—the first step in the quality management cycle.

What we as cardiovascular surgeons can learn from Shewhart, Deming, Sony, and Porsche is to focus on the process of care delivery and its management. They have taught us to conceptualize our health care system as a complex series of interrelated and interacting processes and subprocesses. These processes can be scientifically studied, modified, stabilized, and continuously improved using industrial quality improvement theory and methods. It works for business and industry, it can work in health care, and it makes sense. Improvement in process improves quality and quality controls costs. By continuously striving to improve quality in its broader context, physicians can help to control costs.

Processes become the natural unit of management in a provider-at-risk, cost-based environment.[7] Processes usually span departments, and working with processes helps to develop teamwork and to break down traditional barriers that are so deeply entrenched in our health care institutions. This allows any person who possesses fundamental knowledge about a process to participate in and contribute to a process management team. Physicians will have to accept something other than their usual dominant position in these efforts, but I believe physician leadership is essential to success.

CQI is being widely adopted in health care organizations and facilities. It is being required by the JCAHO as well as by the Residency Review Committee for Internal Medicine in its special requirements for residency training. So far, most applications of CQI in health care have been in administrative support functions and nursing activities. To elicit active and meaningful physician interest and participation, CQI activities must also focus on strategically important clinical priorities. Experience has shown that quality improvement in major clinical areas cannot succeed without active participation of physician clinical champions.[4,11] Physicians will have to work closely with management and administrators, whose role is to manage processes and not physicians.

Learning and implementing continuous quality improvement is not easy. It is a long and expensive process, and its reliance on teams will cause many physicians to fear loss of autonomy. It requires a cultural change in the way we look at health care. There is no guarantee that it will work on a large scale, and it is not a cure for all the financial difficulties in health care. But no alternative approach has been put forward that seems to have the same potential to improve quality.

In his Presidential address before the Society for Vascular Surgery in 1993, Hertzer championed quality, advocated prospective hospital audits to document quality, and stated that "results mean everything."[34] I agree with his basic premise, but *results are not enough.* As Berwick[17] said, knowledge of results is useful only for judgment unless there is a method for discovering the reasons for difference. CQI provides a method for doing this and is consistent with the concept that knowing how something works is different and more important than knowing how well it works.

As health care providers, we are entering into a new age of delivery. Health care is no longer measured only by scientific and caring standards. Today, patients are customers who are shopping for proven quality health care at the best price. In other words, they seek *value.* As competition increases, the differences in cost of services will shrink, and physicians, hospitals, and clinics will be judged on the quality and value of their services. Success will come to those practitioners and organizations who successfully make the transformation from the current practice of assuming quality to actually measuring and improving it. The challenge for the 21st century is that we must learn to understand care processes and we must learn to manage them. Continuous Quality Improvement provides the theory and methods to make this transformation.

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REFERENCES

1. Dickens C. A tale of two cities. New York: Dell Publishing, 1963:11.
2. Chassin MR. The missing ingredient in health reform, quality of care. JAMA 1993;270:377-8.
3. Chemlimsky E. The political debate about health care: are we losing sight of quality? Science 1993;262:525-8.
4. Laffel GL, Berwick DM. Quality health care. JAMA 1993; 270:254-5.
5. Donabedian A. The quality of care. How can it be assessed? JAMA 1988;260:1743-8.
6. James BC. Quality improvement in the hospital: managing clinical processes. Internist (Berl) 1993;34 (March):11-3.
7. James BC. Implementing practice guidelines through clinical quality improvement. Frontiers of Health Services Management 1993;10:3-37.
8. Wagner EH. The cost-quality relationship: do we always get what we pay for? JAMA 1994;272:1951-2.
9. Eddy DM. Clinical decision making: from theory to practice. Rationing resources while improving quality. JAMA 1994; 272:817-24.
10. Berwick DM. Controlling variation in health care: a consultation from Walter Shewhart. Med Care 1991;29:1212-25.
11. Berwick DM. A primer on leading the improvement of systems. BMJ 1996;312:619-22.
12. Deming WE. Out of the crisis. MIT Center for Advanced Engineering Study 1982, Cambridge, MA: MIT Center for Advanced Engineering Study.
13. AHCPR Pub. 95-0045. Using clinical practice guidelines to evaluate quality of care. Vol. 1. U.S. Dept. Of Health and Human Services, Public Health Service, 1995.
14. Mann NR. Why it happened in Japan and not in the U.S. Chance: New Directions for Statistics and Computing. 1988; 1(3):8-15.
15. Sabbagh K. Twenty first century jet: the making and marketing of the Boeing 777. New York: Scribner, 1996.
16. Cash NC. Putting Porshe in the pink: German craftsmanship gets Japanese fine-tuning. New York Times 1996 Jan. 20; pg. 17-9.
17. Berwick DM. Continuous improvement as an ideal in health care. N Engl J Med 1989;320:53-6.
18. Berwick DM. Harvesting knowledge from improvement. JAMA 1996;275:877-8.
19. Branscomb LM, Kodama F. Japanese innovation strategy. Harvard University, Center for Science and International Affairs. Lanham, Md.: University Press of America, 1993.
20. Imai M. Kaizen: the key to Japanese competitive success. New York: Random House, 1986.
21. Chassin MR, Kosecoff J, Park RE, Winslow CM, Kahn KL, Merrick NJ, et al. Does inappropriate use explain geographic variations in the use of health care services? A study of three procedures. JAMA 1987;258:2533-7.
22. Leape LL, Park RE, Solomon DH, Chassin MR, Kosecoff J, Brook RH. Does inappropriate use explain small-area variations in the use of health care services? JAMA 1990;263:669-72.
23. O'Connor GT, Plume SK, Olmstead EM, Coffin LH, Morton JR, Maloney CJ, et al. A regional prospective study of in-hospital mortality associated with coronary artery bypass grafting. JAMA 1991;266:803-9.
24. Williams SV, Nash DB. Differences in mortality from coronary artery bypass grafts surgery at five teaching hospitals. JAMA 1991;226:810-5.
25. James BC, Horn SD, Stephenson RA. Management by fact: What is CPI and how is it used? In: Horn SD, Hopkins DFP. Clinical practice improvement: A new technology for developing cost-effective quality health care. New York: Falkner & Gray, Inc., 1994:39-54.
26. Eddy DM. Applying cost-effectiveness analysis. JAMA 1992; 268:2575-82.
27. Classen DC, Evans RS, Pestotnik SL, Horn SD, Menlove RL, Burke JP. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. N Engl J Med 1992;326:281-6,337-8.
28. O'Connor GT, Plume SK, Olmstead EM, Morton JR, Maloney CT, Nugent WC, et al. A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. JAMA 1996;275:841-6.
29. Nugent WC, Schults WC. Playing by the numbers: how collecting outcomes data changed my life. Ann Thorac Surg 1994;58:1866-70.
30. Hammermeister KE, Johnson R, Marshal G, Grover FL. Continuous assessment and improvement in quality of care. Ann Surg 1994;219:281-90.
31. Brothers TE, Robinson JG, Elliot BR. Relevance of quality improvement methods to surgical practice: prospective assessment of carotid endarterectomy. American Surgeon 1997 (in press).
32. Muluk SC, Painter L, Sile S, et al. Utility of clinical pathway and prospective case management to achieve cost and hospital stay reduction for aortic aneurysm surgery at a tertiary care hospital. J Vasc Surg (in press).
33. Starfield B, Powe NR, Weiner JR, et al. Costs vs quality in different types of primary care settings. JAMA 1994;272: 1903-8.
34. Hertzer NR. Presidential address: outcome assessment in vascular surgery—results mean everything. J Vasc Surg 1995; 21:6-15.

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