# QUALITY MANAGEMENT FOR HEALTH CARE DELIVERY

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## PREFACE

As customers' expectations rise, patient care becomes more complex, and resources continue to shrink, hospitals are finding that traditional approaches to defining, organizing, and staffing quality assurance functions are no longer adequate. More and more, hospitals are becoming convinced that improving quality requires a broad, whole-hospital consensus about what quality means, who is responsible for it, and how key hospital groups should communicate with one another about quality issues.

"Continuous quality improvement" or "total quality control" are names for a philosophy of management that aims to help organizations of all kinds improve performance through eliminating poor quality during production or delivery of the product or service rather than through trying to fix the results after the product has been made or the service given. In brief, it amounts to a call for top management commitment to constant organizational self-evaluation and innovation. Central to the approach are such techniques as setting specifications for a process, monitoring performance against specifications, determining the causes of inappropriate variation (including "quality waste" and low productivity), eliminating that variation, and starting over at a higher level of expectation. Emphasis is placed on the role of top management in developing specifications and achieving continuous improvement against them. Management—not "poor job performance" or "poor morale"—is responsible if quality isn't good or employees aren't productive, and management needs to establish a total organizational climate that builds a team approach and breaks down barriers to quality and productivity improvement.

Of course, much of the best of what has always gone on in health care quality management is based on these very principles and methods. They are taught to clinicians as part of their professional training. They underlie the systematic detective work of epidemiology. They are the basis of "classical" physician chart-based peer review. Until recently, these principles were implicit rather than explicit in health care. However, this is rapidly changing.

A number of individual hospitals, managed care providers and hospital systems have committed to quality management programs based explicitly on continuous quality improvement, total quality control, or the "industrial model." Examples include Katherine McAuley Hospital of Mercy Health Services, Intermountain Health Care, Inc., Hospital Corporation of America, Humana, Inc., Massachusetts General Hospital, Massachusetts Respiratory Hospital, Park Nicollet Medical Center, New England- Medical Center, and the Harvard Community Health Plan. More and more, payers and consumers are coupling the concept of "quality" with that of cost-effectiveness or value as defined in continuous improvement or industrial quality control models. HCFA has recently announced an "effectiveness initiative," and similar programs are being implemented or have been announced by Blue Cross and

Blue Shield plans and by various major employers groups. All these programs have as their goal the elimination of quality waste, the identification of inappropriate variation in outcomes, and the achievement of optimal results at the lowest possible cost.

*Until now, there has been -no document that codifies in one place for health care professionals the principles of continuous quality-improvement and applies them systematically to health care settings*

For those reasons, Brent C. James, M.D., Director of Medical Research at Intermountain Health Care, Inc., and a member of the Quality Measurement and Management Projects Task Force, undertook the task of developing a healthcare, specific continuous quality improvement model. The result is *Quality Management for Health Care Delivery*.

In publishing *Quality Management for Health Care Delivery*, QMMP hopes to promote-understanding of and discussion about the use of the continuous quality improvement model within health care.

Further, we -recognize that for many hospitals, implementing the program described in *Quality Management for Health Care Delivery* will not simply be a matter of deciding that the approach makes sense. Most hospitals that have implemented a successful continuous quality improvement program have built on the foundation of an excellent ongoing quality assurance and quality management program.

In addition, hospitals should keep in mind that institutions in which continuous quality improvement approaches have been successful uniformly report that such programs require willingness to make behavior changes in all aspects of how hospitals- do business, along with very significant investments in time, effort, and—most important—top management and medical staff commitment.

However, if continuous-improvement approaches to quality management are indeed the future of quality management, it behooves all of us to begin to plan for that future. The next few years are certain to bring increased, competitive pressures, continuing resource constraints and rising customer expectations. We hope that *Quality Management for Health Care Delivery* will help physicians, nurses, administrators, and others begin discussing, preparing for, and implementing the changes that may be needed to meet those pressures, constraints, and expectations.

Daniel R. Longo, Sc.D.
President
The Hospital Research and Educational Trust

## ACKNOWLEDGEMENTS

In 1985 Steve Busboom, Gigi Darricades, and Matt Weed—all members of Intermountain Health Care's Department of Finance—had an idea about how to separate a hospital's contribution from a physician's contribution to the care of a patient. Bobbi Ingram, director of quality assurance, and Steve Lewis, M.D., vice president for medical affairs, were soon involved. Careful work over several years eventually led to the first IHC Quality, Utilization, and Efficiency (QUE) study. Ann Ward, Mark Baird, Dave Thompson, Karen Hardwick, and Kelly Anderson all played important roles as more QUE studies were completed and the new methodology was further explored.

The ideas presented in this paper grew out of QUE studies, as we adapted them to deal with small sample size and complicated clinical entries, and tried to insure that the improvements they produced would not fade with time. Credit goes, too, to many individuals who read early drafts and added their extensive experience: members of the QMMP task force and HRET staff, other researchers interested in clinical quality, and experts in industrial quality control.

Finally, I don't believe that the clinical investigations upon which this book rests would have been possible outside of the health delivery system that IHC's leaders have built over the past 15 years. IHC has provided a strong system of hospitals within a well-defined geographic region; a critical understanding of health care costs and the integrated data systems necessary to track them ( a true rarity among health care systems); and the HELP Clinical Information System, arguably the finest and most complete electronic medical management system available today. It also provided the freedom necessary to pursue new ideas and try new approaches.

I extend my heart-felt thanks to all who have contributed to the new ideas in this document. I believe that continuous quality improvement represents the most exciting development I have experienced in my medical career while returning to the well-springs of scientific quality form which modern medicine flows. It could not exist without the selfless attention of the many who built the broad foundation upon which it rests.

## EXECUTIVE SUMMARY

*Quality Management for Health Care Delivery* provides a framework to help hospitals organize for, communicate about, monitor, and continuously improve all aspects of health care delivery. It also presents evidence to support the proposition that an organized system to achieve high quality care can lead to lower health care costs. In the present national environment a highly structured approach to the pursuit of quality is essential.

*Competition*. Price competition and financially- based efforts to limit health care expenditures (such as hospital discounts to insurers, the DRG prospective pricing system, and other managed care plans) have brought most providers to fairly common pricing levels. Many believe that the national focus will next shift to quality, and that future competition will be based on demonstrable excellence in quality. Both clinical outcome ('content') quality and customer service ('delivery') quality will be important.

*Quality and cost*. Recent research has clearly demarcated two major areas—quality waste and productivity—in which high health care quality can lead to substantially lower costs. The pursuit of high quality provides a rational system for cost containment.

*System synergy*. As the health care industry has been exposed to increasing external cost pressures, the major components of the health care delivery system—physicians, hospitals, and insurers—have pursued seemingly conflicting goals with increasing frequency. This has led to increased intra-industry friction and a less than optimal ability to address serious common problems. Given the external threats that we jointly face, the health care system is spending too much of its energy on internal disagreement.

Quality can serve as a common paradigm. It can directly address the major needs of each group, stabilize the partnership among providers, practitioners, and payors, and allow the health care delivery system to effectively address a very difficult environment.

### A Model for Quality Management in Hospitals

Early in its deliberations the Quality Measurement and Management Project (QMMP) task force of system and alliance representatives identified the lack of a common context and framework for quality discussions among care givers, health care managers, and others as a key unmet need in hospitals. Two products are required to address this need:

- A *continuous quality improvement model* that will help hospitals develop a top-down, organization-wide commitment to quality management and improvement. *Quality Management for Health Care Delivery* is that model.

- A *quality assurance* model setting forth a common approach to quality assurance utilization review risk management and infection control within hospitals. Continuous quality improvement programs are nearly always built on the foundation of good ongoing quality review. *Integrated Quality Assessment: A Model for Concurrent Review*, by Daniel R. Longo, Sc.D., et. al., was selected as a model quality assurance foundation upon which continuous quality improvement could be built

The full text of the task force's report, *Quality Management for Health Care Delivery*, proceeds through five steps:

1. ***A functional description of quality.*** While many approaches to understanding quality are available, the task force selected that used within continuous quality improvement (CQI) theory. That particular description is useful because

(a) It clearly delineates the close relationship between quality and cost, and

(b) It leads to a system for coordinated quality/cost control. In particular, it shows how the pursuit of high quality in health care can lead to substantially lower health care costs.

Using CQI concepts, quality may be described as follows:

A 'health care delivery system' is a series of interlinked *processes*, each of which results in one or more *outputs*. 'Quality' represents an individual's subjective evaluation of an output and the personal interactions that take place as the output is delivered to the individual. It is rooted in that individual's *expectations*, which depend upon the individual's past experiences and needs. Quality evaluations therefore arise from, and are part of, an individual's *value system*. As a value system, quality expectations can be measured and changed over time through education. They cannot be dictated.

Quality has two main components—content and delivery. Content quality is concerned with the medical outcome that is achieved. Although patients and payors are playing an increasingly active role in evaluating medical content quality, it has traditionally been the province of physicians and other health care professionals. Delivery quality reflects an individual customer's interaction with the health care system—for a patient, Was the hospital clean? Were the nurses

caring and informative? Were services delivered rapidly, cheerfully, and with understanding of the patient's individual needs and preferences?

A 'customer' is any individual who makes a quality judgment regarding any output or suboutput produced by a health care process, or the personal transaction in which the output was delivered.

*2.* ***The relationship of quality to cost****.* Quality relates to cost in five ways:

*Quality waste* represents the resources required to fix a process's output when a quality failure occurs or, if the output is discarded, the resources that went into its original production. In addition to the direct costs of quality failure, it includes costs associated with lost business and management time spent dealing with dissatisfied customers.

*Low productivity* occurs when two processes produce the same (desired) output, but one consumes more resources to achieve that end. Avedis Donabedian (whose volumes on medical quality are the foundation of modern thinking about quality in health care) notes that, within health care, low productivity does positive harm in that it wastes resources that otherwise could have profitably been employed for another patient.

*Optimalism vs. maximalism* embodies the idea of cost-benefit analysis—if an additional unit of care brings only a small benefit to the patient, but costs a great deal, should it be used? Most physicians claim to be maximalists (maximizing benefit without regard to cost) but, in fact, function at some level as optimatists (balancing perceived benefits with cost). Cost-benefit measurements are very difficult, and can lead to troubling ethical questions.

*New technology* usually increases costs. However, it also usually improves the medical outcome that can be achieved. As with other industries, a better product sometimes carries a higher, but justifiable, cost.

*Preventive medicine and environmental health* prevent disease. They have been shown to be a very cost effective form of health care.

The first two areas—quality waste and productivity—offer potential cost savings while quality is maintained or even improved. Some researchers believe that very significant cost savings could be achieved in these areas, ranging from 20 to 40% of total health care outlays. The next two areas—optimalism vs. maximalism and new

technology—present difficult ethical issues (such as rationing of care) which probably are best addressed on a societal level.

*3.* ***A system for quality/cost control.*** The principles of continuous quality improvement (which, upon review, correspond closely to traditional approaches long espoused but not consistently practiced within the medical profession) may be applied to achieve the highest possible quality at the lowest possible cost (high value care). Such a system requires that quality goals (both for a process's final outputs and subprocesses with their intermediate outputs) be *explicitly* defined in a *measurable* form (called I specifications'); then that *all* outputs (not just failures) be evaluated against the specifications. The aim is to *change the process so that quality failures do not happen,* rather than fixing quality failures after they have occurred. A functional quality/cost management system answers three questions:

*Are we doing the right things?*

*Are we doing things right?*

*How can we be certain that it's done right the first time, every time?*

Such a system is based upon two fundamental principles:

To achieve high quality and appropriately control costs, *eliminate inappropriate variation* and *document continuous improvement.*

*4.* ***Specifications and standards.*** Medical continuous quality improvement systems are nearly always built on the foundation of excellent quality assurance programs. CQI extends the idea of 'standards' to that of 'specifications' based on 'quality absolutes'—standards of 0% failures or 100% successes. That approach formally addresses several problems that quality assurance systems had to overcome with ad hoc solutions, and leads to a natural path from quality assurance to continuous quality improvement.

*5. A* ***model for quality in health care.*** *A* general model of quality in health care can show areas in which quality initiatives are needed, but have been overlooked. It can also elucidate relationships and interactions between important quality areas. The following critical areas of quality in health care are identified:

*Quality of Management.* Quality/cost control has been shown to depend almost entirely on an organization's control systems. These systems are designed and operated by management. Quality/cost control therefore depends almost entirely on management, not on worker motivation. The full report details a number of critical management factors that must be present if a quality/cost control system is to succeed.

*Quality of Delivery.* Patients are our primary customers. It is therefore important to measure their health care expectations and strive to meet those expectations 100% of the time. When patient expectations are not reasonable we must educate so that, over time, reasonable expectations are achieved.

*Value of Care.* The following five areas are considered:

- Physical infrastructure. Issues include technology assessment, system integration, and other long-term questions regarding maintenance of a high quality physical plant, without which high quality health care is impossible.

- Professional infrastructure. High-quality health care depends upon the presence of well-trained, dedicated, health care professionals and managers. Most traditional quality assurance efforts have concentrated on maintaining this important area. Examples include graduate medical education, continuing medical education, traditional peer review, and compliance with standards set by external regulatory bodies.

- Decision to treat. Inappropriate diagnosis can lead to unnecessary hospitalization and treatment. Recent research suggests that, within some diagnoses and procedures, a substantial proportion of health care interventions are inappropriate. Inappropriate therapy wastes resources and damages patients—it is an almost perfect example of quality waste and is of particular importance to health care financiers.

- Manner of treatment. Many studies have demonstrated a very large amount of variation in resource utilization to achieve comparable results for particular diagnoses and procedures. Inappropriate variation, when identical outcomes are obtained, is an excellent example of productivity waste.

- Productivity waste (low productivity) is an important issue for health care financiers and for those areas in which hospitals are at risk for resource utilization (e.g., the DRG prospective pricing system and other managed care plans).

- Avoid/mitigate errors. The health care delivery process is extremely complex. Research has shown that human beings and their systems are imperfect information processors-regardless of intention or human attention, mistakes will occur with increasing regularity as complexity increases. Systems which concurrently monitor the health care process, detect errors, and correct them before damage occurs will be vitally important in the future.

## INTRODUCTION

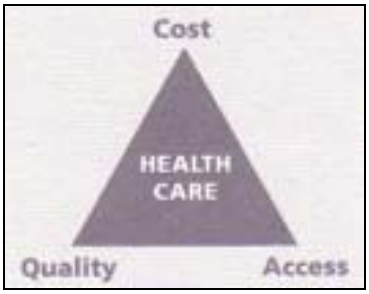



***Figure 1***

*A shifting emphasis in health care.*

For the past 10 years American health policy has slowly shifted focus among three areas: access, cost, and quality of medical care. Each area has successively received concentrated attention, often at the expense of the other two. The situation can be viewed as a slowly rotating triangle that sequentially brings one after another of its vertices into principal focus (figure 1).

For example, access to care received primary attention during the late 1960's and early 1970s. That period saw the implementation of major federal initiatives intended to guarantee that all Americans could easily obtain high-quality health care. Medicare and Medicaid were introduced, a major national program for mental health that reached into almost every community in the nation was instituted, and hospitals and medical schools were given federal monies for health care and health education programs of every description.

But during the late *1970s* the federal government and private health financiers (principally industry) noted the high and increasing costs that grew from earlier 'access to care' initiatives. The triangle turned. Emphasis shifted from a primary focus on access to a primary focus on cost. Federal programs, such as the DRG prospective pricing system for Medicare, were developed to transfer financial risk to hospitals, introduce competition among health care providers, and contain the federal government's rising health care expenditures. Private insurers reacted with similar payment limitations to stop hospitals from shifting the resulting income shortfalls to their sector. Cost control efforts are now being extended to physicians as well as hospitals.

It is not yet clear whether health care costs have been controlled.[1-6] But financial risk sharing and competition have placed providers—physicians and hospitals—in an uncomfortable dilemma: they stand to gain financially if they lower the cost of the care they deliver, but that may simultaneously reduce access and quality. For many providers, cost controls are a matter not of declining profits but of financial survival. A growing chorus of providers, consumers, and political leaders voice a fear that, due to cost controls, needed care is being withheld. Recent research has solidified that fear by showing a close statistical association between stringent cost controls and high mortality rates.[7-12] Anecdotes of cost-driven, low quality care abound. The triangle is changing—it may no longer be acceptable to concentrate primary attention on a single vertex. Cost containment still demands close attention but quality and access are becoming simultaneous, serious concerns. The value of health care the highest possible quality at the lowest reasonable cost-is shifting into primary focus.

But what is quality in health care? What is the relationship between quality and cost? Can health care costs be controlled only by sacrificing quality and access to care? How can a provider consistently achieve high quality care while meeting cost control constraints.?

Continuous quality improvement (CQI) is a general theory for quality in any organized endeavor. It was originally set forth as a formal model in the 1930s by Walter A. Shewhart, an American engineer, and later expanded and refined by W. Edwards Deming and J. M. Juran. It has been widely applied to industry in Japan, where it is credited with that country's competitive success. It is now appearing in industrial settings throughout the United States and Western Europe. Within the industrial setting it is generally called Industrial Quality Control, the industrial model for quality control, or total quality management-even though it is a broad range of ideas and techniques and often appears with different specific features in different industrial settings.

Upon examination, medical applications of CQI theory predate Shewhart by many years. The roots of continuous quality improvement are the same quality principles that medical practice has taught since its inception. The major difference is that CQI theory uses those principles in a formal, explicit fashion. It rigorously applies the scientific method to organized medicine's commitment to 'learn from every patient, so that the next patient will receive better treatment' (see sidebar: The CQI Challenge). Health care is significantly different from other industries. It is therefore not surprising that CQI systems designed for health care have features and emphases that are significantly different from those typically found in industrial quality control.

CQI theory is important in the medical setting because it (1) gives a rational definition of quality that applies in all health care settings, (2) clearly shows the relationship between health care costs and quality, and (3) leads to a system under which the highest quality care can consistently be delivered at the lowest justifiable cost.

The following chapters outline an application of CQI principles to health care. They proceed through five sections: the first introduces a consistent, generally applicable, description of health care quality; the second describes the relationship between quality and cost; the third outlines a system through which quality and cost can be scientifically evaluated, controlled, and documented; the fourth shows how CQI builds on the foundation of existing traditional quality assessment (QA) techniques; and the fifth presents a research model of health care to show that CQI principles offer opportunities for quality improvement and cost savings in *every* area of health care.

***The CQI Challenge***

*Continuous Quality Improvement demands that health care providers answer three questions:*

1. *Are we doing the right things?*
2. *Are we doing things right?*
3. *How can we be certain that we do things right the first time, every time?*

*It offers two general rules to answer those questions:*

*To do the right things, the right way, the first time, every time, eliminate inappropriate variation and document continuous improvement*

*Finally, CQI recognizes that most health care professionals are already deeply committed to the highest-quality work. Quality depends more on good system design , consistent long-term direction, adequate training, leadership, and follow-up—all management functions—than on individual motivation. CQI therefore uses a non-punitive team approach for quality management.*[14-15]

## WHAT IS QUALITY?

In his classic text on health care quality Avedis Donabedian, M.D., presents a fundamental concept regarding the nature of any activity designed to produce a consistent result." Such an activity has three components:

Structure → Process → Outcome

The Process component may itself be regarded as consisting of.

Input → Action → Output

More concretely, the practice of medicine is a process that results in an *output*. It is not the output alone. "Quality of production" refers to the process; "quality of design," or "quality of output, describes the end product.

The "quality" of an output is an evaluation—an individual's personal judgment—of some set of attributes of the output. It is formed from the individual's perceptions of the output and is rooted within the individual's personal frame of reference. It is a relative term with no fixed unit of measurement, that is, a unitless value system. It is assessed by comparison to other similar items or events, so that static terms of "good quality" or "bad quality," as fixed measures, have no firm meaning over time—there is really only "better quality" or "worse quality." The basis for comparison is contained within the individual's past personal experiences and prejudices. This personal history is expressed as expectations: when positive expectations are met, then quality is judged to be acceptable; when expectations are exceeded then quality is judged to be excellent. It is important to note that, more than being a unitless measure, "quality" is not a physical attribute of the service or product—it does not exist until there is an interaction between the product or service and the person making the judgment.

Quality is thus a perception that is based on an individual's value system. It relies heavily on the culture, life experiences, and expectations of each individual. Quality receives a new definition in each interaction between an individual and an item for which the term is evaluated**.** It is "one of those things that is very difficult to define, but that anyone can recognize-I know it when I see it."

A prominent feature of unitless value systems is that, while they may be described, it is extremely difficult to mandate an *a priori* value standard that will be functionally acceptable to most people (see sidebar: *Mandating Value Systems).* A number of modern

philosophers have noted that organizations (such as governments and health systems) operate under an umbrella of values that are generated by the culture of the society in which they exist.[16] While governments and organizations may be able to identify particular quality-based value systems, and even to influence them over long periods of time through education, they are not able to dictate fixed standards for quality that will be acceptable to all or even most individuals who relate to the organization. Individuals bring quality expectations to the organization—the organization does not tell the individuals what their quality values will be. And, as value systems depend upon a particular individual at a particular time, they are in a state of constant change and re-expression; they represent a moving target.

When an organization or individual generates outputs, either as products or services, and delivers those outputs to other organizations or individuals, then a quality judgment can occur.

A **customer** is *any organization or individual who makes quality judgments about, or has expectations regarding, an output.*

Although it is impossible to mandate quality expectations, it is possible to: (1) explicitly identify customer groups, (2) explicitly measure their expectations, and (3) change their expectations over time, through customer education. *In this setting,* **quality** is *meeting or exceeding customers' expectations 100 percent of the time.*

But customer expectations continually change. The definition of quality can therefore be expanded as follows:

**High quality** *is achieved by continual improvement in terms of customers' expectations. The aim of continuous quality improvement is to meet the customer, not just the competition.*

Health care delivery is a complicated process which involves large numbers of workers. Different workers have different customers, depending upon the nature of an individual worker's job assignment. While, by definition, different customers have different expectations, they can be grouped together—general classes of customer expectations can be formed.

**Identifying Customers**

Every division within a hospital has a different set of customer groups. For example (in very general terms), the hospital's primary customers may include patients and their families, secondary care physicians, payers, primary care physicians, employees, regulators, and local communities. A secondary care physician's customers could include patients and their families, primary care physicians who refer patients for care, the hospital administration, and payers.

***Mandating Value Systems***

*Value-based controversies are common in a pluralistic society. A good historical example is religion and moral values. An excellent current example is abortion.*

*Governmental or organizational attempts to mandate value systems usually fail. For example, the government can pass any number of laws regarding abortion, but that will not change individuals' opinions about whether, when, and how abortions should be performed.*

*Similarly, medical groups can set standards for quality in health care. They will be successful, however, only to the extent that those standards reflect the expectations of medicine's customer groups, or educate medicine's customers in order to modify their expectations.*

The laundry department's customers might include acute care nursing floors, surgery, and the maintenance department.

The important concepts are the following:

- Any person or organization who has expectations regarding outputs is, by definition, a customer. Almost everyone—even suppliers—can profitably be treated as customers.

- Different hospital workers have different customers, including internal customers—individuals or departments within the hospital who use the worker's outputs.

- It is therefore necessary for every worker to understand the concept of "customers." They must be able to identify, and should explicitly list, their customers. The list should regularly be reviewed and updated.

- Individual customers can often be grouped together on the basis of similar needs and expectations.

- As will be detailed later in this report, supervisors and managers should not be their employees' primary customer—such a situation is the hallmark of poor management.

**Medical Customers: Content and Delivery**

Customer expectations can be divided into two major areas: expectations regarding the physical attributes, or content, of the output/product that is provided, and expectations about the nature of the interaction between the producer and the customer as the transaction takes place.[17]

*Content quality* refers to whether the output does what the customer believes it should do—does the output functionally meet the customer's expectations?

*Delivery quality* refers to all aspects of the organization's interaction with the customer in delivering the output. It is determined day by day, moment by moment, in thousands of individual, temporary relationships. Does the customer's interaction with the organization's employees meet the customer's expectations?

Within hospital-based health care delivery, content quality is roughly equivalent to medical outcomes. Did the patient receive the medical out come that should have been achieved? Delivery quality describes, in a general way, patients' satisfaction with their hospital experiences (see sidebar: *Patient Satisfaction).* Neither distinction has clear boundaries: content and delivery quality interact extensively. But the dichotomy is useful for understanding and analyzing health care quality.

As was mentioned in the Introduction, health care delivery is different from other industries. A major source of that difference is medicine's traditional approach to *content* quality:

Medicine is one of the "learned professions." As such, it reserves to itself the right to judge its own quality. In functional terms, that means that *the medical profession, as a group, sets its own expectations regarding medical outcomes (content quality)—a profession is sometimes its own primary customer.*

Medical outcome expectations are set by informal consensus as expressed in the medical literature and local "standards of care." Wennberg has written of the *clinical hypothesis* which underlies all diagnostic and treatment decisions.[18-19] A clinical hypothesis describes the disease process, treatment options, and likely outcomes that can be achieved by different treatment strategies within traditional medical practice. Clinical hypotheses are usually not explicitly written out. But, in most instances, there is little debate regarding the outcomes that medical professionals hope a treatment will achieve.

The medical profession's hold over medical content quality is beginning to erode. Patients and payers are becoming more informed and taking a more active part in setting medical outcome expectations. However, medical professionals still play the central rote. Nearly all patients and payers still
to malpractice litigation.

A second, related, major difference between health care delivery and other industries is medicine's opportunity for customer education.

**Educating Patients**

Hospitalization is a rare experience for most Americans. Their expectations regarding medical outcomes are often poorly defined, arising from television and the experiences of friends and relatives. The health care industry therefore has a greater opportunity than most other industries: through patient education, expectations can be set at the time the patient enters the hospital.

In fact, that is exactly what happens in traditional medical practice. But patient (and family) education is often informal, uneven, and incomplete—it is frequently accomplished as a side thought to the 'real' business of medical treatment. But patient satisfaction has been shown to relate directly to how well the health care team informed the patient and family of the disease process and its treatment and whether the patient and family were allowed to participate in treatment decisions. Both of these factors are functions of patient education.

***Patient Satisfaction***

*Brent Jacobsen surveys more than 6,000 individuals to discover factors that determine perceptions of hospital quality within Intermountain Health care (IHC). Random samples from both the general population and from patients recently hospitalized at IHC facilities were drawn. Conclusions were refined through a series of patient and community-based follow-up focus groups.*

*Using cluster analysis, the researcher were able to divide patients into three major segments: information seekers, comfort seekers, and prestige seekers. More than 30 factors that patients associate with hospital quality were identified. The same top 12 factors were used by all three patient segments:*

- *Hospital cleanliness*
- *Smoothness of admission/discharge*
- *Accuracy and clarity of billing statements*
- *Courtesy of hospital employees*
- *Response time for patients' calls/requests*
- *Level of technology available*
- *Nurse competency*
- *Availability of physician specialists*

- *"Track record" for medical complications*
- *Availability of good emergency care*
- *Price*
- *Taste and temperature of food*

*All of these factors were surrogate measures of medical (content) quality, which patients were not confident they could directly evaluate. On further examination, patients' responses to these quality indicators were found to be primarily determined by only two major factors:*

- *Was the health care team able to explain the disease process, the treatment choice, and the likely outcomes in a way that the patient and family could understand?*
- *Did the patient and family participate in the medical decision-making process?*

*Similar results have been anecdotally reported by other hospital groups.*

Said another way, many patients are frightened and confused by their illness and the medical interventions that are employed. They do not know how to interpret sensations in their own bodies and the actions of those in whose hands they have placed their lives. The sutures closing their surgical wound feel like they could tear loose if they cough. Will that happen? Their IV seems to be running more slowly. Does it need to be immediately adjusted? When they call the nurse, why is s/he so long in coming?

Through education, patients are taught what is and is not important in their own condition. They become active members of the health care team. Their anxiety decreases. They can join in treatment decisions. Their satisfaction with the health care system improves. For example, an Intermountain Health Care QUE (for Quality, Utilization, and Efficiency) study on non-acute cholecystectomy detected a physician whose patients left the hospital much earlier than did his colleagues' patients, while achieving comparable medical outcomes (see page 21). That physician used a subcostal incision to reduce post-surgical pain, so that only non-narcotic analgesics were required for pain control. His patients regained bowel function more rapidly and so could be discharged earlier—on the average, within one or two days after surgery. Presented with these data, his colleagues supported his clinical approach, but asserted that patients could not comfortably assume their own care so early and so must be very dissatisfied with the care they had received.

But on review it was found that his patients were among the most satisfied in the study. The difference was patient education. The physician had prepared a videotape that stepped each patient through the events of their coming surgery. They were taught about factors that could be safely ignored and about those for which they should immediately seek help. Finally, they were told that they would recover just as quickly at home and that, with proper home care, they would be just as safe and even more comfortable.

Another branch of patient education is important for risk management: Wennberg has investigated the use of interactive video disks to obtain informed consent for elective surgical procedures. Their use not only educates the patient, but documents the information that was given. Defects in informed consent form the basis for a significant proportion of malpractice actions against hospitals. Better patient education and informed consent could reduce that number.

## Summary

"Content quality" describes the technical component of medical care—it is primarily evaluated by, and based on the expectations of, health care professionals. "Delivery quality" is associated with the interpersonal relationships on which the delivery of any service is based—it is primarily evaluated by, and based upon the expectations of, patients and their families.

The health care industry therefore deals with two primary customer groups: patients evaluate delivery quality but physicians and nurses, representing the patient, usually evaluate content quality. To create a high-quality medical process it is therefore necessary to measure physicians' expectations for medical care content and patients' expectations for medical care delivery. This dichotomy is reflected in traditional health care quality assurance programs and in the research model for quality in health care that is presented later in this paper.

Medical care is further unique in that its primary customers-patients and health care professionals—are usually not financially responsible for the care that is delivered. Health care financiers (government, industry, and insurance agencies) form a third major group of customers. Licensing and regulatory agencies form yet another major customer group.

For the purposes of this report, health care customers will be classified into four major groups: (1) physicians, nurses, and other health care professionals, who evaluate quality of content; (2) patients and their families, who evaluate quality of delivery; (3) health care financiers and regulators, with expectations regarding content, delivery, and cost; and (4) internal customers (e.g., nurses), who use intermediate products within an organization.

## QUALITY AND COST

Walter A. Shewhart, the father of formal continuous quality improvement theory, noted that "Price has no meaning without a measure of the quality being purchased."[20]

Quality and cost are intimately related: **value** is *the combination of the quality of a product and the cost at which that level of quality is achieved.*

When discussing the cost and quality of clinical treatments (the content of care, as opposed to its delivery) that definition can be limited:

**High value clinical care** *results from the most efficient expenditure of resources to achieve an established high level of clinical quality.*

Health care financiers—as represented by those industrial managers who are responsible for workers' health care benefits—have identified the value of health care as their principal focus over the next several years. They want to stop the steady upward pressure of health care costs while maintaining the best possible clinical quality, as reflected by clinical outcomes.

Most health care practitioners would agree that costs and quality are inextricably intertwined, but CQI theory takes an extra step that some practitioners might find counter- intuitive: it asserts that high quality can lead directly to lower costs. To demonstrate the boundaries of that effect, the following paragraphs divide the relationship of cost and quality into five major areas: (1) quality waste, (2) productivity, (3) maximalism versus optimalism in the face of limited resources, (4) the effect of improving the best medical outcome that can be achieved through new technology, new medications, or new techniques, and (5) environmental factors and the role of preventive medicine.

### Quality Waste

As part of the definition of quality developed in the previous section, Donabedian's fundamental quality model-processes that convert inputs into outputs-was introduced. But what happens if a process fails, and an output that does not meet quality expectations is produced? By definition, the output is a quality failure. Two options are available to deal with the offending product: (1) throw it away or (2) fix it.

Within non-health care industries these two options are called, respectively, scrap and rework. For service industries (including the delivery side of health care), scrap corresponds to abandoning a customer before the commissioned service has been satisfactorily performed, while rework takes the form of field service repairmen and customer service representatives. For medical outcomes—content quality—scrap and rework manifest themselves as mortality, morbidity, and the extra medical resources expended in attempts to correct bad outcomes.

The low quality that results when a process fails brings with it a series of high costs. When a unit of output is scrapped, all of the resources that went into its production are wasted. Who pays for the scrapped units? When a unit of output is repaired, additional resources must be allocated to correct the deficiency. Who pays for the repair work? Even more resources are consumed to replace customers (who cease to do business with the organization because they are dissatisfied with the quality of the output they received), in additional warranty costs (the organization may be liable for legal expenses and other, secondary damages that are traced to the original failure), and in time spent by managers who must deal with dissatisfied customers.

Low quality leads directly to higher costs. These costs, arising from an initial process failure and the resulting low quality output, are termed **quality waste**.[21] Quality waste represents the resources that are consumed, in the form of scrap or repairs, when a unit of output fails to meet quality expectations. Quality waste can be traced by identifying scrap and rework. It can then be managed and eliminated from within an organization.

Continuous quality improvement experts have measured quality waste in other (nonmedical) industries.[22] When a welt-managed quality control system was not in place, quality waste was consistently found to account for a significant proportion of the company's total dollar volume. As quality waste was recognized the companies involved made substantial gains in cost control and profitability. Based on conversations with quality leaders from large American health care systems, quality waste also exists in health care delivery. As it is discovered and corrected, quality can be improved and costs lowered. Three examples follow.

**Quality Waste in Hospital Management**

***Supplemental Information***
*Case study on Quality Waste: patient billing process*

When a service function fails repair takes the form of customer service representatives. One service that a hospital performs is patient billing. The bill's goal is to induce the patient to send payment. Bills are sent to patients so that the patient can relate the items for which they must pay to he services they actually received in the hospital. A bill should therefore accurately and completely list the services that were performed and the products that were used in a

manner that the patient can understand and relate to their recent experience in the hospital.

The billing process used by a 500-bed tertiary-care hospital failed to meet these simple criteria. Line items on detailed patient billing statements were so obtuse that even attending physicians could not understand them. A significant proportion of patients called with questions and complaints about bills. The hospital eventually hired a total of 12 full-time customer service representatives to deal with billing complaints alone. Direct costs for this repair activity were more than $300,000 per year. Moreover, hospital administrators spent significant amounts of their time answering patient complaints about bills, and many patients were known to take their health care needs to other providers because of their negative experience with the billing system.

These expenditures all represent the costs of a failed process and a low quality output: they are quality waste. The concept can be summarized by a single basic precept of continuous quality improvement:

*Do it right the first time.*

The hospital is now restructuring its patient bills. Physicians and patients helped plan the new billing system to guarantee that customers' needs will he met. The hospital stands to realize substantial savings as its need for customer service representatives declines.

**Clinical Quality Waste I**

***Supplemental Information***
*Case study on Quality Waste: Differences in rates of hospitalization or the use of specific surgical procedures across small geographic districts.*

Small area variation analysis examines differences in rates of hospitalization or the use of specific surgical procedures across small geographic districts. John Wennberg, M.D., pioneered the methodology through his analysis of the rates at which transurethral prostatectomies (TURPs) were performed in communities in Maine.[29] He discovered that the procedure was performed at widely different rates in different communities, and that those differences could not be explained by variation in the underlying population.

A "clinical hypothesis" is the set of available medical knowledge about a disease process, treatment options, and the medical outcomes likely to result from each treatment option. Clinical hypotheses are usually implicit in medical practice—they are very rarely explicitly written out—but there is little disagreement among practitioners regarding their chief features and endpoints.

Part of the clinical hypothesis for benign prostatic hypertrophy (BPH—the condition for which most TURPs are employed) concerned the natural history of the disease. Physicians know that many men develop BPH during their sixth or seventh decades of life,

but only a fraction will eventually develop severe disease leading to urethral obstruction that requires surgical intervention. But they also know that, as men become older and more debilitated, the risks of any surgical procedure increase. Some physicians in Maine believed, as part of the BPH clinical hypothesis, that it was better to operate on a large group of men when they were relatively young—in their early sixties—than to operate on a smaller population of older men after their BPH became more severe. They thought there were fewer total deaths by pursuing the earlier, more vigorous surgical course.

Wennberg demonstrated that the unwritten clinical hypothesis was wrong. He showed that the death rate from surgical complications was much higher than expected, and that the risks of early surgery in a large population far outweighed the risks of age and advanced urethral obstruction in a smaller population of older patients. Upon publication of his results, the rate at which TURPs were performed in Maine felt precipitously. Fewer procedures were performed at a tower total cost, while the general quality of health care improved because many patients weren't exposed to the unnecessary risks of the procedure.

By definition, a flawed clinical hypothesis means that either poor medical outcomes will be obtained or that the outcomes that are obtained will be relatively valueless. A flawed clinical hypothesis is therefore an excellent example of quality waste. Wennberg identified over 60 additional surgical procedures and medical diagnoses which exhibit similar regional variation. He has shown that such geographic variation can be a sign of a flawed clinical hypothesis. There is tremendous potential to improve the overall quality of medical care and reduce health care costs by studying and improving clinical hypotheses.

**Clinical Quality Waste II**

***Supplemental Information***
*Case study on Quality Waste: detect output failures (deep wound infections) and relate their occurrence to the process of care.*

Postoperative deep wound infections are an important cause of mortality and morbidity—low-quality outcomes—among surgical patients. Antibiotic prophylaxis is one useful step in a process designed to prevent such outcome failures. Members of the department of Infectious Disease at LDS Hospital, a 520 bed tertiary care teaching and referral center in Salt Lake City, Utah, prospectively monitored prophylactic antibiotic usage for all inpatient elective surgeries performed at their hospital during two six-month periods.[30] They wanted to detect output failures (deep wound infections) and relate their occurrence to the process of care.

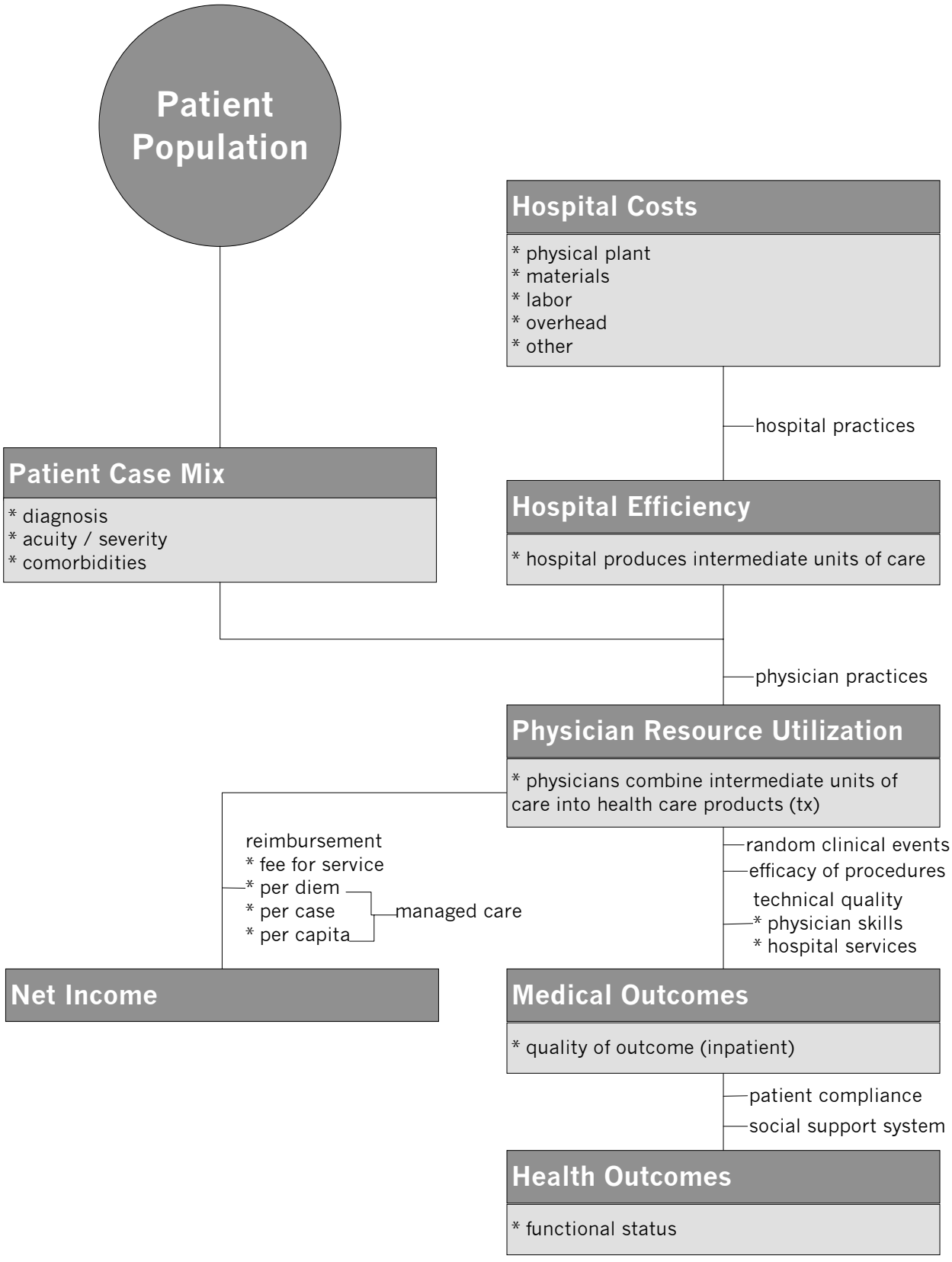
All elective surgical cases that were admitted from June to November during 1985 or 1986 and that received antibiotic prophylaxis were monitored (4,484 cases). The timing of administration of the antibiotic was recorded: Prophylaxis was termed 'premature,' 'optimal,' or 'late' if the drug was given more than two hours before surgical incision time, within two hours before

surgical incision time, or after surgical incision time, respectively. Cases were identified and followed through the HELP Hospital Information System, a complete electronic medical record system developed at LDS Hospital.

Baseline data were collected during the 1985 phase of the study. Then, during the first six months of 1986, steps were taken to modify the process by which prophylactic antibiotics were used at LDS Hospital: The HELP system was programmed to automatically evaluate each new elective surgery patient then insert a reminder that emphasized the two-hour ‚optimal' time period in the patient's electronic medical record. Copies of the reminder were also printed and attached to the patient's chart.

All eligible patients were again prospectively monitored from June to November 1986, under the new reminder system. The total percentage of patients who received antibiotic prophylaxis did not change. But the percentage of patients receiving prophylaxis during 'optimal' times increased significantly, rising from 40 percent in 1985 to 58 percent in 1986 ($P < 0.001$). This was associated with a decline in deep post-operative wound infections from 1.8 percent (28 infections) to 0.9 percent (16 infections; $p < 0.03$).

The deep wound infections found in the study required extended hospitalization and treatment. They ranged from relatively simple, easily manageable, infections of abdominal incisions (e.g., following an appendectomy) to life-threatening deep infections of the mediastinum following open-heart surgery. LDS Hospital spends, on average, between $13,000 and $15,000 to treat every deep wound infection that occurs within its walls. A partial correction of the process of giving prophylactic antibiotics at the hospital reduced the number of infections during the six-month period from 32 expected cases to 16 actual cases. The 16 cases in which infections were avoided translates to a cost savings, for the hospital, insurers, and patients, of over $400,000 per year in fixed costs alone. In addition, postoperative infections may expose the attending physician and hospital to legal action. Most important, such infections can cause permanent damage to a patient and may result in a preventable death.


Patient Population
Hospital Costs
* physical plant
* materials
* labor
* overhead
* other
hospital practices
Patient Case Mix
* diagnosis
* acuity / severity
* comorbidities
Hospital Efficiency
* hospital produces intermediate units of care
physician practices
Physician Resource Utilization
* physicians combine intermediate units of care into health care products (tx)
reimbursement
* fee for service
* per diem
* per case
* per capita
managed care
random clinical events
efficacy of procedures
technical quality
* physician skills
* hospital services
Net Income
Medical Outcomes
* quality of outcome (inpatient)
patient compliance
social support system
Health Outcomes
* functional status

## Productivity

Suppose that two different processes start with identical inputs and produce identical outputs, but that one uses twice as many resources as the other. Which process should be used?

A number of studies have documented the broad range of practice patterns, and widely varying resource consumption, that are employed by practitioners to achieve apparently identical clinical results.[23-27] Donabedian notes that, when total health resources are limited, inefficient practice styles do positive quality harm: wasted resources cannot be used to meet the legitimate needs of other patients.[28] In an era of limited medical resources—as evidenced by medical cost containment efforts and serious questions regarding access to care—suboptimal practice patterns are clearly unacceptable.

### IHC QUE Studies

***Supplemental Information***
*Intermountain Health Care's Quality, Utilization, and Efficiency (QUE) studies*

Both the hospital and its physicians have major impacts on the nature of care that is delivered within a hospital. Researchers at intermountain Health Care in Salt Lake City, Utah, developed *a model that separates the hospital's contribution from physicians' contributions to clinical care.* It is shown graphically in figure 2.

The QUE model (for Quality, Utilization, and Efficiency) focuses on "units of care." Units of care correspond to the individual items on a detailed patient bill—for example, a single dose of a drug, one minute in a surgical suite, or one day on an acute care nursing floor. The hospital is regarded as a factory that produces units of care. The *efficiency* with which the hospital produces each unit of care, as reflected in true unit costs,* can be examined. Physicians then combine varying numbers of different units of care into a health care product. Physician *utilization* patterns, as expressed in numbers of specific units of care employed, can be analyzed. But before either utilization or efficiency can be examined it is necessary to form a balanced group of patients who had equal -acuity (severity of illness), complexity (presence and severity of comorbidities), and out comes (complications and medical results). These factors are jointly viewed as *quality.*

*Figure 2*

***The Quality / Utilization / Efficiency Model***
*(developed by Drs. M. Weinstein, S. Lewis, and B. James with contributions from Dr. D Schumacher)*

***IHC** uses a "labor model" to measure the true costs of production for individual units of care: Management engineers fully analyze every product and service produced within the hospital. For example, for a laboratory test they establish the average amount of technician time required, the amount of reagents and other disposables used, and the overhead of equipment involved. Efficiency, as reflected in costs, cannot be evaluated without such unit cost data. A recent ProPAC Study estimated that only 17 percent of all hospitals in the United States have such information. Most hospitals function through departmental (rather than unit cost) budgets, or have applied published formulas to departmental budgets in order to generate secondary—but not necessarily accurate--"unit costs."

The aim of an IHC QUE study is to compare and contrast physicians (in terms of utilization) and hospitals (in terms of efficiency), with a view to identify and eliminate inappropriate variation. It requires a team approach. While a QUE study can document variation it cannot determine whether the variation is appropriate or inappropriate. A QUE study's blinded results are therefore reported to the hospitals and physicians involved to act upon as they deem best. A major precept of CQI theory states that most individuals-85 to 90 percent-pursue high-quality work as a personal value; it is only necessary to supply adequate data and training to achieve high-quality results. This may be even more true in clinical medicine, which tends to attract those with a personal commitment to serve.

IHC has completed QUE studies for six clinical entities. Very high variation was observed from physician to physician (in terms of utilization) and from hospital to hospital (in terms of efficiency) for every clinical area examined. Examples of variation in utilization patterns for transurethral prostatectomy (TURPs) are shown in figure 3.

Nine months after utilization variation data for TURPs were shown to physicians at three hospitals, a follow-up TURP QUE Study was conducted to determine if the original findings had had any impact. Comparative figures between the first and second TURP QUE studies are shown in the last graph in figure 3 (Hospital 2 was a natural control). The only action taken following the first study was to confidentially share variation data with individual physicians. Following that action utilization declined significantly-the example given in figure 3 demonstrates changes in length of stay. More important, the amount of variation from physician to physician also declined for most major units of care.

The second principle of quality management states: to *achieve high quality*, ***eliminate inappropriate variation,***

Inappropriate variation—in this case, variation that increases costs but does not lead to improved medical outcomes—is a hallmark of low productivity. When differences in the processes that lead to apparently identical medical outcomes are identified, three possibilities exist: (1) some practitioners are under-utilizing and run an increased risk for quality failures, (2) some practitioners are over-utilizing and use resources that aren't really required, or (3) there are differences in skills and clinical acumen among the practitioners—some physicians require more resources to achieve the same output. In the first case, utilization should be appropriately increased. In the second, it may be appropriately decreased. In the final case, the underlying variation clearly is not inappropriate, although recognition of this situation can lead to additional training and improvement in clinical skills.

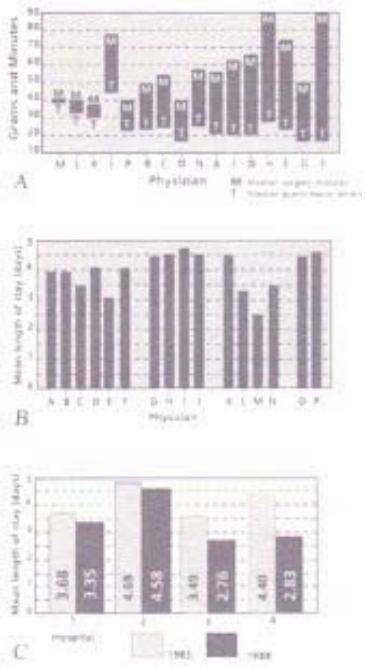



***Figure 3***

***IHC 'Uncomplicated TURP' QUE Study***

***Part A:*** *Variation in process factors (median surgical time and gram weight of tissue removed) by physician (1985 TURP data).*

***Part B:*** *Variation in a process factor (mean length of stay) by physician (1985 TURP data).*

***Part C:*** *Change in a single process factor (mean length of stay) following presentation of initial data to urologists (Hospital 2 is a natural control).*

## Optimalists and Maximalists

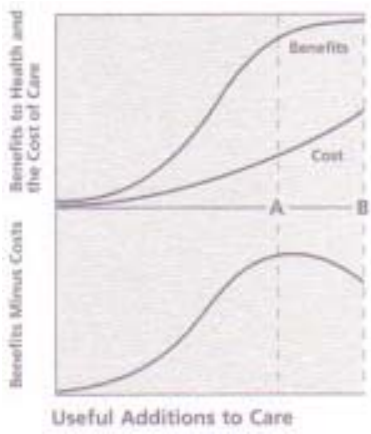



***Figure 4***

*Hypothetical relationship between health benefits and cost of care as useful additions are made to care.*

***A** indicates optimally effective care.*

***B** indicates maximally effective care.*

*(Source: Donabedian, 1988; see citation 28 p. 56. Reprinted with permission from the Journal of the American Medical Association.)*

Quality waste represents the process failures in medical care, their inherent low quality, and the high costs required to repair them. Low productivity—the use of techniques that are not as cost effective to achieve an equivalent output—is harmful by displacing more effective care. Donabedian has shown that costs and quality are confounded in a third way as in figure 4.[28] It is believed that as one adds to the total care delivered for a particular episode of illness, the marginal content qualityachieved by each additional unit of care declines. In the extreme, marginal quality gains become trivially small while costs rise without limit. A point may be reached where the gains in quality cannot justify the in creased consumption of limited medical resources. Those who hold this view may be called optimalists," as they attempt to achieve an optimal level of quality achieved for resources consumed (that is, they try to maximize *value*). The main potential harm resulting from optimalism is that while a very high level of quality may be achieved, the ultimate pinnacle of potential content quality for an individual patient may not be reached.

A second view holds that, from an ethical standpoint, health care professionals cannot be placed in the position of limiting medical content quality on the basis of cost. The best possible medical output should always be pursued, regardless of cost. Those who support this view are called "maximalists." As with low productivity, the principal harm engendered by maximalism is that, by consuming unlimited resources for limited gains, it potentially displaces more useful care. Maximalism differs from low productivity in that, by definition, low productivity occurs when an alternative approach will achieve the same quality using fewer resources; maximalism achieves higher quality but at an increasingly unfavorable cost.

Donabedian notes that health care practitioners tend to be maximalists because they then need only decide if an additional element of care will be useful. Optimal care requires added expertise regarding cost and some method of balancing the usefulness of each additional element of care against its cost.[31] In fact, traditional American medical practice has long included a strong dose of optimalism—it is legitimate, ethical, and even necessary when limited medical resources must be allocated among unlimited medical demands, so long as the costs and benefits are jointly weighed by the health care professional and a fully informed patient. A much more difficult (and, often, ethically unacceptable) situation arises when a third party—typically a health care financier or regulator—independently establishes and then enforces a particular level of care as being optimal.[32]

## New Technology

The science and technology of medicine continue to rapidly advance. There is little question that improved technology, new pharmaceuticals, and updated therapeutic approaches provide a greater likelihood of a superior medical outcome. Government regulations require that new technology be demonstrated to be "effective and efficacious" before it can be distributed throughout the country. New techniques are demonstrated through clinical research and reported in the medical literature before they find widespread acceptance.

New techniques and technology change the final output expectations for medical content. Such changes mean that the underlying process has been modified to produce a different, superior output.

These improvements nearly always involve higher costs. At a fundament at level, significant improvements in the best final output that the process of medical care can hope to achieve consume more resources than their less capable predecessors.

The optimalist/maximalist debate often intrudes in discussions of new technology. While existing techniques and technologies are somewhat protected by their traditional use, new innovations may be criticized on the basis of their perceived cost-benefit ratio. But the fact remains—some advances in medical care, which improve the best output that can he achieved, can be had only with the expenditure of more resources.

## Environmental Factors and Preventive Medicine

Finally, the role of preventive medicine and environmental health in controlling the costs of medical care, while improving the overall quality of Americans' health, should not be overlooked. Environmental and personal lifestyle factors (e.g., air quality, toxic wastes, automobile trauma, and tobacco usage) have been shown to have a profound impact on the rates of disease within our communities and, thus, upon the total cost of medical care that society must bear. As a related discipline, preventive medicine is generally recognized as being much more cost-effective than the treatment of established disease in achieving positive health outcomes. If one accepts the premise that there is a limited fund of health care resources from which essentially unlimited health care demands must be satisfied, then there is a strong incentive to eliminate those known environmental and lifestyle factors which lead to disease and consume large amounts of medical resources. Some of the harshest critics of American medicine's high costs—leaders in industry, government, and special interest groups—are in the best position to control medical costs by controlling those environmental and lifestyle factors that lead to disease.

## Summary

In summary, quality is intimately related to cost. In some cases (quality waste, productivity, and preventive medicine), high quality leads to lower costs. In others (new technology), improvements in clinical content nearly always carry higher costs. Finally, resource limitations may require the practice of optimal health care, rather than maximal health care. It may be necessary to marginally reduce final medical outcome quality for some individuals in order to significantly improve medical outcomes for some other, larger, group.

By eliminating quality waste and improving productivity in health care, it may be possible to achieve significant reductions in costs and concomitant improvements in the quality of the care that is delivered. If analogs in industry are to be believed, the potential savings may amount to as much as 20 to 40 percent of all health care expenditures. Until potential savings in these areas have been exhausted the debate between optimalism and maximalism, as it applies both to established methodologies and new technology, arguably should not be the primary focus of cost control efforts.

Quality improvement principles apply equally to both of the major aspects of medical care: content, as evaluated primarily by physicians, and delivery, as evaluated primarily by patients. With regard to medical care content quality, every patient should receive the best possible medical outcome. But delivery quality—the personal comfort aspect—is a separate issue. Most employers offer, and patients regularly purchase, different levels of health insurance. Their purchase decisions reveal the relative expectations each person places on the manner in which their health will be maintained. Some now assert that health care systems will legitimately differentiate themselves on the basis of personal services.

Finally, CQI theory demonstrates that the appropriate way to control costs is to focus on continuous quality improvement. Uninformed cost controls can damage production processes, produce low-quality outputs, and generate even higher costs as quality failures must be repaired or scrapped. Quality provides a more sophisticated understanding of costs: under CQI, high quality leads to appropriate cost controls.

## A SYSTEM FOR CONTINUOUS QUALITY IMPROVEMENT AND COST CONTROL

Achieving high quality and appropriate cost reductions involves three major steps: (1) prepare to improve, (2) implement, and (3) innovate. Once a CQI system is in place, steps 2 and 3 cycle continuously. These steps can also be stated in CQI's two primary principles:

To continuously improve quality and appropriately control costs, *eliminate inappropriate variation and document continuous improvement.*

Their effective application depends upon a clear understanding of the nature of quality ("quality is meeting customer expectations"), the role of process in achieving quality, and the relationship between quality and cost.

To "prepare to improve," steps 1 through 5 are all necessary in some form:

1. ***Find a process.*** Health care is a complicated series of related processes. A large number of those processes are already well defined through clinical practice—individual diagnoses and procedures (health care products) each represent a process. Taken together they form the heart of health care delivery. Other processes cut across diagnostic lines. For example, admission to the hospital, billing, or analyzing a single blood test are all definable processes that cross diagnostic lines. The first step is to choose a process that needs quality improvement and cost control.

2. ***Assemble a team that knows the process.*** Those who best understand a process are nearly always those who perform it on a daily basis—frontline workers. Through its members, the team must also have an understanding of continuous quality improvement principles, statistical quality control, the use of data management systems, and access to management so that organizational roadblocks to improvement can be overcome.

3. ***Identify customers, identify process outputs, and measure customer expectations regarding the outputs.*** By definition, quality is meeting or exceeding the expectations held by a process's customers (with the proviso that expectations can be changed, over time, through customer education). But different processes have different outputs and often have different customers. The team's first task is therefore to list the outputs of the process, identify its customers, and measure their expectations of its outputs.

### *Forgetting the Customer*

*During the 1970s Japanese automobile manufacturers made major inroads into American care markets. Japanese cars were widely recognized as having higher quality than their American counterparts.*

*When charged with having comparatively low-quality products, American care manufacturers protested that they actually had better quality, and had the data to prove it. They pointed to tests that showed their cars accelerated more rapidly, developed more power, and had more internal space.*

*The difference between American and Japanese manufactures was the source of their quality measures. Japanese manufacturers asked American consumers what they wanted in a car. They got answers like high gas mileage, handling ability, and low maintenance (the trim shouldn't fall off). They built cars to those expectations and American consumers bought them in unprecedented numbers. Detroit used its own internal quality expectations—measures of self-gratification. They eventually resorted to import restrictions to raise Japanese prices and force American consumers to accept Detroit's product.*

It is important that these steps be done explicitly—in writing. Too often American organizations have confused their customers' expectations with their own, internal expectations. Such quality standards are called measures of self-gratification-they soon degenerate into systems for making the company look good in its own eyes, instead of meeting customers' expectations and thus protecting the company's survival (see sidebar: *Forgetting the Customer*). The best way to avoid this trap is to explicitly list the process's customers and then measure their expectations. The customer list, output list, and expectation measurements should be updated from time to time; they are the foundation upon which the entire quality process is built. They can change as customer groups shift, the process evolves, and customers gain knowledge.

Within clinical medicine, the customer is the medical profession as a whole. Its expectations are expressed through clinical hypotheses as defined in the preceding section. For clinical diagnoses or procedures, "measuring expectations" corresponds to discovering and writing down clinical hypotheses. Obviously, because clinical expectations are generated by the profession as a whole rather than by individual practitioners or hospitals, they can best be documented on a profession-wide scale.

4. ***Document the process.*** A process consists of a series of steps that convert inputs into outputs. They are usually hierarchical; that is, the main process may be broken down into subprocesses, each with subinputs and suboutputs. Each of the resulting subprocesses may similarly be broken down into sub-subprocesses, again with sub-subinputs and sub-suboutputs. The hierarchical chain may be followed to that level of detail necessary to understand the process.

Some elements in a process are associated with its outputs but do not actually cause them. Others are causal—their presence or absence determines whether an output or suboutput will have features that meet explicit expectations: **key process factors (KPFs)** *are process steps that causally determine whether an output will meet quality expectations.* The team must explicitly document—in written form—those KPFs that lead to the desired output:

**Fundamental (or substantive) knowledge** *describes the steps* in a process and *identifies its key process factors*. Fundamental knowledge usually resides in front-line workers who deal with the process in a detailed manner on a daily basis. It leads to ideas about how the process can be changed and improved over time. A process cannot be managed without fundamental knowledge.

5. ***Generate output and process specifications.*** A **specification** is an explicit, measurable, statement regarding an important attribute of an output(a customer expectation) or the (sub)process that produces it (key process factors).

In Steps 3 and 5 above the team is charged to generate lists of customer expectations and KPFs. Those lists may be used to generate a list of specifications—statements regarding the output features that are to be produced and the process steps that will lead to them. Specifications define measurement variables. They make no statement about "acceptable" levels of achievement (see sidebar: *Specifying TURPs).*

Note that specifications are generated in two areas: external, customer expectations and internal, process expectations. They reflect both the goals that a process was created to achieve, and the manner in which those goals are planned to be accomplished. They must be stated so that they are explicitly measurable. Finally, they should be updated as customer expectations change and as the process is improved.

Specifications are a necessary part of any process, whether managed through CQI or some other system. The only real question is whether they will be explicitly stated. If the specifications for a process or subprocess are not explicitly stated, then it is impossible to measure whether the process is consistently achieving its goals. Explicit specifications form the basis for an objective measurement system as well as providing opportunity for criticism of and improvements to the specifications themselves:

**Quality cannot be achieved** *without a sufficient set of measurable specifications that reflect customer expectations and key process factors.*

Specifications therefore provide the basis for managing quality. As they are framed in terms of customer expectations, they are the definition of "quality" for a process. That is, when specifications are property stated, achievement of the specifications is equivalent to achievement of quality. Much of the effort of a quality organization centers around producing suitable specifications and implementing effective measurement systems. If all of the necessary pieces are in place, then the achievement of quality reduces to a single principle:

**Quality** is *conformance to specifications.*[33]

The fact that specifications are explicitly written means that they can be criticized and modified. They can—and should—be adjusted as the process is more clearly understood or the desired outputs, as measured through customer expectations, change.

6. ***Eliminate inappropriate variation*** (Implement). Specifications define measurement points. Once specifications are in place, those data points can be recorded for every input/output that transits the process. The goal is to detect quality events (outcomes) in subprocesses and final outputs, then to relate them to variation in the performance of KPFs in the process.

### *Specifying TURPs*

*Researchers at IHC and QUE studies (see page 21) and the clinical hypothesis to generate hierarchical process and output specifications for transurethral prostactectomies (TURPs). The list on the opposite page gives their preliminary specifications. Note that (1) it is hierarchical, being pushed down to different levels of detail in different areas; (2) it combines outputs and process; (3) it gives measurement variables, not "acceptable levels;" and (4) it can be modified as more is learned about the process and its desired outputs.*

**Preadmission**

1. *Demographics*: Patient age and race.

2. *Disease history*: Is this the patient's first TURP procedure, or a redo?

What were the patient's presenting symptoms/lab and their severity?

Are comorbidities present and, if so, how serious are they?

3. Admit lab: Was all admit lab work done prior to admission, and were the data available to the clinician at the time of admission? What tests were ordered?

4. Admitting process: Were all appropriate admitting questions, including information on insurance

5. Patient education: Was the patient educated about the treatment process and the likely events that will happen during the hospital stay? Was true informed consent obtained?

**Hospital course**

6. Day of admission surgery: Date/time of admission, date/time of surgery.

7. Surgical process: When did the patient enter the surgical suite, when did the actual operation commence, when did the actual operation end, and when did the patient leave the surgical suite? How many grams of prostatic tissue were removed? Was cancer found upon pathologic examination? Were other major procedures performed or diagnoses treated during this hospitalization?

8. *Foley catheter management*: Date / time Foley catheter was initially removed. Did the patient require recatheterization? If so, how many times, with date and time? Was the patient discharged with a Foley catheter in place? What type of Foley catheter and irrigation system was used?

9. *Short-term complications*: Did the patient experience (a) excessive blood loss (requiring transfusion), (b) atelectasis or pneumonia, (c) thrombophlebitis, (d) infection or fever, (e) water intoxication, or (f) other in-hospital complications?

10. *Laboratory*: What lab tests were ordered? When were they ordered?

11. *Pathology*: How much time elapsed from surgery until the pathology report was available in the chart?

**Medical outcomes**

12. Outplacement: Discharge destination (home, nursing home, etc.). Who was available to help the patient with home care? Was they patient, or someone associated with the patient, able (physically and through adequate knowledge) to provide the necessary post-hospital care?

13. Long-term complications: Did the patient experience (a) impotence, (b) incontinence, (c) urethral contractures, (d) death within one month of discharge , (e) readmission to the hospital within 30 days, (f) recatheterization at the ER or physician's office, or (g) other complications arising from the procedure after hospital discharge?

14. *Medical outcome*: Were the patient's urinary symptoms corrected? Was the patient's functional status improved!

**Patient satisfaction**

15. *Was the patient satisfied* with his or her hospital stay, the manner in which the procedure was performed, and its final results?

**Quality is improved** by *measuring and modifying the Process, not sifting the Output to identify failures that need to be reworked or thrown away.*

Or, to quote Philip Crosby's statement of the same principle:

*The system for causing quality is prevention, not appraisal.*[14]

CQI theory describes the act of evaluating exceptions as "sorting through failures," or *inspection.* Sorting failures does little to guarantee that a process wilt "do the right thing, the right way, the first time, every time." Systems that focus on identifying bad outputs *after* they have occurred, and that fail to specifically associate output failures with variation in the process (Usually because they fail to monitor the process for every case) do not improve quality as effectively as systems that prevent quality failures before they happen. Quality is built in during the process, not added on at the end.

CQI emphasizes the same concept by distinguishing two types of analysis: enumeration is the act of classifying then counting—statistically analyzing—outcome data. Analysis is the act of tracing enumerated outcome data back to their causes in the production process. CQI, by relating Outcome to process, provides a formal mechanism for analysis. Within traditional health care delivery evaluation often stops after enumeration—a statistical study is done, quality failures are found, and "bad apples" are identified. Too often quality failures are not traced to their real cause in the process.

CQI theory defines two types of variation:

*Random variation* (random causes, common variation or causes) *results from variation in the inputs that a process receives or inherent factors in the process itself.* It is the "random noise" within the system. It occurs in the process all of the time, for every output.

*Specific variation* (specific causes, special variation or causes, attributable variation or causes) *represents an attributable contribution to variation arising from one or more specific components within the process.* It is variation that is not present at all times as background noise.

The aim of CQI is to eliminate specific variation for every KPF so that only random noise remains. If key process factors truly "cause" the desired output then, as they are consistently carried out, high-quality outputs will be consistently produced. Any remaining quality failures wilt result from random error in the system, not preventable process failures. (Random variation is removed by improving the process over time, as described in Step 7, below.)

***Building a Clinical Lab***

*A primary premise of medical practice is that a physician should learn from every patient, so that the next patient receives better treatment. But in a traditional practice patient care evaluations arc mostly subjective-physicians base their treatment decisions on their memory of previous patients.*

*CQI provides the tools to explicitly document the process of care for each patient and the outcomes that result. After inappropriate variation is driven from a system, innovations can be tested: Only random noise remains in the system, so the impact of specific changes to the process can be directly observed. Within the CQI setting, a clinical practice becomes a true clinical laboratory.*

*Recent trends in the United States leave no question that hospital beds will go empty and private practices will go without sufficient patients. The question is: Whose beds? Whose practices? CQI provides a means to generate optimal health*

***Figure 5***

***Relationship of Cost to Quality.*** *From Out of the Crises by W. Edwards Demming. MIT press, 1982, 1986; page 3.*


*Delivery—the best outcomes at the lowest appropriate cost. It can also document that accomplishment. A competitive medical environment will reward hospitals and physicians who continually improve medical value—they will attract more patients. The rewards to be gained through a clinical laboratory are (1) better medical quality, (2) lower costs, and (3) survival (see figure 5).*

Statistical quality control (SQC) is a methodology that separates random variation from specific variation. It offers a means by which specific variation may be identified and then removed, by eliminating performance variation at key steps in the process. It also prevents well-meaning but uninformed changes that waste effort and, potentially, damage the process. (CQI theory defines tampering as changes implemented in an attempt to correct random variation. By definition, such variation results from random noise in the system. It cannot be traced to a specific cause so attempts to "correct" it in the process will necessarily fail.)

Within clinical medicine, CQI forms a natural basis for cooperation between hospitals and health care professionals: hospitals have the data to document variation, but only health care professionals can say what is appropriate. Hospitals and health professionals can consistently achieve high-quality care only by working as a team.

The measurement systems used to eliminate inappropriate variation must be explicit. Experience has repeatedly shown that implicit systems—under which progress toward a goal is intuitively evaluated—are frequently tainted by the reviewers' (often unconscious) preference for a particular result. Quality improvement systems must he designed to reflect factual performance against written specifications. This axiom is reflected in a principle of quality management:

*Within an effective quality management program, a goal without an explicit measurement system to document continuous progress toward that goal is meaningless. The goal of* ***eliminating inappropriate variation is*** *to create a stable system*, a system in which all specific variation has been eliminated and only random variation remains.

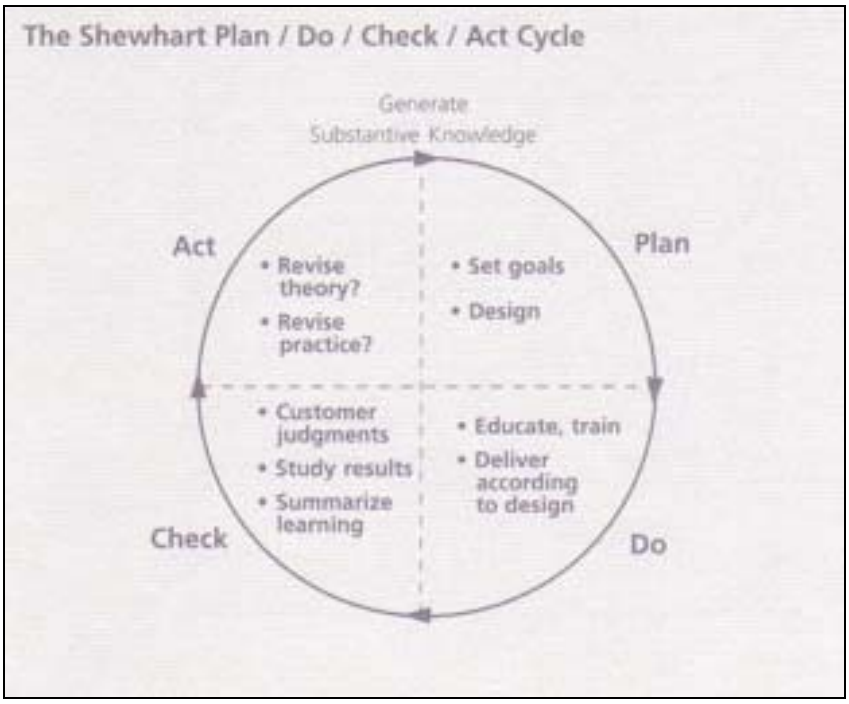



***Figure 6***

***The Shewhart Cycle***

***Step 1****: Plan- a change or test.*

***Step 2****: Do- carry it out on a small scale.*

***Step 3****: Check- observe the effects of change.*

***Step 4****: Act- adopt or modify the plan.*

*(This version developed by Paul Bataldan M.D., HCA, Inc.)*

7. Document continuous improvement (Innovate). Once nonrandom variation has been removed from a process, that process becomes a research system within which the scientific method may be applied to test innovations (see sidebar on page *30: Building a Clinical Lab)*. Team members using fundamental knowledge of the process, can generate ideas about how the process may be changed to improve quality ("lead the customer") or increase productivity. The team can select those ideas that seem most promising and then apply them on a test basis within their process. Because other causal factors of variation have been eliminated, the impact of the innovation can be directly observed. The proposed change can then be discarded, implemented, or modified and tried again, based upon the results of the test.

The use of a stable process to test process improvements was described by Walter A. Shewhart in the 1930s. He called it the "PDCA Cycle, for " Plan-Do-Check -Act." It is graphically displayed in figure 6.

## Summary

Continuous quality improvement is a process. The same CQI principles that are used for other processes can be employed with CQI itself Teams can apply the Shewhart Cycle (PDCA) on the steps listed above. The aim is to continuously improve not only the process and its outputs, but also understanding of the process and the specifications used to manage it. But it should again be emphasized that continuous quality improvement can not take place in a subjective realm. All steps must be documented and tracked with objective data.

***FOCUS-PDCA***

*Paul B. Bataldan, M.D., vice president for medical care at the Hospital Corporation of America, developed an acronym to teach CQI at hospitals:*

- ***F****ind a process to improve*
- ***O****rganize a team that knows the process*
- ***C****larify current knowledge of the process (PDCA)*
- ***U****nderstand causes of process variation (PDCA)*
- ***S****elect the process improvement*

*-then-*

***Plan Do Check Act***

*HCA offers classes on implementing CQI at the hospital level with a fixed curriculum customized for specific levels of the hospital hierarchy.*

Finally, the concept of continuous improvement suggests that only one quality goal is ever acceptable: one should strive to meet customer expectations 100 percent of the time. But different hospital activities take place on different scales. In particular, medical content quality—medical outcomes—must be evaluated on the basis of expectations set by the medical profession as a whole. It is therefore necessary to eliminate inappropriate variation in medical outcomes across the medical profession, not just within a single hospital or practice. Medical outcome data can reasonably he compared across physicians, hospitals, and systems to eliminate variation and achieve optimal processes. Within that setting, it is not acceptable for a single hospital to document continuous medical outcome improvement within its own walls, while its outcomes are far below those achieved for comparable patients at other centers.

Other hospital processes take place within a smaller scope. For example, patients have expectations regarding admissions procedures, billing, and general satisfaction. For those processes the goal is to satisfy the hospital's local customers, not the medical profession as a whole. Unless a hospital is a partner with other hospitals, and shares identical processes with them, comparative process and output data from these activities serve only two purposes: (1) they can be used for marketing (for example, a hospital could advertise its patient satisfaction scores compared with those of its competitors in an attempt to attract more patients); and (2) they can motivate hospital leaders to begin a continuous quality improvement effort. Otherwise, such comparative data are of little use to continuous quality improvement within a hospital.

## SPECIFICATIONS AND STANDARDS

Successful medical CQI systems are nearly always built on the foundation of an excellent traditional quality assurance QA) system. Beyond its description of the relationship of cost to quality and its explicit approach to process (in addition to outcome) measurement, CQI's main contributions to traditional QA are a series of formal mechanisms to deal with situations that traditional QA leaders were forced to solve on an ad hoc basis. Most of those situations center around the difference between specifications (within CQI) and standards (within traditional QA).

### Inherent arbitrariness

Most standards contain an unavoidable element that is inherently arbitrary. By using quality absolutes (0 percent failure or 100 percent success), CQI circumvents them. For example, many cardiac surgery programs insist that their overall mortality rate be no more than 3 percent. But why is 3 percent acceptable? Why not 2 percent (as a quality manager might choose) or 4 percent (as a physician being "managed" might choose)? Some standards are based upon statistical measures generated from an index population. For example, a mortality standard could be set at 3 percent because that was the mean mortality rate for some collection of hospitals for which data were available. But what makes the average (or any statistical measure) an acceptable standard for "quality"? By definition, some hospitals had to have a rate better than the average. If that superior rate could be obtained why is any lower standard acceptable.? How good is "good enough?"

The inherently arbitrary nature of most standards is reflected in the fact that it is often much easier to achieve agreement among medical professionals on specifications for a clinical process-the end results that a course of treatment is intended to achieve-than on standards for the same process.

### Inherent misclassification

CQI avoids a two-level classification system with an inherent misclassification rate. Many standard-based systems exist to flag some cases or providers for intensive review. This approach forces QA managers to deal with three difficult issues: (1) standards sometimes flag "good" cases, or fail to flag "bad" cases; (2) "intensive review" may itself he regarded as a judgment (and a punishment); and (3) standard-based systems usually focus only on flagged cases (potential failures), so they fail to associate process data with outcome data on every case. They can become a classic

#### *Generating Bad Data*

*A hospital in the western United States developed a system for flexible nurse staffing on acute care patient floors. Each patient was assigned a composite score, ranging from I (very little care required) to 6 (intensive care required), that was designed to represent the amount of nurse effort that was required for that patient's care. Each floor's head nurse was required to score each patient each day. Beyond a minimum core number, nurses were assigned to the floor for each shift based on the patient scores.*

*The resulting system subtly punished nurses. If the calculated scores were low then the floor received fewer nurses and the work load on the remaining nurses increased. Many nurses*

example of trying to "inspect" quality into a process after the failures have already occurred, as described in the last section.

For example, consider the following actual standard: "patients with head injuries, who require a cranial CAT scan, should receive that procedure within four hours of admission to the hospital." But some patients should receive a cranial CAT scan much sooner—even a three-hour delay might be inappropriate. A different, more complex, diagnosis may appropriately require a cranial CAT scan on the second day of hospitalization—the standard would incorrectly flag that case. Appropriate variation may sometimes lead a good provider to fall on the "bad" side of a standard. A standard may fail to detect inappropriate variation in other cases. Said another way, a standard fails to distinguish random causes from attributable (special) causes, as described in the previous section.

*complained that the system left them with insufficient manpower to accomplish assigned tasks. Over the first year of operation the calculated severity scores for individual patients increased by almost a full point. But other measures of severity used by the hospital, such as case-mix indexes, remained unchanged.*

*The nurses had learned to "game the system" to achieve the staffing level they believed was required. The management system became just another layer of management waste. And the severity, data generated through the nursing system, which initially had a sound theoretical base, became suspect-nurses had gradually changed their subjective judgments to avoid the punishments inherent in the system.*

If a standard-based QA program is not carefully administered, providers may be held responsible for random causes over which they have no control—the intensive examination that results from a flagged case may itself become the punishment. In the example given above, a provider may order a cranial CAT scan on every patient with head injuries, regardless of indications, in order to avoid being flagged and subjected to detailed examination. That is, a provider may erroneously modify his/her process in an attempt to remedy a random cause. But, by definition, a random cause cannot be corrected by tampering with the process. The only effect of tampering is to introduce more variation and damage the process.

CQI theory shows that it does little good to identify quality failures if those failures are not traced to specific variation in the production process. That implies that the production process must be simultaneously monitored and that every case—not just failures—should be recorded. That viewpoint rejects the idea of measuring outputs to "flag" some cases for further review.

Finally, a dichotomous scale is not appropriate for a large subset of quality data—semi-continuous or continuous scales are much more effective analytic tools. The chief reason for a dichotomous scale (that is, a standard) is to reduce the work load for quality evaluators. It reduces the amount of data that must be reviewed and makes it easier to classify cases and providers as "good" or "bad."

**Artificial floors and ceilings**

CQI avoids artificial floors and ceilings. Most standards carry a subtle message that is very hard to dispel: by definition, a standard represents an "acceptable" level of performance. Therefore, once a standard has been met, the drive for further improvement can be greatly diminished. In other words, a standard can become an artificial quality floor or ceiling. Within CQI, the only floors and

ceilings are quality absolutes-0 percent failures or 100 percent successes.

In some circumstances standards must be employed. But in those cases there should be a standing procedure that they will be re-evaluated and adjusted on a regular basis, to avoid artificial floors and ceilings.

**Accurate primary data**

CQI generates more accurate primary data. Most standards form at the base of "acceptable" versus "unacceptable" flagging systems. Nearly all are associated with some sort of overt or covert punishment, he it as subtle as an intensive review process, loss of professional prestige, or failure to receive an incentive reward, or as blatant as loss of a provider contract or a professional license. At the same time, most providers generate some portion of the data upon which they are evaluated. As a result, it is not unusual to see consistent (but often subconscious) changes in patient classification and evaluation that favor the provider. That is, a classification system with subtle, inherent disincentives can lead to bad primary data even among conscientious providers. What started as a quality improvement system can devolve into a game of "beat the system." A good example is HCFA's recent mortality data release and some hospitals' reaction to it. (see sidebar on page 34: *Generating Bad Data).*

Within CQI the only acceptable standards are quality absolutes—100 percent success or 0 percent failure. That view avoids some of the inherent operational difficulties that traditional standards have forced QA leaders to face. From a CQI perspective, any "standard" other than perfection leads to the following definition:

A *traditional* **standard** *measures the amount of "acceptable" waste, through quality failures, that is intentionally built into a system.*

Not all traditional quality assurance programs are excellent. A system that lacks a true dedication to quality can degenerate to finding "bad apples" and actually damage overall quality. An excellent article, by Donald Berwick, M.D., on that subject is included in the Recommended Readings.

CQI recognizes that errors will occur. It differs in its response to them:

- It avoids artificial quality ceilings and bad data by relating outcome to process, and using specifications instead of standards.
- It objectively traces quality failures to process failures by measuring process factors as well as outcome factors for all cases, not just failures (that is, it analyzes as well as enumerates).

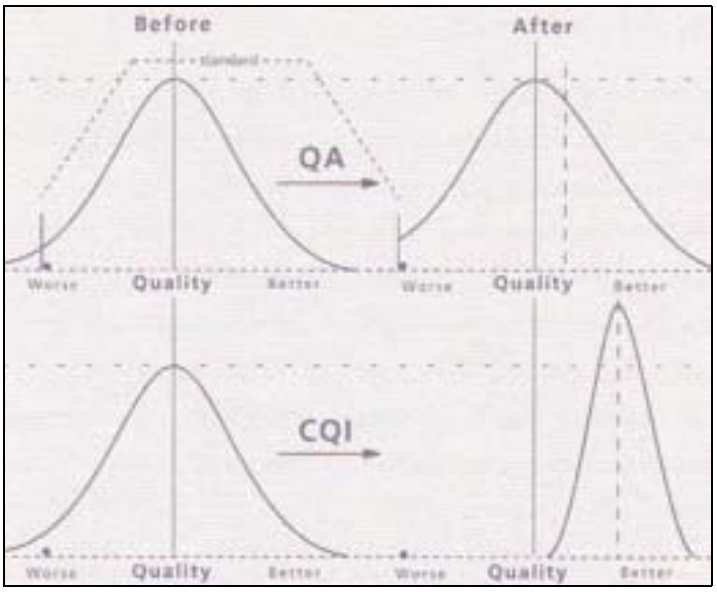
- It attempts to correct errors by fixing the process, not the people. It also must pay the price of better, more extensive data collection and requires the same intense dedication to quality that has allowed some traditional QA programs to overcome the hurdles that standards can present.

**Dichotomous standards**

Finally, an uncritical dependence upon dichotomous standards can lead to the erroneous conclusion that, if the bad are eliminated, what is left will somehow be excellent. Figure 7 graphically displays that major difference between standards and specification-based continuous quality improvement. Each of the curves represents a distribution of quality outcomes, using a hypothetical perfect quality measure. The top two curves are "before" and "after" an application of an operative dichotomous standard that eliminates the bad outputs represented by the left tail of the curve. The bottom two curves represent the CQI approach in the same situation:

***Figure 7***

*The impact of effective standards versus continuous quality improvement on the location and spread of a quality indicator.*




the principle of *eliminate inappropriate* variation draws the curve higher and tighter about its central point, and the principle of *document continuous improvement* shifts the entire curve to the right.

The dot on the left side of each curve represents a low-quality producer—a true "bad apple" that traditional standards are designed to identify and eliminate. Using standards, a low quality producer can hide just within the line. But as CQI tightens the curve and shifts it to the right, low-quality producers become more and more exposed. They must improve their process or be easily identified as consistent (and severe) quality outliers. CQI can eliminate true "bad apples" as efficiently as standards.

## AN OPERATIONAL MODEL FOR QUALITY IN HEALTHCARE

*Experience without theory teaches nothing. In fact, experience cannot even be recorded unless there is some theory I however crude, that leads to a hypothesis and a system by which to catalog observations.*

*C.I. Lewis*[15]

An operational model is useful for several reasons: It provides an explicit description of health care quality-because it is explicit, it can be criticized, updated, and improved. It can describe relationships between areas of medical quality assurance that experience teaches are useful, while highlighting other areas that may have been overlooked.

The question is not whether a model will be employed, but whether the model that is used will be explicitly stated—and so amenable to criticism and improvement—or implicitly accepted without conscious thought regarding its strengths and weaknesses.

The foregoing discussion on the nature of quality and the relationship of quality to cost identified several areas of quality management. It noted medicine's unique division between delivery quality (as measured by patients' expectations) and content quality (as measured by health delivery professionals' expectations, acting on behalf of patients). It also observed that the achievement of quality depends almost entirely on the systems that health care delivery employs, and thus on the management teams who oversee those health care delivery systems. Finally, a number of fundamental concepts of quality management, necessary parts of any successful quality control effort, were set forth.

Four areas provide the major divisions that form the highest level of the proposed model. Each is of primary importance to a different group within health care. Therefore, they are presented in the order of complication of presentation, saving the most complicated, and hence the lengthiest, for last. The four major divisions of the model are the following:

- Quality of Management
- Quality of Evaluation
- Quality of Service (Delivery Quality)
- Value of Care (Content Quality)

The four divisions are graphically represented in figures 8-13.


***Figure 8***

*The four major divisions of an operational model for quality health care.*

**Quality of Organization / Management**

Continuous quality improvement is rooted in the culture of a health care organization. It requires that all workers in the organization understand the same quality terms, speak the same quality language, and share the same quality vision. Further, the consistent achievement of high-quality outputs depends upon the processes that an organization employs. The organization's management team constructs and oversees those processes. Arguably, good management is the most important factor that determines whether an organization will succeed in continuous quality improvement.

Earlier sections made the point that health care delivery is different from other industries, Therefore, Industrial Quality Control (IQC), which represents the application of CQI principles in industrial settings, often cannot be applied directly to health care. But the management theory used by CQI differs little whether it is viewed from the standpoint of industry or health care. Many IQC texts focus heavily on management theory. With minor modification, they can be applied directly to hospital management. A number of IQC/management theory texts are therefore included in the Recommended Readings list at the end of this report.

**Measurement, Specifications, and Reporting**

The organization that is managing quality has regular answers to two questions: Are we doing the right things (strategic quality)? Are we doing things right (system quality) ?[36]

Consistent, planned progress in any endeavor is usually a two-step process: One first establishes a goal (strategic focus), then one tries to move toward that goal (systems focus). The primary quality goal is to meet reasonable customer expectations, as set forth through output and process specifications, 100 percent of the time. Consistent, planned improvements in quality therefore require two measurement systems. The first tracks the moving goal of customer expectations. The second measures movement in relationship to that goal, to show whether a particular effort brought one closer to the goal or moved one farther away. As customer expectations are reflected in hierarchical specifications, the act of measuring progress toward a quality goal is equivalent to measuring the output of a process vis a vis the specifications for that process.

Organizations usually display a hierarchical structure. Specifications can mimic that hierarchical structure, so that each subcomponent has the requisite freedom to define its internal role and accomplish it goals, while meeting the organizational purpose of its existence. This structure also recognizes the fact that, in most organizations, those at the lowest management level-on the front line of interaction with

customers—are those who best understand the organization's processes, know best how to improve them, and are best able to implement effective change.

Hierarchical specifications can also form the foundation of a consistent reporting system. By following the structure set forth in a complete set of hierarchical specifications, a measurement system can evaluate quality at every level of an organization with an appropriate level of detail. The hierarchical structure ensures that, as reports move up the organizational chain, they can be meaningfully combined to reflect quality goals set for each level of the organization. In a very real sense, a set of hierarchical specifications are a direct statement of what a health care entity hopes to achieve at each level of its organization, and the means by which progress toward those goals can be measured. This concept provides one of the more useful forms of the underlying quality principle:

*Quality is how well an organization accomplishes that which it says it intends to do.*

This implies that the organization knows what it intends to do:

- It knows who its customers are (in content, delivery, and other areas) and it measures their expectations
- It knows what its outputs/products are-they have been specified and are appropriately monitored on the basis of those specifications
- It understands the structures and processes that lead to its outputs—subprocesses and intermediate outputs are also specified and monitored
- It understands the nature of quality management.

Obviously, an organization's top management is responsible for explicitly establishing the organization's quality goals.

**Quality Mission Statement**

Management's first responsibility is to clearly establish the quality focus of the organization. This takes the form of a quality mission statement (see sidebar: *Quality Mission Statements).* It is a general statement defining the outputs the organization plans to produce. It is thus the top-level specification from which all other output specifications used within the organization will derive. In order to be fully useful, a quality mission statement should include the following features that relate directly to the organization's management function:

*Constancy of purpose.* Quality is a function of the processes that exist within an organization. Its successful accomplishment is the keystone by which the entire organization will stand or fall. Success

***Quality Mission Statements***

***3M Corporation:***
*"Quality" is consistently meeting customers' expectations*

- *Measurements of quality are made through indicators of customer satisfaction, rather than indicators of self-gratification.*
- *The objective is to satisfy expectations 100% of the time.*
- *Quality is attained through improvement projects that place a premium on preventing problems before they happen.*
- *Management is committed to lead the quality process.*

*(Note the focus on the Customer; the commitment to constant improvement the inclusion of a metric; and the leadership of top management.)*

***Humana:***
*The best technical rendition of the best options selected for a specific patient with the patient's consensus and delivered with the utmost compassion and respect.*

or failure in achieving quality is therefore first the responsibility of the organization's managers. It is directly determined by the processes that the managers create and the managers' ability to lead: It begins in the board room, not on the hospital ward. Quality requires a long-term, hands-on commitment from the top leaders in an organization.

*Dedication to continuous improvement.* As noted above, quality is a moving target. An organization must be dedicated to constant change and improvement, starting with its internal systems and moving to the products and services it offers. Specifications bracket the target, so as the target moves the *specifications* will change.

***Hospital Corporation of America (HCA)***

*Our mission:*

- *To attain international leadership in the health care field.*
- *To provide excellence in health care.*
- *To improve the standards of health care in communities in which we operate.*
- *To provide superior facilities and needed services to enable physicians to best serve the needs of their patients.*

***Kaiser Permanente**:*

*Our mission: The Kaiser permanente Medical Care Program is a community service that seeks to improve the health of its members by providing accessible, comprehensive health care of high quality on a prepaid basis in a cost-effective manner.*

*Focus on the customer.* An organization depends for its continued existence on its ability to anticipate, educate, and serve its customers. "Customer" is used in a very broad sense—the successful organization is seen as serving and educating nearly all with whom it comes in contact. A hospital's customers include patients, physicians, health care financiers, internal departments, suppliers, and other outside groups.

*Understanding the service or product.* The organization must understand the underlying nature of the service or product that is delivered, and the process that leads to its successful production (also sometimes called "substantive, or fundamental, knowledge").

*Measurement systems.* The statement of a goal without an explicit measurement system to document progress toward that goal is meaningless. Within a quality-based organization, hierarchical specifications serve to define the measurement system and to guarantee that quality reports can be meaning fully combined as they move upward through the management chain.

**Management's Role**

*High quality depends primarily on good management, not worker motivation.*

In most instances workers within a health care system have inherent personal pride in the work they do. The achievement of a particular level of quality is more a result of the systems under which they work than a problem with commitment or motivation. Quality is a function of process. Process depends on the systems by which the organization operates. These systems are directly structured and controlled by management. Therefore, the starting place for quality in any organization is top management. Organizations that attempt to establish quality by focusing exclusively on the end product and front-line workers, while ignoring the underlying management systems and their critical impact on quality, will fail to achieve high

quality and the full range of secondary cost benefits it brings over time (see sidebar: *Attributes of Total Quality, Managers,* page 42)

CQI theory presents several principles regarding an organization's management and its role in quality:

*Top-down process.* The establishment of quality in an organization is a top-down process. Quality should therefore be a major concern of the chief executive officer of the corporation. While a committee or some other officer may be assigned day-to-day oversight of specific quality-monitoring operations, the CEO should have a direct, day-to-day responsibility to manage that process.

*Front-line focus.* A quality organization recognizes that most workers are motivated by pride in their job, and builds systems that allow them to express that pride in terms of high quality. It recognizes that front-line workers best understand the problems involved in serving customers and producing health care products. It recognizes that most workers are already motivated, and only need an outlet for their innovative ideas. Finally, it recognizes that attitudes held by employees regarding the organization are often transferred directly to customers as health care services are delivered. If an employee believes that the organization strongly supports high quality, then this viewpoint will be conveyed to the customers served by the employee. All workers in the organization:

- Should know that they can have a direct impact on the structure of the systems used by the organization (that is, their concerns will be promptly and competently addressed)
- Should not fear overt or covert reprisal for criticizing the systems used by the organization
- Should he encouraged by the structure and operation of the organization to be oriented to the needs of their true customers rather than to those of their supervisors

Ultimately, quality is delivered by the employee who builds the product or interacts with the customer. "At the interface" employees have the best understanding of customers' needs and expectations on an individual basis and are directly responsible for meeting them. The remaining structure of the organization—including management—exists to support front-line employees in their critical rote. Successful organizations find ways to stimulate, test, and implement the quality improvement ideas that their front-line employees generate. They also recognize that every employee of the organization is, in one sense, a front-tine employee—it is just that managers work on the "front-line" of producing management systems, rather than the traditional products envisioned by the

### *Attributes of Total Quality Managers*

- *Top management is vigorously committed to quality and productivity. This is evidenced in practical management actions.*
- *A customer orientation permeates the organization, needs and requirements of both internal and external customers are sought, and the level of customer satisfaction with service becomes the basis of improvement efforts.*
- *Teamwork at all levels is seen as key to improving processes and services.*
- *Quality management and improvement training are provided at all levels of the organization.*
- *Accountability for quality and productivity improvement is tied to managers' performance evaluations.*

company's leaders. The same quality principles that apply to improvements in operational processes may also be applied to achieve improvements in management processes.

**Management's principal tasks are to:**

*1. Commit*
- Demonstrate constancy of purpose
- Imbue the organization with a stable long-term strategic vision
- Establish an organization-wide quality mission statement
- Show top-down management commitment to quality in actions as well as words (quality starts with the board and CEO)

*2. Understand*
- Know the business of the company (sometimes called substantive or fundamental knowledge); management must have hands-on experience with the processes and products upon which the organization depends for its continued existence
- Learn the following principles of quality measurement, and teach them throughout the organization:

  Specification, data collection, and process measurement
  The nature of random ("common") versus attributable ("specific") variation

  Enumerative versus analytic techniques

*3. Identify*
- Customers, products, and processes (i.e., generate valid specifications)

*4. Educate and train*
- Employees, in their jobs and in quality principles
- Customers (at all levels, as defined above), in order to guide their expectations

*5. Measure*
- Customer expectations, process outputs, and outcomes

*6. Manage*
- Eliminate quality waste
- Increase productivity

*7. Test*
- Use the Shewhart cycle and front-line employees to constantly improve the organization’s production and management processes

*8. Establish appropriate incentives*
- Most improvement is team based; reward teams, not individuals

- *Recognition and incentive programs are established throughout the organization, are targeted at service improvement efforts, and are used creatively.*
- *Productivity and quality measures are established, and high standards are set for quality service delivery in all programs (errors and inefficiencies are not tolerated).*
- *Barriers to productivity and quality improvement are eliminated or reduced.*
- *Personnel are constantly stimulated to improve quality and productivity (communication, workshops, newsletters, bulletin boards, contests). Celebrate success.*


## Quality-based mission statement

* in intelligible terms
* with a measurement system
* customer-based

## Commitment of top management

* constancy of purpose
* systems determine quality, and management controls the system

## Dedication to continueous improvement/innovation

* quality is based on expectations
* expectations ar a moving target
* document continuous improvement

## Focus on the "customer"

* two-way communications and education are required if expectations are to be reasonable and have some change of being met
* "customers" include physicians, financiers, (industry and government), suppliers, and hospital divisions as well as patients and their families
* supervisors should never become the primary "customer"

## Remove obstacles to improvement

* build systems that encourage innovation
* eliminate fear/system defects which promote fear
* avoid inspection / firefighting / tampering

## Understand basic principles

* role of theory in controlling systems
* need for leadership to achieve quality
* underlying processes involved in systems
* true costs of decisions

## Educate

* all members of system in theory of quality
* improtance of "employee" (including physician) attitutdes in conveying an idea of quality to customers

Dr. Williams Stason's (VAH) research on barriers to quality in organizations

- Focus incentives on (1) reductions in quality waste and (2) tested and proven innovation
- Eliminate incentives that reward behavior that benefits an individual or a particular unit, but damages the organization as a whole

9. *Lead* (rather than supervise)
- Remove quality barriers
- Empower front-line employees

and always: *Eliminate inappropriate variation and document continuous improvement*.

Finally, Philip Crosby identified the following principle for quickly identifying high-quality management practices within an organization:

> *What originally began as "quality" has now expanded with experience into an understanding that "hassle elimination" and "quality improvement" are the same.*[37]

Figure 9 expands upon the major management elements listed above.

## Quality of Evaluation

Quality is a moving target. Its attainment is a function of process within an organization. It is therefore necessary to continually measure progress toward quality goals and to study the underlying processes of the business in order to encourage innovation and continual improvement. Major elements of this important function are described in figure 10.

***Figure 9***

*Factors that must be present for an organization to effectively and consistently pursue quality goals.*

In order to effectively evaluate quality, management must understand the principles of random variation as they relate to quality. Management must also be committed to the use of proper methodological toots to detect and then reduce the inappropriate variation found in the processes of the system. These include an understanding of the differences between enumerative and analytic techniques, the ability to measure random variation, the ability to identify "common" causes (also known as random causes) as opposed to "special" causes of variation in the system, and an understanding that inordinate attention to "common" causes damages the system rather than improves it (this forms an objective definition of "tampering" within a system). Commitment to quality requires that objective measures of process and output be recorded, substantive knowledge be identified, then improvements to the processes that make up the system be implemented. The Shewhart Cycle (figure 5) describes a proven methodology for the detection and implementation of changes to a system that will result in higher quality and lower costs.

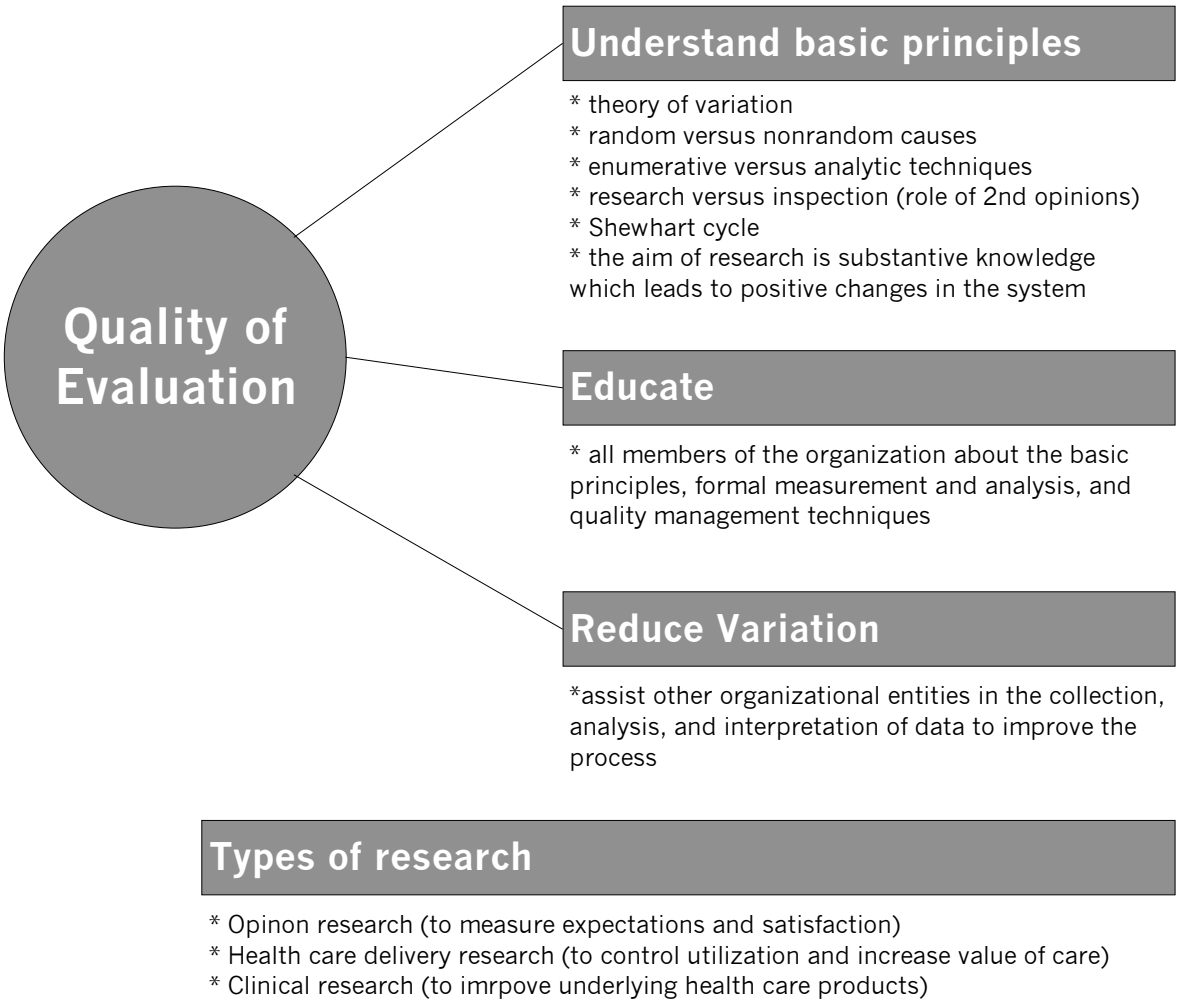



***Figure 10***

*Factors that must be present for an organization to study and understand quality*

**Quality of Service** (Delivery Quality)

Quality is defined in terms of the wants and needs of the customers that an organization serves. It is therefore critical that the organization understand the wants, needs, perceptions, and expectations of its customer groups. For the purposes of this presentation (and the proposed model), these factors are grouped under the heading of Quality of Service. Figure 11 diagrams this important area.

A first critical step in understanding customer satisfaction and expectations is to clearly define those customers an organization serves. As noted above, the definition of customer extends well beyond the group that uses an organization's final product—but the same principles that allow an organization to successfully satisfy its traditional customers can also be profitably applied to almost any other group with which the organization works. For example, a hospital serves not only patients but patient families, physicians, health care financiers, and suppliers. A physician serves not only not only patients but other physicians and the hospital. A hospital

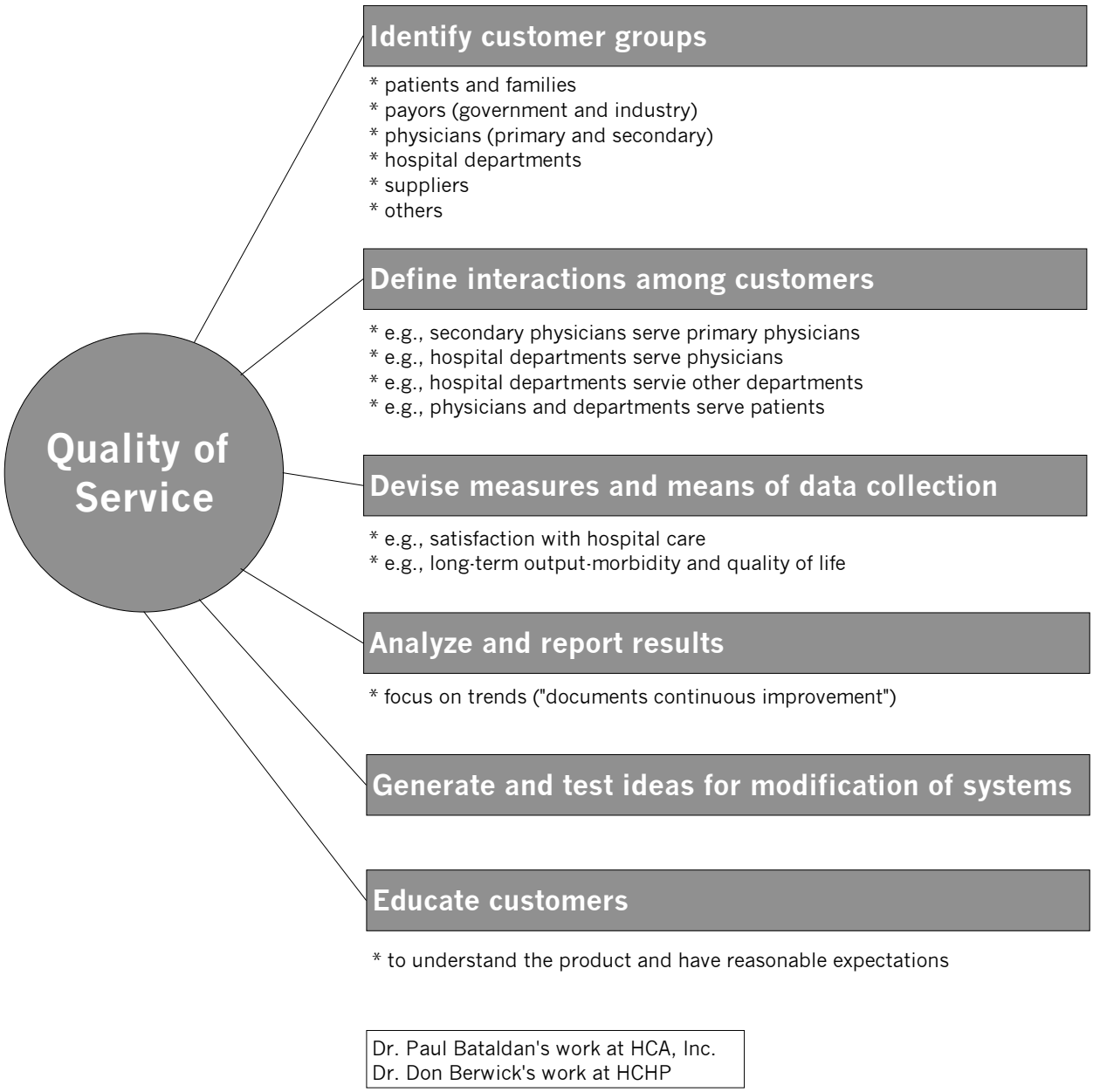



***Figure 11***

*"Customer" expectation and satisfaction. (Quality in terms of patient perception.)*

department serves not only patients and physicians, but other departments within the hospital. The hospital administration attempts to serve all groups associated with the hospital. In the past, some organizations have attempted to assess customer needs (as broadly defined above) by examining complaints that are brought to the organization. While this method has value in addressing the needs of individual customers (and of averting malpractice suits), it is seriously flawed as a means Of understanding the reaction of an entire customer population to the organization's products and services. Recent research has shown that many customers, though extremely dissatisfied, never complain—they simply never return to the organization and advise all of their associates to stay away too.[38] Sole concentration on complaints does not detect those problems,

great and small, that customers consistently judge not to be worth the effort of a complaint.

The chief tools for understanding the concerns, needs, and expectations of a broad customer population are questionnaires and customer focus groups. A number of health care delivery researchers have made considerable progress in designing survey instruments to measure customer satisfaction (with customer broadly defined, as above) and to devise measurement systems that track progress in these areas, rather than setting artificial numerical goals. Of particular note is the work done by Paul Bataldan, M.D., at HCA, Inc., and Don Berwick, M.D., of the Harvard Community Health Plan.

Quality in any industry is based upon the principle of continual innovation and improvement. However, most major innovations have not taken place in response to stated customer needs—for example, no customer focus group told Alexander Graham Bell that what was really needed was a device for communicating over tong distances through the use of electrical signals. The principle of innovation suggests that an organization will Study its Customers to understand their needs, even though the customers do not recognize those needs themselves. The goal is to develop innovations that exceed—not meet—a Customer's reasonable expectations.

Finally, it should be noted that good Customer service requires two-way communications. Customers can have reasonable expectations only if they understand the product, its natural limitations, and the proper way to use it.

***Figure 12***

*A simple model of health care delivery*

**Value of Care** (Content Quality)

While patients or other external customers determine expectations for the quality of delivery of medical care services, the medical content of care that is provided is still almost exclusively the province of the medical profession itself. This section therefore concerns itself with the quality of the content of medical care, as determined by health care professionals. Value, as defined above, represents the combination of the quality of the medical care content that is delivered and the price (in terms of resources consumed) at which it is achieved.

Figure 12 presents a very simple model for organized health care. In order to treat a patient, a health care organization must have an infrastructure. It must have the necessary tools (which may be as simple as a stethoscope, or as complicated as a tertiary care hospital) and the necessary knowledge (as embodied in its professional medical staff) to intervene in disease processes with a positive result. Once the infrastructure is in place, a decision must be made to intervene (the diagnostic process) and a particular intervention (course of treatment) must be undertaken. The final result of this entire process is a health care outcome.

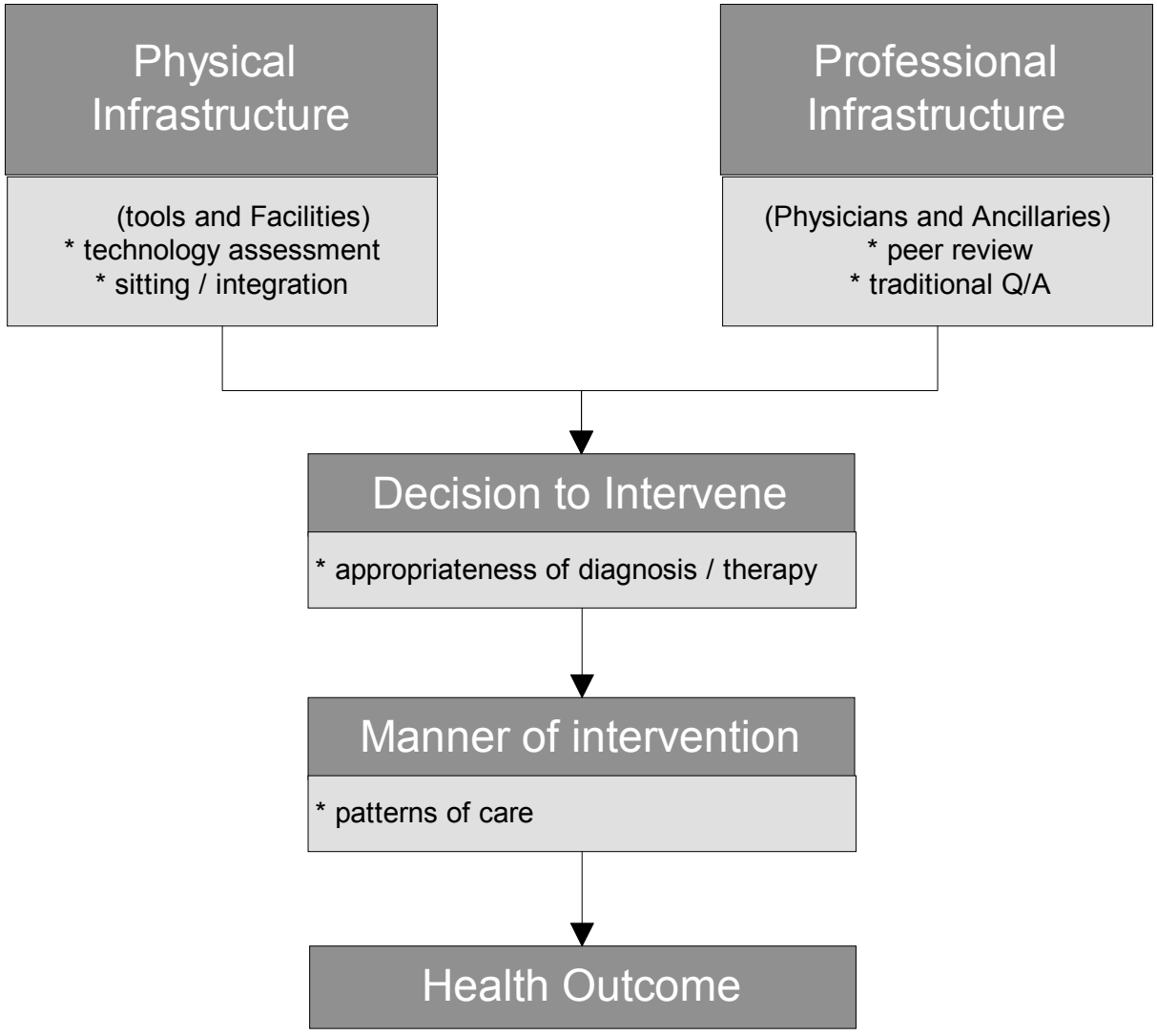

Physical Infrastructure
(tools and Facilities)
* technology assessment
* sitting / integration
Professional Infrastructure
(Physicians and Ancillaries)
* peer review
* traditional Q/A
Decision to Intervene
* appropriateness of diagnosis / therapy
Manner of intervention
* patterns of care
Health Outcome

Figure 13 expands this simple structure into a model for content quality in health care. Major areas that are considered include the following:

- *Establish the infrastructure*. A health care delivery organization must have the necessary physical plant and professional expertise to deliver high-quality care at a reasonable price.

  Hospitals have cooperated with the medical profession to establish processes that ensure professional quality, such as peer review, continuing medical education, and external standards. These efforts have largely been successful. While parts of the process may in some circumstances be improved (such as credentialing/privileging in some systems) the underlying principles of professional review are welt understood and usually welt applied. Humana's Allen Schaffer, M.D., has devised a computerized system that coordinates and manages the large number of external standards, propagated by a variety of external bodies, that a health care delivery system must satisfy.

  Issues regarding physical facilities for high value care are not well established. Improved analytic techniques are required to effectively address the acquisition of new technology (which may be very expensive and may at least partially duplicate existing, well established, capabilities), new procedures, and the siting of facilities within a hospital system to best serve a patient population.

- *Define indications for treatment*. A number of researchers have demonstrated a profound lack of clinical consensus on indications for treatment within a wide range of medical and surgical conditions.[39-41] This lack of consensus is expressed as widely varying rates of utilization of particular procedures and treatments among the various regions of the country. Substantial improvements in both value of care and clinical outcome may be possible if better scientific knowledge regarding the clinical hypotheses that underlie a decision to institute treatment are available. Failures of diagnosis and clinical hypothesis usually result in quality waste.

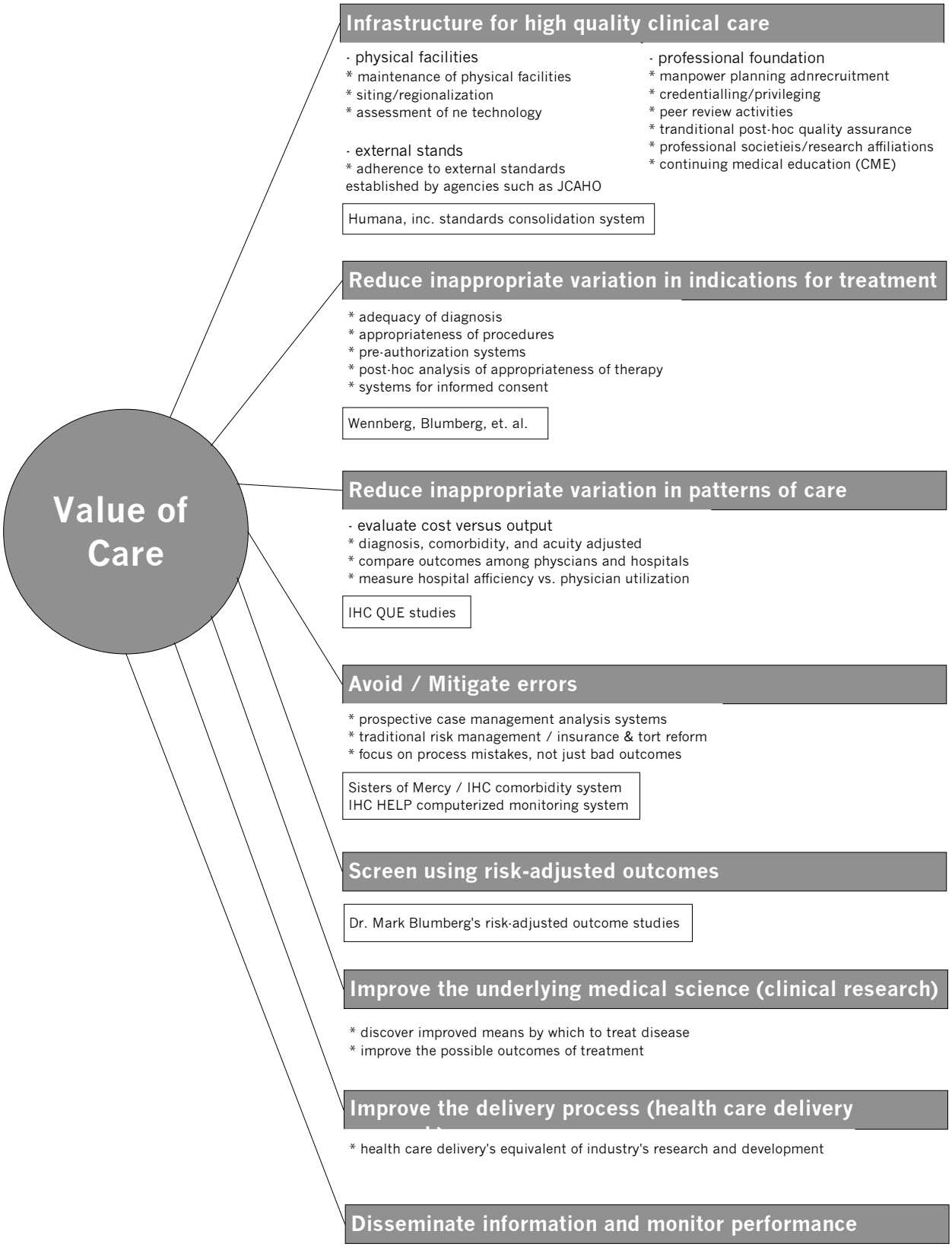
- *Evaluate cost versus output of competing treatment patterns*. just as there is a wide range of clinical opinions regarding indications for treatment, there is also a wide range of practice patterns once a decision to treat has been made. This has been shown by a number of studies regarding patterns of care, including the IHC QUE studies.[23-26] As with indications for treatment, improvements in this area could lead to substantial improvements in both the value of care delivered and the outputs that are achieved. Failure to establish efficient patterns of care results in low productivity.

***Figure 13***

***Value of Care***

*Value combines quality, in terms of professional perception / medical fact, with cost: "Price has no meaning without a measure of the quality being purchased."*

*W. A. Shewhart*


Value of Care
Infrastructure for high quality clinical care
· physical facilities
* maintenance of physical facilities
* siting/regionalization
* assessment of ne technology
· external stands
* adherence to external standards established by agencies such as JCAHO
· professional foundation
* manpower planning adnrecruitment
* credentialling/privileging
* peer review activities
* tranditional post-hoc quality assurance
* professional societieis/research affiliations
* continuing medical education (CME)
Humana, inc. standards consolidation system
Reduce inappropriate variation in indications for treatment
* adequacy of diagnosis
* appropriateness of procedures
* pre-authorization systems
* post-hoc analysis of appropriateness of therapy
* systems for informed consent
Wennberg, Blumberg, et. al.
Reduce inappropriate variation in patterns of care
· evaluate cost versus output
* diagnosis, comorbidity, and acuity adjusted
* compare outcomes among physcians and hospitals
* measure hospital afficiency vs. physician utilization
IHC QUE studies
Avoid / Mitigate errors
* prospective case management analysis systems
* traditional risk management / insurance & tort reform
* focus on process mistakes, not just bad outcomes
Sisters of Mercy / IHC comorbidity system
IHC HELP computerized monitoring system
Screen using risk-adjusted outcomes
Dr. Mark Blumberg's risk-adjusted outcome studies
Improve the underlying medical science (clinical research)
* discover improved means by which to treat disease
* improve the possible outcomes of treatment
Improve the delivery process (health care delivery
* health care delivery's equivalent of industry's research and development
Disseminate information and monitor performance

- *Avoid/mitigate errors.* Research into human-computer interfaces has confirmed what most health care professionals have always recognized: Humans are inherently imperfect information processors.[42] When dealing with large amounts of complicated data (as in a medical setting) human errors and oversights will certainly occur, regardless of the level of expertise or attention given by the humans involved. Recognizing this inherent human deficiency, it is possible to build systems to crosscheck and verify decisions. These systems not only can prevent errors but also can lessen the impact of errors when they do occur. The focus should be on process, not just output, so that errors can be corrected before permanent harm results. Whether they are associated with failures in decisions to treat (diagnosis, evaluation of clinical hypotheses) or patterns of care (manner of intervention), treatment errors represent quality waste in its most straightforward form.

- *Improve the underlying medical science.* Medical science represents the product in which health care delivery organizations deal. Improvements in basic clinical knowledge allow health care professionals to improve the outcomes they can achieve and to reduce the costs necessary to reach a particular outcome. Some new treatments from which patients would benefit are available only in the research setting. Finally, an active program of clinical research tends to attract the best physicians and ensures that they remain at the pinnacle of their profession. Ultimately, all of these factors serve to improve the value of care that a health care organization can deliver. Clinical research is equivalent to research and development in other industries.

- *Improve the delivery process.* Health care delivery research directly addresses the primary activity in which a health care system is engaged. Improvements in this process are critical factors for achieving and maintaining quality. Hospitals and other health care organizations have as much responsibility to improve the efficiency of their operations as physicians do to deliver only the highest quality medical care.

- *Screen health care providers (physicians and hospitals) in terms of the outputs and outcomes they achieve.* Case-adjusted analysis of outputs is a screening tool that can be used to detect potential deficiencies within a hospital or within a practice style. As a screening tool, these measures cannot prove that true deficiencies exist or locate them precisely within an organization. However, they can serve a very useful function in directing attention and further study to areas in which positive change might possibly be accomplished. The principle of continual improvement suggests that analysis of outputs should be extended to include the processes that result in a particular output. As clinical screening tools, these measures may be evaluated in terms of specificity and sensitivity, as with any other clinical screening test.

## Summary

A number of researchers have recently demonstrated that a large amount of variability in two of the areas described—indications for treatment and course of therapy once a treatment decision has been made—exists within this country. This variation can, in many instances, be directly related to quality waste and low productivity. It can be traced to a lack of consensus on basic clinical facts within the medical profession: There is insufficient clinical data upon which to base common treatment decisions. White health care professionals should strive to document continuous improvement in all areas of health care delivery, these two areas seem to offer outstanding opportunity for quality improvement and simultaneous cost savings.

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## RECOMMENDED READING

**Background:** Avedis Donabedian's three volumes on quality in health care supply the basic model for understanding health care processes. They provide a theoretical framework for traditional quality assurance approaches for health care and for application of CQI theory to health care. Walter Shewhart is widely regarded as the father of statistical quality control. An overview of his original work is included for a historical perspective. *In Search of Excellence* documents the use of CQI techniques in American companies that have consistently Succeeded over extended periods of time. Close examination reveals that their success was based upon the use of CQI principles, although Peters does not explicitly use that name.

Donabedian, A. *Explorations in Quality Assessment and Monitoring, Volume 1: The Definition of Quality and Approaches to its Assessment.* Ann Arbor, MI: Health Administration Press, 1980.

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Peters, T. J., and R. H. Waterman, Jr. *In Search of Excellence: Lessons from America's Best-Run Companies.* New York City: Warner Books, 1984.

Shewhart, W. *A. Statistical Methods from the Viewpoint of Quality Control.* Washington, DC: U.S. Department of Agriculture Graduate School, 1939.

**Industrial Quality Control/CQI Management Philosophy:** The following texts describe the application of continuous quality improvement theory in nonmedical settings. Because clinical medicine often differs from other endeavors, the texts must be translated and adapted for the medical setting.

All of the texts listed here place a heavy emphasis on management. The management theory they describe can he applied directly to hospital management with only minor modifications. Walton and Scherkenbach provide excellent, focused reviews of Deming's methods; they are highly recommended. Crosby's works are

especially useful for understanding and managing quality waste. Juran derives the same principles starting from a slightly different view, which may be more appealing to some readers.

Crosby, P. B. *Quality Without Tears: The Art of Hassle-Free Management.* New York City: New American Library, 1985.

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Walton, M. *The Deming Management Method.* New York City: Dodd, Mead & Company, 1986.

**Specific CQI techniques:** The following volumes each address specific management factors or analytic techniques. Ishikawa is an introductory, how-to text on simple graphical and statistical techniques for statistical quality control. Ryan presents a rigorous, wide-ranging approach to advanced graphical and statistical methods that is suitable for professional statisticians. Cleveland's *The Elements of Graphing Data* is a classic general text on proven methods for transmitting scientific information using graphs and charts. Guillory and Scholtes address the important area of the worker-customer interface. Guillory describes the CQI philosophy of giving workers the responsibility and authority to perform high-quality work, while Scholtes discusses the use of teams to implement such an interface and effect continuous quality improvement.

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**CQI in health care delivery:** The following articles describe the specific application of CQI principles to health care delivery. Berwick's article is an excellent overview that should be required reading for any interested party.

Berwick, D. M., Sounding board: Continuous improvement as an ideal in health care. *New England Journal of Medicine.* January 5, 1989; 320(l):53-56.

Demos, M. P., and Demos, N. P., Statistical quality control's role in health care management. *Quality Progress.* August, 1989; 22(8):85-89.

## GLOSSARY

**analysis** Actions and studies undertaken to discover the cause of a particular value, difference, or outcome (see also: enumeration).

**attributable variation** Process variation that may be tracked to a specific cause within the process. Attributable variation is not present at all times as background noise, but comes and goes as some step in the process varies over time.

**capability** The ability of a process to predictably meet Specific Output specifications. The capability of a process cannot he discussed until that process is Linder control.

**clinical hypothesis** The body of medical knowledge that describes a disease process, possible treatments, and likely Outcomes from each of the treatments. Common clinical hypotheses are widely shared among medical practitioners, although they are rarely explicitly written down. They roughly correspond to the local "standard of practice."

**clinical laboratory** A patient treatment setting in which data are collected to document the treatment process and Outcomes achieved for every patient. The basis for a clinical practice in which knowledge is systematically and objectively obtained from every patient who is seen so that the treatment process can he improved for all subsequent patients.

**constancy of purpose** An unswerving strategic vision developed and communicated by the leader of an organization. The term embodies the stable system view, reaching over years, that is necessary for a continuous quality improvement program to permeate the Culture of an organization, modify its operation, and lead to its long-term Success.

**Continuous Quality Improvement** The general theory Of Output and cost control as it applies to any organized system in which a process converts inputs into outputs. The term is often used generally to describe applications of the theory to specific endeavors, such as industrial quality control or medical quality control.

**Control** A process that exhibits only random variation Over time, with no evidence of specific variation using statistical quality control techniques, is said to be "in control." X-Bar and R charts may be used to identify attributable variation and bring a process under control. When a process is in control the Shewhart Cycle may be used to test improvements. One major class of improvements aims to reduce random variation within the process and improve its capability.

**CQI** See Continuous Quality Improvement.

**customer** Any individual, group, or organization that has expectations regarding the physical attributes of an Output made by a process, or the interaction through which the output was delivered. One who receives the Output of a process. A customer may be external or internal to the producing agency.

**empowerment** Removing management obstacles from workers, so that they can freely apply continuous quality improvement principles within the purview of their own areas of responsibility. Giving workers the total responsibility and authority to consistently accomplish quality within their assigned areas.

**enumeration** The act of classifying and counting, that is, performing statistical evaluation. Enumeration can document the existence of levels, rates, and differences, but does not trace those measurements back to a root cause (see also: analysis).

**fundamental knowledge** Detailed working understanding of a process, its key process factors, its inputs, its outputs, and customer expectations regarding its Outputs. Fundamental knowledge is the basis for process control and improvement. Quality management cannot take place without fundamental knowledge.

**key process factors** Steps in a process that causally lead to output attributes that meet customers' quality expectations (as measured through Output specifications).

**KPFs** See Key Process Factors

**leadership** The ability of a manager to train employees (-about effective quality management techniques and fundamental knowledge), remove institutional roadblocks that hinder employees' natural tendency to produce quality, and empower employees to achieve quality goals. "Leadership" implies that the manager has fundamental knowledge about critical processes. It is contrasted to "supervision" under which the manager becomes the employees' primary customer.

**outcome** The combination of a product and a customer's quality evaluation of it.

**output** The product generated by a process as it transforms inputs.

**Pareto chart** A statistical quality control graph that lists factors in order of their frequency or relative importance.

**PDCA cycle** See Shewhart cycle

**process** A series of linked steps through which an input is converted into an output. Processes tend to be hierarchical-a step within a process may itself be a process, with a series of substeps. A hospital is a complicated network of processes.

**productivity** The efficiency with which a process uses resources as it converts inputs into outputs. A process that uses fewer resources to produce an

identical output from identical inputs is said to be "more productive" than a competing process.

**quality mission statement** An organizational mission statement that (1) focuses on meeting customer expectations, (2) stipulates the use of explicit quality measurements, (3) demonstrates the organization's ongoing commitment to continuous improvement and (4) clearly notes the central role of top management in achieving organization-wide quality. A quality mission statement embodies the organization's long-term vision of quality as the primary basis for its success and survival.

**quality waste** When a process fails and produces an output that does not meet quality expectations, the costs associated with repairing (rework) or discarding (scrap) the faulty Output.

**R charts** A graphical statistical quality control technique that displays the degree of consistency of variation within a process over time. R charts may be used to separate specific sources of "variation in variation" from random sources of "variation in variation." When specific sources are found, they can be backtracked to a cause and eliminated to bring the process into control.

**random cause** See random variation

**random variation** Process variation that cannot be traced to a specific, Consistent cause. The random background noise that is constantly present in any system, arising from small differences in inputs and uncontrollable fluctuations in the system itself.

**Shewhart cycle** Continuous improvement through application of the scientific method to a process. The steps are Plan a change; Do (test) the change on a small scale; Check (evaluate) the results of the test; then Act upon the results of the test, by either implementing the change within the process, abandoning the change, or modifying and retesting it. The Shewhart Cycle works within processes that are in control; that is, it requires a process from which attributable variation has been eliminated, so that the impact of the change can be clearly seen.

**specific cause** See attributable variation

**specific variation** See attributable variation

**specification** An explicit, written statement regarding attributes of the output of a process or of a key process factor. Specifications identify measurement variables, but typically don't establish acceptable limits or standards.

**SQC** See Statistical Quality Control

**standard** A numerical production goal, usually set at an inherently arbitrary level with an aim to separate the "unacceptable, or bad, from the "acceptable," or good. Often becomes an artificial floor or ceiling that halts

continuous quality improvement, and can lead to invalid data. Within CQI theory, a standard is a direct statement of the amount of waste or error purposefully built into a system.

**statistical quality control** A group of related statistical methodologies that may be used to evaluate measurement data collected from a process or the outputs it generates. They are designed to separate random from attributable variation, and may be used to bring a process within statistical control.

**substantive knowledge** See fundamental knowledge

**tampering** The act of changing a process in response to random variation instead of specific, or attributable, variation. Tampering nearly always increases the amount of variation in a system and thus damages the process.

**value** The combination of quality and cost. Within clinical medicine, for example, the best possible medical outcome at the lowest cost necessary to consistently achieve that outcome.

**value system** The learning and past experiences from which an individual makes personal judgments, including quality expectations. An individual's set of assumptions about what is worthwhile or valuable.

**X-bar charts** A graphical statistical quality control technique that tracks the center (average) of a process over time. It can help separate random variation from specific variation.

## ABOUT THE AUTHOR

Brent C. James, M.D., M.Stat., is the director of medical research and continuing medical education for Intermountain Health Care, Inc. (IHC), a not-for-profit health care delivery company with 24 hospitals located in Utah, southeastern Idaho, and southwestern Wyoming. He is an adjunct assistant professor in the Division of Biostatistics, Department of Family and Preventive Medicine, University of Utah Medical Center, Salt Lake City, Utah, and a visiting lecturer in the Department of Biostatistics, Harvard School of Public Health, where he was an assistant professor in the Department of Biostatistics and a biostatistician with the Eastern Cooperative Oncology Group. From 1979 to 1983 he was the Cancer Department assistant director and consultant for the American College of Surgeons, Chicago.

Dr. James received Bachelor of Science degrees in computer science (1974) and medical biology (1975), a Master of Statistics degree (1984), and an M.D. degree (1978—with subsequent residency training in surgery) from the University of Utah. He also completed a fellowship in biostatistics (1984) at the Harvard School of Public Health. He represents IHC on the Hospital Research and Educational Trust's Quality Measurement and Management Project (QMMP) task force. He recently completed *Quality Management for Health Care Delivery,* which describes the application of continuous quality improvement to clinical medicine. The QMMP has accepted the model described in this document as the next evolutionary step in hospital quality.

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