CONTINUOUS QUALITY IMPROVEMENT:

Leo Bennett MD and Lee Slavin MD MPH

Introduction

Recognizing the characteristics of quality is something that all of us would claim to be able to do. A vehicle that handled with ease, had standardized options and extras, provided warranted preventative maintenance programs, guaranteed emergency repair coverage, and actively sought high customer satisfaction ratings with respect to these services and overall vehicle performance might represent quality characteristics in the automotive world. Quality performances in the world of drama could be appreciated by the execution of a flawless rendition of classic theater that the audience could relate to, demonstrated moments of tragedy and comedy, challenged popularly held opinions and beliefs, and increased a sensibility and awareness of the world and its complex systems of interaction and interdependencies

Ask Americans after the Second World War, how they would recognize quality in health care delivery, and most would define quality health care as the provider or health care organization that was able to provide all the resources that were needed by patients to handle their specific illness requirements. That is, for many of the traditional health care advocates, quality health care was synonymous with abundant health care. Many have considered healthcare in the United States as the greatest in the world because it offered the largest array of the latest technology, performed the greatest number of procedures by the greatest number of specialists, and with the fastest availability that money could buy. The American public, indeed the world, rapidly became accustomed to the image that unlimited access and treatment availability equaled quality of care regardless of the cost or value.

However, as the population requiring health care grew in the 1970s and 1980s, combined with a further development of more advanced diagnostic and therapeutic modalities, the costs of this unlimited access and care became an issue. The rise in the cost of health care far exceeded the rise in the cost of living in the United States, and those who actually assumed the brunt of paying for these increased costs, industry and government, rebelled at the thought that health care expenditures would consume an ever increasing percentage of the country's gross domestic product. [2] These payers then, sought out ways of limiting their economic expenditures for health care by means of altering the value, quality and cost equation. That is, they pursued means of increasing value by lowering costs. This reaction to the new reality of cost containment has shaped health care economics for the last two decades of the twentieth century. And the search for ways to reduce the costs of health care delivery led many to examine the root causes of the health care cost crisis. The results of this investigation showed

that while inappropriately high utilization did have much to do with rising health expenditures, there were a myriad of other reasons why this was so. From rapidly developing (and usually expensive) technology to cost shifting by providers to pay for care rendered to patients who either could not pay or were covered by systems that did not pay the full cost of care, from shifting demographics as our population aged and continues to age to high expectations for long and healthy lives, from the current legal environment leading to defensive medicine to administrative costs, from wide variations in efficiencies and quality of care provided to serious inequities and variations in income between all types of providers regardless of efficiency or quality of care all led to a pursuit of an improved way to deliver quality health care. [3]

Enter managed care. By attempting to reduce over utilization of health care through utilization review, "quality assurance", and "case management", health maintenance organizations (HMOs) "managed" care of their beneficiaries. This relieved the ever-rising costs of healthcare, but, only temporarily. Patients valued "choice" of providers, did not value or trust decisions that HMO medical directors made that were at time incongruous with those of their personal physicians. Patients and government authorities began to take legal actions against the HMOs for actions that did not seem to hold the patient's best interests at stake. Health care costs could be held at bay only briefly. The cost of care resumed an upward course. These rising costs, along with increased patient awareness, interest, knowledge, and access to information about "the right care, at the right time, at the right place, by the right provider" have now, more than ever, required that health care providers demonstrate the "quality of their care". [4]

Overview

The economic and technological healthcare landscape is dynamic and ever changing. Since the original version of this chapter just two years ago, new economic influences and quality management methods have come into play. New approaches are being described, tested, implemented and re-evaluated.

In this revision, a case example from the recent medical literature will introduce the environment of healthcare quality management in a realistic way.

In addition to the expanding the historical background of Quality Management in the manufacturing and service industries, this revision will include parallels in Healthcare Quality Management history.

Tools and methods for the healthcare manager from the first version of this chapter will be supplemented with a discussion of a thinking process (Theory of Constraints) and methods used in High Reliability Organizations. Feedback tools and methods such as "report cards" and "instrument panels" will be presented. Methods from manufacturing and service business models of quality management including ISO9000, and Six Sigma are being applied to healthcare quality management either supplementing or potentially

replacing conventional Total Quality Management aspects of healthcare systems as surveyed by the Joint Commission on Accreditation of Healthcare Organizations.

The Institute of Medicine of the National Academy of Sciences has proposed major changes in the way health systems will address patient safety issues through error reduction (*To Err is Human*) [5] and reshape how healthcare is delivered (The *Quality Chasm*) [6]. These documents are now part of daily parlance in the environment that all current healthcare managers must understand.

Finally, businesses and communities are beginning to communicate and work together to shape future trends through collaborative efforts in educational and research and by translation of evidence-based efficacy to patient-centered and community focused effectiveness.

A Case Example

Ms G, a 58-year-old woman had ambulatory, same-day knee surgery. During the procedure she was given an anesthetic agent that was not the one for which she had provided consent. This change in her intended care process delayed her ability to walk postoperatively. Additionally, clinicians did not heed her comments about the frailty of her veins, resulting in unnecessary pain. Finally, the staff in the recovery room area left her alone for nearly an hour without an escort to meet her ride home at the entrance of the hospital. However, overall, the patient states she is very satisfied with the care she has received from her primary care physician, Dr.B.

Ms G - The Patient's Comments: " …for the record, during my preop interview prior to the day of surgery with an anesthesiologist, only lidocaine was listed as an option, not bupivacaine, for spinal injection. On the day of surgery, my surgeon told me that I was going to get lidocaine and would be out of recovery in 2 to 2 ½ hours. He was as surprised as I was when he learned after the fact that I had been given bupivacaine. Although he agree that the anesthesiologist had the right to use what he thought was best, he expected the anesthesiologist to explain the ramifications of that choice. My main objective was that I was not advised beforehand of the drug and its effects and the utter arrogance of a physician to think that a patient should not be apprised or involved in a decision concerning a procedure being done on him/her. I am glad that I was being "shadowed" so the process was witnessed by someone else!"

Dr.B – The Primary Care Physicians Comments: " Since her knee surgery, Ms G has continued to feel well, and notes the overall success of the procedure. Though I do not foresee any surgical procedures in the near future, she does state that she will insist on being an informed patient, regardless of the circumstances."

A Reviewer's Comments: " in defining quality of care, it is critical to consider both technical quality, or 'doing the right thing right,' and interpersonal care, also called

'service quality,' which relies on communication, trust, mutuality of goals, and respect for the patient." Assessing quality needs to be done not only from the professional perspective, but must include the perspective of the patient. Evidence suggests that patients who are more satisfied with patient-centered aspects of their care have better outcomes. This case is an example of what we see too often in today's healthcare arena, "good technical outcome, poor service experience."

What can be learned from this case example?

Improving service quality requires developing well-running systems, specifically establishing "service recovery systems," whereby an error can be assessed, handled quickly, and solved in a way that will also prevent it from recurring. High-performance multidisciplinary teamwork, methods, and tools exist in other industries, and health care should learn from other system design disciplines.

Physicians play a central role in improving care and improving core processes. From the patient's perspective this requires sustained leadership from the top of every health care organization. [7]

History of Quality Management- the Manufacturing and Service Sectors' Perspective

Quality improvement in industry has a long history in the United States and around the world. Quality improvement icons like W. Edwards Deming, Walter Shewhart, and J.M. Juran have introduced the concepts of quality improvement to American industry over the past fifty years, and largely, were responsible for renewing the competitiveness of American industry. These quality improvement tools help reduce problems in the production and distribution of manufactured goods, but they have also been applied to companies that supply services. These service applications have led to the present use of quality improvement in health care. [8] Quality improvement is based on the science of improvement that pursues knowledge of general truths or operation of general laws, especially those obtained and tested through the scientific method. To create improvement then, you need knowledge relevant to the particular problem at hand. The science of improvement is concerned with how knowledge of a specific subject matter is applied in diverse situations. [9]

Shewhart Walter Andrew Shewhart was born 18 March 1891 in New Canton, Illinois. He would receive his Ph.D. in physics in 1917 from the University of California at Berkley. After a brief teaching career, he joined the Western Electric Company, a forerunner to the famous Bell Telephone Laboratories. This work necessitated ensuring reliability of telephone communication devices. Dr. Shewhart applied what he learned about statistical techniques in graduate school to the task of producing a consistently high-quality telephone. Coupling this knowledge of statistics with Robert Brown's and Albert Einstein's work on the random movement of atomic particles, Shewhart proposed that a high quality reliable product need not be "perfect" (the standard expectation of the factory's engineers) but "in control". He proposed that the finished

product meet specifications that would and could vary to a certain irreducible extent. He called this normal difference "common cause' variation. Attempts to eliminate this common cause variation were time consuming, costly, wasteful, and made things in the factory worse rather than better. On the other hand, he also described "special cause" variation. Special cause variation was a difference in an outcome of a process that required investigation in order to assure quality and maximize productivity. In order to differentiate common cause variation from special cause variation, Dr Shewhart mathematically calculated values that would be displayed on a "control chart" (See 'Tools" Section below). [10] A statistical process control (SPC) chart indicates whether or not observed variations in a defective apparatus of a given type are significant by plotting individual values, which included statistically generated upper and lower limits. For this work, he would later be called the "Father of Statistical Quality Control". [11] His work would serve as a foundation that would influence Dr. W.Edwards Deming and Dr. Joseph M. Juran. Through Deming, Shewhart's tool became one of the greatest contributions to the improvement of quality in this century

Deming William Edwards Deming was born on October 14, 1900, in Sioux City Iowa. Deming attended the University of Wyoming earning a Bachelor's Degree in engineering. Subsequent study in mathematics and physics earned him a Master's Degree from the University of Colorado in 1925 and a Ph.D. from Yale University in 1928. During work in the summers of 1925 and 1926, he met and worked with Dr. Walter Shewhart at Western Electric's Hawthorne plant in Chicago. He would carry knowledge from this collaborative work forward in work he did for the U.S. Government at the Bureau of the Census and later during World War II. He is well known for his work after World War II as an advisor to the Japanese census and the Japanese Union of Scientists and Engineers. In 1956 he was awarded the Shewhart Medal by the American Society for Quality. Four years later, Deming was awarded the Second Order of the Sacred Treasure by the Emperor of Japan. [12]

Dr. Deming made an important contribution to the science of improvement by recognizing that there are certain elements of knowledge that underpin all improvements in the entire spectrum of applications. He gave these elements of knowledge the name " System of Profound Knowledge." [13] *Profound* denotes the deep insight that this knowledge provides in making changes that will result in improvements in a variety of settings. *System* denotes the emphasis on the interaction of the components rather than on the components themselves. According to Deming, to comprehend the workings of a system and thus be able to improve it, one has to have an *appreciation* of the system as an entity onto itself, have an *understanding of its variation*, *theory of knowledge* of how to bring about change, and *psychology* of personnel.

Appreciation of a system helps us to understand the interdependencies and interrelationships among all components of a system and thus increases the accuracy of our predictions about the impact of changes throughout the system. *Understanding of*

Variation helps us to understand that all systems constantly exhibit variation. We are forced to make decisions in our lives based on our interpretation of this variation. The ability to make those decisions is inseparable from making improvements. In the context of quality improvement, the *Theory of Knowledge* pertains to change as a prediction-if a change is made, improvement will result. This prediction is made and a plan must be developed from it, even though no one can predict the future. The more knowledge one has about a how the particular system under consideration functions or could function, the better the prediction and the greater the likelihood that the change will result in an improvement. Building knowledge by making changes and observing or measuring the results is the foundation of the science of improvement. Knowledge of *Psychology* helps us to understand people, how they interact with each other and with a system. It helps us to predict how people will react to a specific change, why they resist change, and how to overcome this resistance. Changes that are aimed at improvement will have to recognize these differences and account for them. [14]

Deming offered practical and pragmatic approaches to the improvement of quality and productivity that relied heavily on his components of the "System of Profound Knowledge" and proposed fourteen quality principles [15] that led to the development of quality improvement approaches that changed the focus of enlightened managers from trying to change people to changing processes and systems to improve output and reduce cost through redesign and reengineering:

1. Create constancy of purpose toward quality improvement of product and service, with the aim of being competitive

2. Adopt the new philosophy of leadership and change for the new economic age

3. Cease dependence on inspection for quality by building quality into the product in the first place

4. End the practice of awarding business on basis of a price tag by minimizing costs through a single supplier for any one item built on long-term relationships of loyalty and trust

5. Improve constantly and forever the system of production and service, to improve quality, productivity, and cost reduction

6. Institute training on the job

7. Institute leadership by helping people do a better job through enlightened supervision

8. Drive out fear, so that all may work effectively

9. Break down barriers between departments so that people in research, design, sales, and production work as a team

10. Eliminate slogans, exhortations, and targets asking for zero defects and new levels of productivity; eliminate work standards (quotas) and management by objective, numbers, and numerical goals; realize that low quality belongs to the system and is beyond the power of the workforce; instead substitute leadership.

11. Remove barriers that rob workers their right to pride of workmanship by charging supervisors with the responsibility of quality over

12. Remove barriers that rob people in management their right to pride of workmanship by eliminating ratings systems and management by objective

13. Institute vigorous programs of education and self-improvement.

14. Put everyone to work to accomplish this transformation.

The theory underlying the science of improvement is interesting in itself. Nevertheless, improvement comes from action: the developing, testing, and implementing of change. [16] Change can be developed by examining the current system using pictures, flow diagrams, or data and based on a learning, a common understanding, and an identifying of possible changes in some or all aspects of the current system-in other words, by *redesigning the existing system* OR by inventing a new idea, without recourse to the way things are presently done-that is, by *designing a new system*. After developing a change we then find a way to test it on a small scale to minimize risks, and observe how the system reacts to the change over time. The change might have to be modified or discarded but whatever the outcome, something will be learned and the next test or trial will be better informed than the previous one.

The pursuit of improvement relies on cycles of learning. But it is not enough to show in a test that a change is an improvement. The change must be fully integrated into the system. This takes some planning, and usually some additional learning in matters of dealing with those who the change will effect and who will implement the change and make these changes sustainable.

Both Dr. Shewhart and Dr. Deming recognized the importance of these philosophies in the scientific method of hypothesis generation, experimentation, observation and hypothesis testing. Testing a change is not always easy. To help people develop tests and implement changes the science of improvement uses the Shewhart Cycle. This cycle consisting of what has come to be referred to as a PDSA (Plan, Do, Study, Act) cycle. [17]

PDSA is a framework for efficient trial-and-error methodology. As the words imply, the cycle begins with a plan and ends with an action based on the learning gained from the PDSA phases of the cycle. Improvement comes from the application of knowledge—of medicine, engineering, teaching, driving a truck, or simply the way some activity is currently done. Generally, the more complete the appropriate knowledge, the better the improvements will be when the knowledge is applied to making changes. Any approach to improvement, therefore, must be based on building and applying knowledge.

This view leads to a set of fundamental questions, the answers to which form the basis of improvement :[18]

1) What are we trying to accomplish?

(2) How will we know that a change is an improvement?

(3) What changes can we make that will result in improvement?

These questions provide the framework for a "trial-and learning" approach. The word "trial" suggests that a change is going to be tested. The term "learning" implies that criteria have been identified that will be used to study and learn from the trial. Focusing on the questions accelerates the building of knowledge by emphasizing a framework for learning, the use of data, and the design of effective tests or trials. This approach stresses learning by testing changes on a small scale rather than by studying the problem before any changes are attempted.

Juran Joseph Moses Juran was born in Braila, Romania, in December 1904. His family immigrated to Minnesota in 1912. As a youth he showed great proficiency in science and mathematics. He was able to skip the equivalent of four grade levels, and enrolled in the University of Minnesota in 1920. He also worked at Western Electric in the mid 1920s. By 1937 he had become the chief of industrial engineering at Western Electric's home office in New York. During World War II, Juran served in the government improving the efficiency of processes eliminating paperwork and hastening arrival of supplies to overseas allies. In 1951, he published the *Juran Quality Control Handbook* that led to international eminence. He also went forward to influence Japanese management's responsibility for quality control. In 1979, Dr Juran founded the Juran Institute to better facilitate broader exposure of his ideas. Similarly to Dr. Deming, Joseph Juran received the Second Order of the Sacred Treasure award from Emperor Hirohito for," the development of quality control in Japan and the facilitation of U.S. and Japanese friendship."

Juran teaches a project-by-project, problem-solving, team method of quality improvement in which all levels of management must be involved-- "Total Quality Management" (TQM). Quality doesn't happen by accident; it must be planned. His key

points involve: implementing organizational wide quality planning including identifying customers and their needs, establishing optimal quality goals, creating measurements of quality, planning processes capable of meeting those goals under operating conditions, and producing continuing results in improved market share, premium prices, and reduction of error rates. Dr. Juran was the first to incorporate the human aspect of quality management, embraced in TQM. [19]

His writings can be accessed at www.juran.com/research/back_articles.html.

Crosby Philip B. Crosby was born in Wheeling, West Virginia, on June 18, 1926. He attended Western Reserve University. Crosby worked as a reliability engineer and quality manager in industry where he created the 'zero defects" concept. Later, he worked as a corporate vice president for ITT. In 1979, he founded Philip Crosby Associates (PCA) PCA taught management courses on how to establish a quality improvement culture. Clients included large corporations such as GM, Chrysler, Motorola, Xerox and many others. His *14 Points of Steps to Quality Improvement* included ideas involving: management commitment, education and training, measurements, costs of quality, quality awareness, corrective action, zero defects, goal setting and recognition.

Crosby articulated four absolutes:

1. Conformance to requirements is the only definition of quality
2. What causes quality is prevention, not appraisal
3. Zero defects is the only acceptable performance standard
4. The price of nonconformance is how quality should be measured. [20]

Further information can be reviewed at the PCA Web site:
www.philipcrosby.com/main.htm

History of Quality Management- the Healthcare Sector Perspective

Effective health care managers have recognized that the principles described in the manufacturing and service sectors can and should work in medical practices and organizations by changing regimens of treatment and health care delivery in order to fit a patient's or an organization's needs. Fitting the curative environment to individual or organizational variation is important in achieving production goals. That same approach can and should be applied to the management of health care delivery to an individual patient or a population based disease management program. Therefore, reflecting on the lives of some past and recent healthcare quality leaders is insightful.

Nightingale Florence Nightingale (May 12,1820 to August 13,1910.) is remembered as a pioneer of nursing and a reformer of hospitals. When Nightingale started her nursing work, nurses were thought to be lacking in training. They were usually coarse and ignorant women, given to promiscuity and drunkenness. By the end of her career, nursing would be grounded in science and nurses would be expected to serve in a devoted manner centered on service to God through service to mankind. [21]

Florence Nightingale redirected her work toward the British military health-care system during the Crimean War (1854) and saved lives of thousands. She was able to present her observations of death statistics to others by documenting data on "polar-area diagrams". Casualty losses were presented on graphs. "Line diagrams" presented data that compared mortality causes in military and civilian circumstances. Innovations in this arena led to dramatic changes in nursing care and hospital administration. Florence's leadership had profound impact on changing the social expectations and outcomes of nursing care in Britain. [22]

Codman What Florence Nightingale did for a healthcare at the profession and national health care system level; Ernest Amory Codman would do on an individual level in an attempt to bring individual accountability and quality to health care provision.

Codman was born in Boston on December, 30, 1869. He was educated at Harvard College and Harvard Medical School. Later, he trained and worked on the staff of the Massachusetts General Hospital. As the turn of the 20th century dawned, Dr. Codman would generate in his mind the " end result idea". It struck him to describe his concept to Edward Martin in London in 1910. Martin seized upon this idea as the "catalyst to crystallize" his obsession to form the American College of Surgeons. Both men thought that the measurement of end results – what we now think of as outcomes of medical care (mortality, morbidity, complications, successes) – would be the tool by which all claims to special surgical competence would be verified, and the practice of surgery in hospitals "standardized". [23]

The end result idea lead to the development of the "end result card". On a small pocket-sized card, Dr. Codman recorded the patient's case number, preoperative diagnosis, operating team members' names, procedure(s), and results (both short and long-term). Codman encouraged his colleagues to do likewise. This recommendation was totally unacceptable to his peers! Dr. Codman was criticized and ostracized. Open discussion of poor outcomes and errors was unthinkable. Ernest Codman resigned from his position at the Massachusetts General Hospital and founded his own hospital the "End Results Hospital". To those who judged Codman, the End Results Hospital eventually closed as a failure. However, today these efforts are now considered the work of a martyr. [24]

Donabedian Avedis Donabedian was born in Beirut, Lebanon, but grew up near Jerusalem. He studied at the American University of Beirut, where he obtained his BA

and MD degrees. Later, he obtained his MPH degree from the Harvard School of Public Health. His career included academic medical education, research, clinical care and scholarship centered on systemization of knowledge in various areas of health care organizations – especially of quality assessment and monitoring in health care. His work has been widely recognized internationally. [25]

In his classic paper, [26] Dr. Donabedian described and evaluated methods of assessing and measuring the quality of care at the level of the physician-patient interaction. He identified three approaches to assessment:

1. *Outcome* of care
2. *Process* of care
3. *Structure* – attributes of care providers, settings, and arrangements.

Outcome variables describe some relevant characteristic, usually of the patient, after provision of care that is presumed to result from the care given (ie survival, death, length of hospital care, complications, etc.). These may be difficult and expensive to measure.

Process variables describe what care is provided or characteristics of its provision. (ie doctor's orders, the procedure to obtain a test and its results, or the steps by which a patient gains access to a doctor). This may still be difficult and expensive to do. But, it is not as difficult to do as outcome measurement.

Outcomes variables are the least expensive and easiest to obtain. These variables describe the characteristics of inputs to care processes (ie hospital's physical structure and condition, doctors' training and qualifications, nursing training and competence, etc.). [27]

"Toolbox" and Methods

Tools Ever since Shewhart, quality engineers have used innumerable tools to achieve process and outcome measurement. Although these tools have been applied in industry for decades, they have only recently found application in health care. Part of the reason for their increasing adoption by health care managers is the reliance on statistical thinking rather than rigorous statistical analysis. [28] Statistical thinking is the approach of quality engineers that utilizes descriptive statistics to validate quality evaluations, without elaborate mathematical analysis. Descriptive statistics includes mean, variance, and standard deviation to evaluate quality improvement opportunities. Quality engineers have seven frequently used tools available for each of the four steps in the quality improvement cycle. [29] Additionally, payors for health care and governmental agencies are expecting reporting of results of care processes via two other forms of reporting – report cards and instrument panels – from providers and HMOs.

Measurements

Process

PROBLEM IDENTIFICATION

1. Pareto Charts
2. Fishbone Diagrams
3. Histograms
4. Run Charts

DATA COLLECTION

5. Check Sheets

INTERVENTION DESIGN

6. Flowcharts

Outcomes

PROCESS CONTROL

7. Control Charts

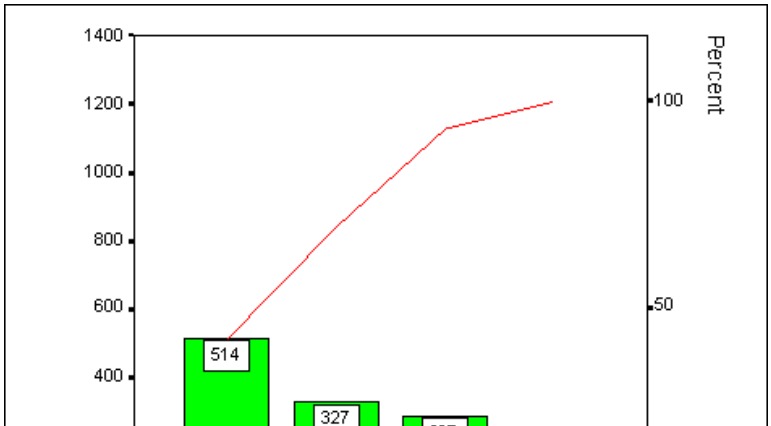
REPORTING RESULTS

8. Report Cards
9. Instrument Panels

These tools have come to define the classic approach to quality improvement, and they are used to insure that each step in a quality improvement process provides valid conclusions.

PROBLEM IDENTIFICATION tools define the source of variation in a process, allowing planning to decrease inappropriate variation and improve quality. In order to validate the problems identified. Examples of these 'cause and effect' tools are the Pareto chart and analysis and the Fishbone diagrams. The **Pareto** chart (see Chart#1) [30] and analysis is used when dealing with chronic problems and helps one identify which of the many chronic problems to attack first. The chronic problem with the highest number of events will show up on the Pareto chart with the tallest bar, which represents the most frequent occurring problem. The idea behind Pareto analysis is the 20/80 rule in that 20% of your errors / customers / input accounts for 80% of your complications / income/ output**.**

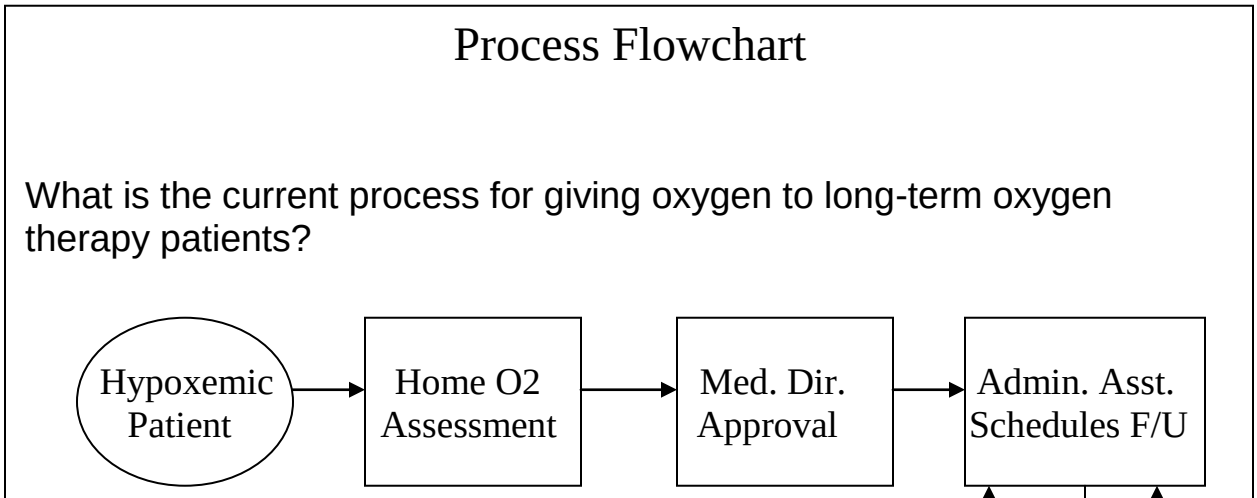
Chart#1-Pareto Chart



Fishbone diagrams are another form of cause and effect methods whereby the step-by-step process is followed from beginning to end in a way to look at each stage of production. In this way factors involved in each step are determined, identified, isolated. DATA must be COLLECTED and analyzed, and a **checksheet** (data collection sheet) design provides a scientific approach to gathering information to improve the validity of decisions and interventions.

INTERVENTIONAL DESIGN makes use of the fact that variation in a process exists because the process does not operate the same way every time. To get a handle on how the system ideally operates or should operate, standardization of the process must occur.

Flowcharting has proven extremely valuable for health care managers in understanding and optimizing processes. Often, the very act of producing a flowchart (see Chart#2) uncovers problems in process flow that respond to simple intervention. In more complex processes, flowcharting may present the only means of understanding the true structure of a system.



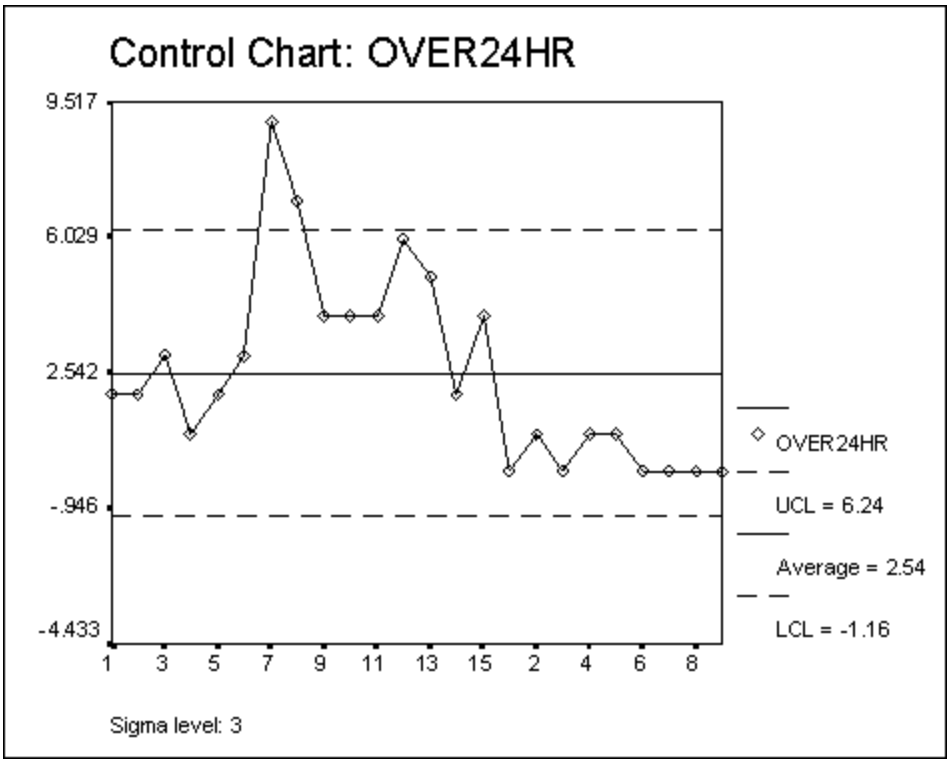
-
-
-
-
-
-
-
-
-
-
-
-

Chart#2-Flowchart

PROCESS CONTROL is considered by many as the most critical measure of quality improvement. Through the use of statistical process control charts, data can be expressed in terms of means and up to three standard deviations above and below that mean, over which data collection points are plotted. Based on these data points, variations in the process that are outside expected limits can be identified and targeted for intervention.

Control Charts (see Chart#3) are most useful for ongoing processes in which variation is a source of cost and diminished productivity, and these statistical models allow rapid analysis and intervention for active processes. In health care, control charts are useful for analyzing performance and outcome measure in diagnostic and therapeutic systems of care for specific disorders or preventive care. Using control charts, health care managers can usually identify sources of variation that determine approaches for improvement.

Chart#3-Control Chart



In the Control chart above, we noted significant variation in turn-around-times for operating room specimen delivery. The variation was outside of the dotted line which represented upper control limit averages that would normally be understood by chance variation. By instituting a change in the system at week 16, we were able not only to reduce the special cause variation that caused the extreme variation, but we were also able to reduce the chance or common cause variation to essentially zero by week 20(or week 4). [31]

Reporting Results One of the advantages of the quality improvement approach in health care is the application of an evidence-based approach to decision making. One of the major criticisms of the PDSA cycle approach and the evidence-based approach to health care improvement is the lack of a scientific basis around the recommendations for care made by this approach. Since a substantial majority of medical care is based on an individual clinician's anecdotal experience, rather than scientific evidence, many decisions on medical necessity lack the kind of scientific validity that physicians desire. Thus, disputes arise as to the meaning of disparate clinical experience. While the traditional clinical trial approach insures that critical analysis, however costly and time-consuming, will continue indefinitely as medical science advances and improves, the utility of PDSA data in the quality improvement process should be intuitively evident, as effective, efficient and explicit. While criticized in some circles as 'statistical-lite', CQI and PDSA have in fact as one of their central dogma the statement, "In God we trust, all

others bring data." Instrument panels and report cards are functional ways to display this data.

Instrument Panels Pareto-charts and control charts display frequencies of events and outcomes well, as described above. Frequently the quality manager, or process improvement team, chooses key variables occurring during a quality improvement project and groups these data displays in an array of multiple figures or tables that capture the events and work. These instrument panels: 1) illustrate real-time monitoring as action is taking place, 2) they present information, at present time, that is dynamic and occurring in "real time" that may target future goals, and 3) they empower those improving the process thru informed decision making. [32] An example of a simple instrument panel in real life is the dashboard instrument display in your car that helps you operate the vehicle during travel. It shows you speed, mileage, fuel reserve, gearshift selection, etc.-- all of which are useful to you while traveling to a destination. An analogous healthcare instrument panel would be a display of data, perhaps histograms and control charts, that would advise and monitor a quality improvement teams efforts to treat acute myocardial infarction inpatients with timely thrombolysis, administration of aspirin and beta-blockers, length of cardiac care unit stay, complications of care, and enrollment in smoking cessation and rehabilitation efforts. In summary, instrument panels convey a careful and thoughtful approach to the display of data that is very helpful in stimulating action toward a goal.

Report Cards During quality improvement work, a health care manager may be asked to present information, such as outcomes data in the form of charts or instrument panels, to upper management, corporate boards or leadership, community officials, payor organizations, or regulatory agencies at the state or federal levels. These information displays usually report results that demonstrate accountability for care. They usually display past successes or lack thereof. This display of data is: 1) somewhat static,
2) usually reflecting past summaries of information, 3) shows results that may be open to judgment that may produce apprehension, rejection, or sometimes joy, and 4) center around conclusions about outcomes on or around average expectations.
Specific report card examples are: 1) state health department reports on local cardio thoracic surgery results reported as for mortality and cost for coronary artery bypass surgery [33] or 2) Health Plan Employer Data Information Set (HEDIS®) reports to payors or employers on health plan quality issues relating to immunizations, cancer screening, acute and chronic disease management, customer service, access to care, and claims processing. [34]

Methods Good intentions, teamwork, data acquisition and analysis, and changes tested in improvement cycles are all essential to improving healthcare. All too often, the focus for improvement results in personal "shame or blame". When, in fact, studies show that most often failures are due to process or system deficiencies that lead to inefficiencies,

error, or poor results. Flow charts can help the manager visualize the process that exists. However, usually in healthcare processes and systems much more complex and even at times chaotic. [35] These complex process interactions in systems are best evaluated using methods known as "root cause analysis" (RCA) or the "theory of constraints" (TOC).

Root Cause Analysis Root cause analysis is a method which can help individuals learn as much as possible from adverse events or poor outcomes of processes in systems. It is not enough to just learn about what happened when expectations fail to be met. It is more important to know *WHY* something happened and learn how to prevent a recurrence. A *root cause* is the *most basic reason* that a situation did not turn out ideally. Most often, a root cause is a known or unknown system vulnerability (human weakness is almost never a root cause). In complex scenarios, there may actually be more than one root cause –seemingly a paradox, but not. [36] The evaluation of root causes involves a rigorous thoughtful team approach to flow diagramming and construction of cause and effect diagrams after consideration of: 1) failures in human factors of communication, training, and fatigue or scheduling, 2) environmental or equipment failures, 3) factors relating to rules, policies, or procedures, and 4) barriers. One enters into each of these areas of consideration asking the question "why" at least five times, thus delving deeply into each process or system interaction beyond simple explanations. [37]

Theory of Constraints Similarly, theory of constraints is a method of evaluating multiple interactions among processes and systems that ultimately effect thru-put. It involves a thinking process that emphasizes: 1) *WHAT* to change, 2) *TO WHAT* to change, and 3) *HOW* to cause a change. By rigorously identifying conflicts in a problem system, one arrives at a '*core conflict'* and then goes on to construct a complete solution having considered complex interdependencies that exist in a problematic system. Changes are considered and proposed, but only tested after thoughtful evaluation of interactions among processes and systems that may be interrelated. [38] In effect, TOC involves RCA in principle. However, TOC goes beyond conventional cause and effect diagrams by constructing diagrams that show interdependencies and interactions. This thinking process and resultant diagramming helps focus improvement team members on identifying the solutions which may lead to a breakthrough solution-- especially in thru-put scenarios. [39]

Evolving Practices and Initiatives The historical contexts of the manufacturing and service sectors of the economy have influenced the tools and methods being applied to health care system quality management. Presently within the business community, a multitude of process improvement champions seem to be vying for attention and leading others toward a "best" method. Each champion advocates adoption of his or her favored improvement methodology. Three current methodologies include "Six Sigma", "Lean Thinking", and TOC. As is usually the case, there is not one method for all situations. An understanding of these programs, their application, and implementation is worthy of brief discussion. [40] In addition, the business improvement programs of the

Baldrige Awards, ISO 9000, and principles involved in the management of high reliability organizations
(nuclear power plants, aviation, and aerospace) are entering the environment of healthcare as coalitions of businesses, payors, providers, and regulators come together. A brief summary of these follows.

Six Sigma Six sigma refers to the statistical likelihood that there will only be 3.4 failures or defects in a million opportunities. This quality management method was first implemented in industry at Motorola. In addition, it has been popularized by tremendous successes in management at General Electric. Some experts believe it should be equally as successful in healthcare. [41] Reduction of variation in the areas of medication administration, surgical procedures, assignment of caregivers, emergency treatment triage, patient falls, and disease management are just a few applications where the DMAIC – Define, Measure, Analyze, Improve, and Control-guidelines of six sigma resemble and complement PDSA cycles of improvement. The focus of six sigma is centered on reducing, and hopefully removing, failure and defects within work processes.

Lean Thinking Lean thinking is sometimes called lean manufacturing and was popularized in manufacturing by the Toyota production system. "Lean" focuses on the removal of waste in work environments. Waste is defined as anything not necessary to produce the product or service. The common measure is 'touch time'-- the amount of time the product is actually being worked on or touched by the worker. Frequently, lean's focus is manifested in an emphasis on *flow* through a process. Five essential steps in lean are: 1) to identify features that create value, 2) identify the sequence of activities called the value stream, 3) make the activities flow, 4) let the customer pull the product or service through the system, and 5) perfect the process. Recent collaboration between General Motors and its employee's healthcare providers have reduced costs and improved outcomes [42] – truly a win-win for the purchaser, users, and providers of health care.

Baldrige Awards The Malcolm Baldrige National Quality Award was created by Public Law 100-107 and signed into law on August 20, 1987. The award is named for Malcolm Baldrige, who served as secretary of commerce from 1981 until his untimely death in a rodeo accident in 1987. Baldrige's managerial excellence contributed to long-term improvement in the efficiency and effectiveness of government. The award not only recognizes quality: but, also establishes a framework within which quality initiatives take place. Most organizations that apply for the award, believe that even greater gains accrue through evaluating their system than may result from being awarded one of the coveted awards. Thru the Baldrige performance excellence criteria any organization can improve overall performance in seven categories- leadership, strategic planning, customer and market focus, information analysis, human resource focus, process management, and business results. [43] More information is available at: http://www.quality.nist.gov/ .

ISO9000 ISO 9000 is a series of international standards first published in 1987 by the International Organization for Standardization (ISO), Geneva, Switzerland. It is updated nearly yearly. Expectations centered about "standards" were the inspiration for Shewhart et al at Western Electric in the 1920s. Since then, and more recently, standards have ensured that materials, products, processes and services fit their purpose. ISO defines standards as documented agreements containing technical specifications or other precise criteria to be used consistently. These criteria take the form of rules, guidelines, or definitions of characteristics. A current ISO edition applicable to healthcare is ISO9000: 2000. Under the ISO 9000 approach, organizations establish written quality management systems based on the quality elements listed in the ISO 9000 requirements documents and its updates. These standards include domains defining: 1) the quality management system, 2) management responsibility, 3) resource management, 4) product realization, and 5)measurements accompanied by analysis and improvement. [44] Once these quality management systems are documented and implemented, a third-party registrar audits the endeavor for conformance. If conformance is verified, the organization is recognized and registered as a certified entity. [45] ISO increases the reliability and effectiveness of goods and services. ISO certification is useful in healthcare because it conforms to the healthcare sector, as JCAHO has traditionally intended; yet, it appeals to the manufacturing or service sectors because of their familiarity with ISO methods and assurances.
Additional information is available at: www.iso.ch/iso/en/ISOOnline.frontpage .

High Reliability Organizations- "Management of the Unexpected" Lessons have been learned from other complex and error-prone environments that can, and must, be applied to management of health care systems. The aerospace, aviation, and nuclear energy industries – known of as high-reliability organizations (HROs)-- must consistently
produce safe, reproducible, error-free services and products. The National Patient Safety Center has been charged with teaching applications of these principles and actions to reduce human and system error in healthcare organizations. Recently Weick and
Sutcliffe [46] have described the five hallmarks of HROs. These five are: 1) a preoccupation with failure, 2) reluctance to simplify interpretations, 3) sensitivity to operations, 4) commitment to resilience, and 5) deference to expertise. Tools for assessing an organization's preparation and implementation of "mindful management" are essential for the management of quality and error prevention in medical care systems.

Future Directions

Despite the long history of quality theory and practice--both inside businesses and in the healthcare sector, the availability of usable tools and methods, the influence of nongovernmental and governmental and policies, and JCAHO Accreditation requirements; it seems difficult to implement and sustain quality improvement efforts in daily operations within healthcare settings and systems. [47] Therefore, one must pose the question, "What will lead to successful implementation and sustained quality improvement in health care systems in the future?"

First, economic forces will continue to drive efforts to improve quality. Employers who pay their employee benefits--especially large businesses such as General Electric, General Motors, AT&T, IBM, Boeing and others trying to compete in a world market in which other countries spend less on benefits for employees; and thus, more on research and development-- are forming consortia such as the Leapfrog Group. [48] These business leaders are thinking about steering their employees health care dollars toward those providers with the "best quality" and "value" as evidenced by: 1) computer order entry to avoid medication errors, 2) specialist staffing of high-cost Intensive Care Units, 3) volume requirements for high risk procedures for optimal outcomes, 4) and electronic medical records for information access. Leapfrog is creatively partnering with JCAHO and Premier Inc.--a provider alliance. They are also sharing provider information with employees. [49]

Secondly, scandals regarding poor quality of care [50] and attention focused on life threatening errors in daily medical care, [5,51,52] in the United Kingdom and here in the United States respectively, have become household news. These have resulted in reduced public trust in their care providers. The British National Health Service and the Institute of Medicine are advising healthcare providers to seek "breakthrough improvements" in the way they function daily. *The Quality Chasm*, [6] recently published by the Institute of Medicine, suggests ways to bridge the gap between what patients expect and how providers currently perform. Continued pressure from coalitions of healthcare users and those paying for healthcare will only accept "best practices' based on "scientific evidence". The challenge for providers will be to translate best practices from the research institutions (efficacy of care) into practical processes in multiple care settings (effectiveness) without over utilizing expensive technology (efficiency) while not under utilizing resources (ethical conflicts due to misaligned incentives).

Additionally, visionary healthcare management leaders-- such as those who have reported on the work of the *National Demonstration Project on Quality Improvement in Healthcare*—are looking forward. [53] Health services researchers and educators continue to seek future models for quality management in healthcare. [54]

On the other hand, skeptics believe --perhaps realistically so-- that only new economic incentives or models will succeed [55] in driving successful implementation of sustainable

quality improvement action in health care. These skeptics propose that when a "business case" for quality is demonstrated, only then, will enthusiastic followers rally. Given what some consider being only small limited projects and the complexity of healthcare stakeholder expectations, a quantitative business case seems elusive. However, some reputable investigators believe that the business case for quality in health care is certainly qualitatively measurable. [56] All the same, there seems to be no mistake about consumer demand and expectations for clinical quality coming from several perspectives – individuals and communities. [57]

Summary The study of quality improvement is crucial for health managers to effectively promote cost effective, high quality, high valued health care. Patients, payers, and regulators are and will continue to demand performance-based data that documents an understanding, application, and implementation of quality improvement principles with regard to the services that they need and expect. Knowledge of and application of continuous quality improvement will be the only valued approach to health care change and survival in the future.