Basics of Quality Improvement in Health Care

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With the rapid expansion of knowledge and technology and a health care system that performs far below acceptable levels for ensuring patient safety and needs, front-line health care professionals must understand the basics of quality improvement methodologies and terminology. The goals of this review are to provide clinicians with sufficient information to understand the fundamentals of quality improvement, provide a starting point for improvement projects, and stimulate further inquiry into the quality improvement methodologies currently being used in health care. Key quality improvement concepts and methodologies, including plan-do-study-act, six-sigma, and lean strategies, are discussed, and the differences between quality improvement and quality-of-care research are explored.

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CQI = continuous quality improvement; DPMO = defects per million opportunities; PDSA = plan-do-study-act; QI = quality improvement; TPS = Toyota Production System; VSM = value stream mapping

In the past 2 decades, innumerable advances have occurred in medicine and technology. However, the health care system continues to perform far below acceptable levels in the areas of ensuring patient safety and addressing patient needs.[1] The publication *To Err is Human* from the Institute of Medicine galvanized health care system response and public demand for change when the US population learned that medical errors cause 44,000 to 98,000 deaths annually.[2] The abyss between what physicians know should be done for patients and what is actually done accounts for more than $9 billion per year in lost productivity and nearly $2 billion per year in hospital costs.[3]

Despite our complex medical environment, physicians rely primarily on paper tools, memory, and hard work to improve the care given to patients. However, creation of reliable and sustained improvement in health care is difficult with use of traditional methods. Improvement often requires deliberate redesign of processes based on knowledge of human factors (how people interact with products and processes) and tools known to assist improvement. The clear ethical imperative to enhance the quality and safety of care and meet external accreditation requirements and consumer expectations requires physicians to address quality-of-care issues systematically.[4,5]

The goals of this review are to provide clinicians with sufficient information to understand the basics of quality improvement (QI), highlight the basics of major improvement methodologies, provide a starting point for improvement projects, and stimulate further inquiry into QI methodologies currently being used in health care.

DEFINING AND APPLYING THE CONCEPTS OF QUALITY

The US Agency for Healthcare Research and Quality defines quality health care as "doing the right thing, at the right time, in the right way, for the right person—and having the best possible results."[6] Quality was first studied as an industrial process in 1931 by Shewhart.[7] Shewhart's concepts include identifying customer needs, reducing variations in processes, and minimizing inspections. Influenced by Shewhart's work, Deming[8] recognized quality as a primary driver for industrial success and subsequently introduced these methods to post-World War II Japanese engineers and executives. Applied strategically, these methods produced considerable growth in the Japanese automobile industry and subsequent worldwide recognition for quality.[8]

MEASURING QUALITY

Measurement of defects is integral to QI. A systematic measurement of quality demonstrates whether improvement efforts (1) lead to change in the primary end point in the desired direction, (2) contribute to unintended results in different parts of the system, and (3) require additional efforts to bring a process back into acceptable ranges. Using samples of success as the numerator and total opportunities as the denominator, events can be graphed using a control chart to evaluate performance over time (Figure 1). An average line can be used in the run chart to clarify movement of data away from the average. Two other horizontal lines called *the upper control limit* and *the lower control limit* can also be used in a control chart. As long as data points plot within the control limits, the process is assumed to be in control, and no further action is necessary.

Avedis Donabedian,[9] often considered the father of quality measurement, described quality design in relationship to structure, process, and outcomes. Structural measures assess the availability and quality of resources, man-

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A question-and-answer section appears at the end of this article.

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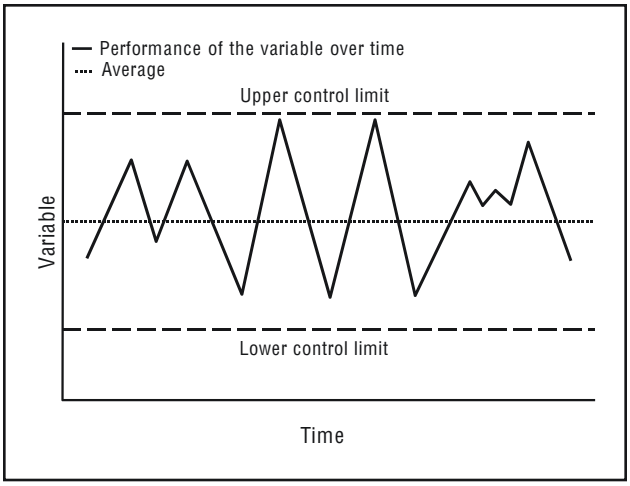

FIGURE 1. Quality of care can be measured using samples of success as the numerator and total opportunities as the denominator. Events can be graphed using a control chart to evaluate performance over time.

agement systems, and policy guidelines and are often critical to sustaining processes over time. This type of assessment is used primarily for licensing and for hospital accreditation. An example of a health care structural component is the decision to use intensivists in the intensive care unit to decrease mortality.[10] Process measures use the actual process of health care delivery as the indicator of quality by analyzing the activities of physicians or other health care professionals to determine whether medicine is practiced according to guidelines. An example of a process measure is the proportion of diabetic patients who undergo an annual retinal examination. Outcome indicators measure the end result of health care and often depend not only on medical care but also on genetic, environmental, and behavioral factors. They are usually based on group results rather than individual cases and thus do not indicate the quality of care delivered to an individual patient. Examples of outcome measures include mortality and patient satisfaction data.

IMPROVEMENT TOOLS

Historically, health care has focused on quality assurance (ie, a system for evaluating the delivery of services or the quality of products) and quality control (ie, a system for verifying and maintaining a desired level of quality). These methods used alone are not adequate to enhance outcomes. Checking for defects and recommending changes without recognizing the effects of these changes on other parts of the organization may improve one process but harm others. Consequently, the best organizations are now combining quality assurance with proactive QI.

Continuous QI (CQI) subscribes to the principle that opportunity for improvement exists in every process on every occasion.[11] Within an organization, it requires a commitment to constantly improve operations, processes, and activities to meet patient needs in an efficient, consistent, and cost-effective manner. The CQI model emphasizes the view of health care as a process and focuses on the system rather than the individual when considering improvement opportunities.

With or without CQI as part of the organizational improvement philosophy, QI methodologies can be used to accomplish improvement goals. The most common QI methodologies used in health care are plan-do-study-act (PDSA), six-sigma, and lean strategies. The choice of methodology depends on the nature of the improvement project. Within most methodologies, users will find similar techniques. Most methodologies typically include iterative testing of ideas and redesign of process or technology based on lessons learned. More recently, experts have been using principles from the different methodologies for the same project (ie, use of "lean-sigma" methodology), thus making distinctions less relevant.

PDSA Cycle

The PDSA cycle is the most commonly used approach for rapid cycle improvement in health care. This method involves a "trial-and-learning" approach in which a hypothesis or suggested solution for improvement is made and testing is carried out on a small scale before any changes are made to the whole system.[12,13] A logical sequence of 4 repetitive steps (Figure 2) is carried out over a course of small cycles, which eventually leads to exponential improvements. In the plan phase, ideas for improvement are detailed, tasks assigned, and expectations confirmed with the testing team. Measures of improvement are then selected. In the do phase, the plan is implemented, and any deviation from the plan is documented. These deviations are often called defects. The defects are then analyzed in the study phase. In this phase, the results from the test cycle are studied, and questions are asked regarding what went right, what went wrong, and what will be changed in the next test cycle. In the act phase, lessons learned from the study phase are incorporated into the test of change, and a decision is made about continuation of the test cycles. For the next cycle, the aforementioned steps are repeated.

Varkey et al[14] used PDSA cycles to enhance medication reconciliation (the process of ensuring the most complete and accurate list of medications across the continuum of care) in an ambulatory clinic. Each cycle of improvement lasted 24 hours, with changes made to the medication reconciliation process on the basis of lessons learned from each previous cycle. The first cycle entailed the creation of a data collection form to assess medication use among

patients. On the basis of feedback, the second cycle modified the form to prompt patient response to a medication list from the most recent visit to the clinic, which significantly enhanced patient participation and efficiency of collection. Other cycles included further modification of the form to make it patient and physician friendly, education of health care professionals, auditing, and feedback regarding physicians' performance of the reconciliation process. The average number of discrepancies per patient decreased by more than 50% (from 5.24 to 2.46) by the end of the project; the physician-documented medication list contained 47.3% of patient-reported medications at the start of the study and improved to 92.6% by the end of the study. At the end of 1 month, the new medication reconciliation process was standardized and implemented in the clinic.

Langley and Nolan et al developed the Model for Improvement to assist those contemplating an improvement initiative. The model recommends setting a focused aim, clearly articulating time frames, and identifying measurable goals at the start of a project. All 3 steps can then be incorporated into the PDSA process.[12,13]

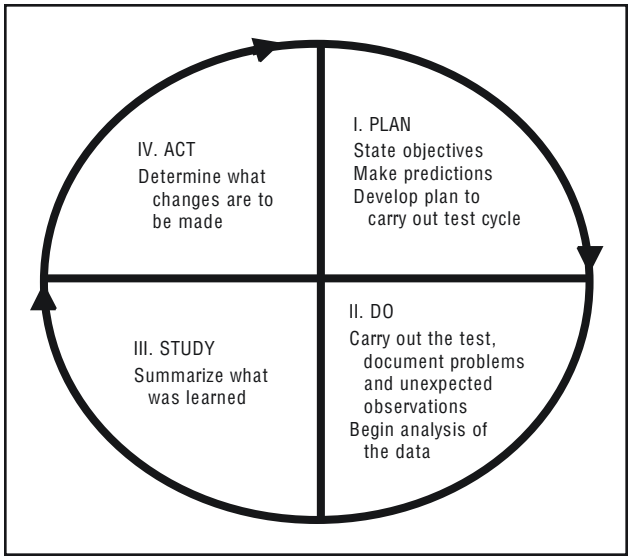

FIGURE 2. The approach most commonly used for rapid cycle improvement in health care is the plan-do-study-act method in which 4 repetitive steps are carried out over the course of small cycles. Adapted from Langley et al,[13] with permission from Jossey-Bass.

Six-Sigma

Originated by Motorola, Inc (Schaumbrug, Ill) in the mid 1980s, six-sigma is a rigorous statistical measurement methodology designed to reduce cost, decrease process variation, and eliminate defects.[15] "Sigma" is a statistical unit reflecting the number of SDs a given process is from perfection. For example, at the level of six-sigma, a process has about 3.4 defects per million opportunities (DPMO) and is virtually error free (99.9996%). Once DPMO has been calculated, sigma values can be looked up in tables that can be found in common statistics books or software packages. Teams can then identify the level of intended magnitude of improvement.

Six-sigma is achieved through a series of steps: define, measure, analyze, improve, and control. The first step (define) entails the creation of a project charter. A project charter defines the customer's needs, project scope, goals, success criteria, team members, and project deadlines. In the second step (measurement), a data collection plan for the process is developed, and data are collected from several sources to determine the depth of defects or errors (DPMO) in the system. Control charts are created to study the process further. In the third step (analyze), data analysis occurs, deviation from standards is identified, and sources of process variation are used to test a hypothesis. In the fourth step (improve), creative solutions and implementation plans are developed. In the final step (control), the process is controlled by implementing policies, guidelines, and error-proofing strategies to make reverting to the old process impossible. Quality controls are developed for ongoing monitoring of the new process.

Organizations that use a combination of lean and six-sigma (lean-sigma) methodologies incorporate a testing phase during the fourth step (improve). In this step, teams create solutions, develop tests of change, learn from the test, improve the change, and then test again, eventually finding the best-fit solution. By the time a solution is ready to be implemented, it has undergone many tests of change and has a greater chance of acceptance.

The Charleston Area Medical Center (Charleston, WV) used six-sigma methodology to evaluate and improve its rate of colon and vascular surgical site infections. At the start of the project, the surgical infection rate was zero-sigma. A multidisciplinary team of surgeons, an anesthesiologist, safety personnel, an epidemiologist, the chief of nursing, and 2 six-sigma specialists was assembled to assist with the project. A business case was developed, and data were collected with use of a detailed abstraction tool. After careful analysis, a preoperative order set was developed with a checklist that included recommended antibiotics and weight-based dosages. Education of team members, use of physician report cards, and prompting of surgeons by anesthetists and nurses (if the patient arrived at the preoperative holding area without an antibiotic order) were some of the other interventions implemented during the project. At the time of the publication of the report, the surgical site infection rate at the Charleston Area Medical Center had decreased by 91% (2.86 sigma), with a potential annual savings in excess of $1 million.[16]

Lean Methodology

Taiichi Ohno, a Toyota Motor Corporation engineer, revolutionized thinking about process inefficiency or "waste" in the early 1950s, leading to the creation of the Toyota Production System (TPS).[17] Application of TPS resulted in the use of the term *lean* in many industries, including health care. Lean methodology is driven by the identified needs of the customer and aims to improve processes by removing non–value-added activities. Non–value-added activities, also referred to as waste, do not add to the business margin or the customer's experience, and the customer is often not willing to pay for them. Seven different types of waste have been identified, including overproduction or underproduction, wasted inventory, rework or rejects (ie, assembly mistakes), wasted motion (ie, poor work area ergonomics), waste associated with waiting (ie, patients waiting to be seen for appointments), waste associated with processing (ie, outdated policies and procedures), and waste from transport or handling (ie, transporting patients unnecessarily).[18] Lean tools maximize value-added steps in the best possible sequence to deliver continuous flow. Services or products are delivered when the customer needs them and how the customer requests them.

One of the most commonly used tools in lean methodology is called *value stream mapping* (VSM). This tool graphically displays the process of services or product delivery with use of inputs, throughputs, and outputs. A current VSM is typically done at the beginning of a project, and opportunities for improvement are highlighted. Thereafter, front-line staff generate ideas for improvement. The improvement team is expected to test their ideas using kaizens, highly choreographed, rapid-change events in which improvement ideas are expeditiously tested and implemented. Future state VSMs are often designed during the kaizen workshops to depict new ideas.

To create an organized, cost-efficient workplace that has clear work processes and standards, lean experts often recommend the 5S strategy: *s*ort—sorting items in the immediate work area and keeping only those that are needed frequently; *s*hine—cleaning the workplace and inspecting equipment to look for abnormal wear; *s*traighten—set work items in order after the efficiency of the workflow has been optimized through VSM; *s*ystemize—standardization of workflow processes; and *s*ustain—sustaining gains made from the previous 4 steps.

Using TPS techniques, the Park Nicollet Medical Center (Minneapolis, Minn) decreased patient waiting times, allowing the center's new ambulatory clinic to eliminate waiting rooms. Before implementation of the lean strategy, patients were scheduled to see their physicians in groups, which led to the need for waiting rooms. With the lean plan, patients were checked in using a concept of continuous flow. Appointments were scheduled in 10-minute intervals, with the appointments for the nurse, doctor, and diagnostic testing services scheduled in sequence. The Park Nicollet Medical Center also addressed surgical case cart content standardization using lean concepts. By agreement on a standard set of instruments for surgical procedures, instrument counts were reduced by 60%. As a result, 40,000 fewer instruments are sterilized each month, saving thousands of dollars for the hospital. The clinic saved about $7.5 million in 2004 using lean techniques.[19,20]

QI VS RESEARCH

Confusion often exists about whether a project is associated with QI or research.[21-24] Most QI projects include data collection in small samples, frequent changes in protocols and interventions, discarding poor ideas, and pursuing ideas that work. This constantly changing baseline makes it problematic to think of QI as traditional research. However, the concepts of QI projects and QI research are not mutually exclusive.

Clearly, the objective of most QI projects is to efficiently address the need of a local situation. Research seeks to address problems in a manner that will provide more generalizable results. However, a QI project can also be considered research if (1) the tested intervention involves a deviation from established practices, (2) individual patients are the subjects, (3) randomization or blinding is conducted, and (4) participants are subjected to additional risks or burdens beyond usual clinical practice to make results generalizable.[25-27] Furthermore, the activity should collect baseline data from large data sets to allow appropriately powered statistical testing. Randomized controlled trials, controlled studies, preintervention and postintervention studies, and time series are commonly used methods in QI research.[28,29]

CONCLUSION

During the past 2 decades, a increase in QI activities has been slow but steady across the health care sector, perhaps influenced by market and regulatory pressures that encourage health delivery plans, employer and consumer involvement, and public reporting of performance information. A structured approach to QI using established rules of engagement has demonstrated utility in many situations common to medical care, including standardization of care, enhancement of patient safety, management of chronic disease, and preventive care. Pay-for-performance initiatives,[30] accreditation standards for health care systems,[31] and a focus on outcome-based competencies in medical education[32,33] provide increasing urgency for clinicians to engage in QI initiatives. Front-line health care professionals will be most effective in optimally

improving quality and performance in their environment if they first appreciate the characteristics and tools available for enhancing quality of care as discussed in this review.

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Questions About QI in Health Care

1. Which <u>one</u> of the following would be the <u>*most valid*</u> outcome measure for the effectiveness of hypertension treatment?
   a. Number of antihypertensive prescriptions
   b. Prevalence of heart disease in the population
   c. Incidence of stroke in the population
   d. Cost of hospitalizations for the population
   e. Number of clinic visits related to hypertension per year

2. Which <u>one</u> of the following is the <u>*correct*</u> definition of PDSA?
   a. Plan-design-survey-action
   b. Plan-do-study-act
   c. Process-deployed-suggestions-action
   d. Product-development-score-audit
   e. Product-design-satisfaction-analysis

3. At the level of six-sigma, a process has which <u>one</u> of the following measurements?
   a. 3.4 DPMO
   b. 1.2 DPMO
   c. 6.8 DPMO
   d. 0 DPMO
   e. 6 DPMO

4. Which <u>one</u> of the following tools is <u>*commonly used*</u> in lean methodology to display process inputs, throughputs, and outputs?
   a. Flow stream mapping
   b. Lean value streams
   c. Flow streams
   d. VSM
   e. Swim lane mapping

5. Which <u>one</u> of the following is the <u>*best*</u> example of a QI project?
   a. Randomized trial of the effect of an upgraded colonoscope
   b. Patient survey to assess the prevalence of depression in the population to enhance management of the disorder in that population
   c. Use of a new heart-lung machine for surgery when it has been shown to be efficacious in animals
   d. Reduction in patient "no show" rates in an ambulatory clinic
   e. Prospective trial of a modified pneumonia vaccination to reduce rates of pneumonia among elderly patients

Correct answers:
1. *c*, 2. *b*, 3. *a*, 4. *d*, 5. *d*