CHAPTER 4

Defining Healthcare Quality and Value

Quality means doing it right when no one is looking.

—Henry Ford

Improving safety, quality, and value are the cornerstones of healthcare transformation. Although there are many ways in which quality and value are defined and measured, healthcare organizations (HCOs) must adopt and internalize their own definitions of quality in order to create quality goals, objectives, and targets that are meaningful and relevant to the organization and, more importantly, the patients they serve. The adage, "You can't improve what you can't measure," applies to healthcare analytics; this chapter will discuss why and how quality must be defined in quantifiable terms so that data analytics can be effectively leveraged to measure, monitor, and maintain healthcare improvements.

What Is Quality?

From the patient's perspective, healthcare is often thought of in terms of quality and expressed in questions such as, "Which hospital or provider will provide me the best healthcare possible?" Because patients are concerned with receiving high-quality (and affordable) care, quality of care delivery should be of utmost importance to every HCO. Many HCOs stake their reputation on the quality of their care, and patients' lives literally depend on it. Hospitals, clinics, and providers that are deemed to be of high quality earn stellar reputations, attract patients, are successful at attracting top staff (including both clinical and research professionals), and earn more money, which can be in part reinvested into QI initiatives.

What is *quality*? Some people claim to be able to know quality when they see it when it comes to things like automobiles, clothes, and houses. But how do they "know" quality? In vehicles, the attributes that owners associate with quality range from how solidly the door closes to more quantifiable attributes such as gas mileage. For some people, the perception of quality may all be in the brand name. With regard to everyday items, most people have defined their own sets of desirable attributes and criteria for identifying quality in their favorite products and brands.

Tip

Quality must be defined in quantifiable terms to enable measurement, monitoring, analysis, and, most important, decision making and action.

The Institute of Medicine defines *quality* as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] This definition implies that healthcare is expected to have a net benefit to the patient and that the measurement of quality must reflect patient satisfaction, health status and quality-of-life measures, and the patient/provider interaction and decision-making process. By this definition, the provision of care "should reflect appropriate use of the most current knowledge about scientific, clinical, technical, interpersonal, manual, cognitive, organizational, and management elements of health care."[2.]

A textbook definition of *quality* provides a starting point, but it is up to HCOs to apply and adapt the sentiments contained within such a definition to their own particular needs and circumstances. Quality has many facets in healthcare, so it is necessary for every HCO to thoroughly understand and define in meaningful terms what quality is to all relevant stakeholders, including and especially patients.

Many HCOs are well-meaning when initiating QI activities but falter because quality is defined in too broad or general terms consisting of good sentiment but little substance. Applying the analytics lens early in the QI process helps to remind HCOs that quality must be defined in terms that are quantifiable—meaning they can be measured, monitored, analyzed, and acted on.

Quality

According to the Institute of Medicine, "quality" is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

Defining Value in Healthcare

Common themes in healthcare quality include performing the right actions correctly and consistently while achieving outcomes that are considered to be desirable to the patient. Related to this is the concept of *value*, which means that the care provided was able to improve the patient's health and well-being, resulted in a positive experience, and, most important, achieved the desired outcomes. According to corporate strategy expert Michael Porter, "rigorous, disciplined measurement and improvement of value is the best way to drive system progress";[3] he also asserts that healthcare, even now, remains largely unmeasured and therefore misunderstood. Activities that add value to a patient's visit (known as "value-added" activities) must meet the following three criteria:[4]

1. The customer (or patient) must be willing to pay for the stated activity (or activities) being performed.
2. The activity must in some way transform the product or service being provided.
3. The activity must be completed properly on the first attempt and achieve the desired outcomes.

The concept of value-added is one way to measure how much of an activity directly contributes to an outcome versus how much is "non-value-added," or waste. Non-value-added activities are those that do not directly contribute to the outcome in a significant way except perhaps to delay it. Inefficient processes and workflows negatively impact outcomes, slow down patient flow, may cost more, and result in poor patient satisfaction.

(In some jurisdictions such as those with publicly funded healthcare insurance, patients do not pay directly for many healthcare services. In these cases, the concept of "paying" for service includes other healthcare rationing methods, including waiting. Although patients may not have to pay out-of-pocket for a service, how long they need to wait for a particular service or procedure becomes a measuring factor of value.)

Value is always defined in relation to a customer—that is, whether the customer experienced value or not. When one thinks of the "customer" in healthcare, the patient immediately comes to mind. But there are many other examples of customer relationships in healthcare; in fact, any interaction that involves some combination of healthcare provider, unit, department, or service and the exchange of information, material, and/or patients can be considered a customer relationship and examined as such. For example, the emergency department may be considered a customer of the diagnostic imaging department when emergency patients are sent for X-rays or other imaging tests.

Value = (Outcomes) / (Cost)

According to Porter, value can be quantified by the ratio of desired outcomes relative to cost (as illustrated in the previous equation).[5] This representation helps to ensure that value is measured relative to the outcomes achieved via service delivery, not simply by volume of services provided. Porter states that outcomes are condition-specific and multidimensional—that is, no single outcome can capture the results of care. Costs, according to Porter, are the sum of costs for the full cycle of care for a patient's medical condition, and are *not* the cost of individual services provided.

Also related to value is patient satisfaction. For a variety of reasons, ranging from long wait times to a doctor's perceived poor "bedside manner," all aspects related to the treatment of a patient could be done technically correct yet the patient might not be totally happy with his or her experience. Given how quickly word of bad healthcare experiences can spread on social media and negatively impact the reputation of an HCO, it is vitally important for HCOs to identify and rectify the causes of poor patient satisfaction.

Table 4.1 highlights some examples of value-added and non-value-added activities that can be found within healthcare. For example, interacting with a healthcare provider or receiving treatment may be considered adding value to a patient's experience, whereas sitting idle in a waiting room waiting to be seen or suffering through repeated blood draws due to botched testing or faulty equipment is most definitely *not* adding value.

RATIO OF VALUE-ADDED TO NON-VALUE-ADDED ACTIVITY

As a general rule of thumb, somewhere between 5 percent and 20 percent of activity in healthcare can be considered value-added, whereas the remainder is considered non-value-added.

TABLE 4.1 Examples of Value-Added and Non-Value-Added Activities in Healthcare

Role	Value-Added Activity	Non-Value-Added Activity
Diagnostic imaging technician	Performing an X-ray	Waiting for porter to deliver patient to diagnostic imaging unit
Patient	Being assessed or treated by a clinician	Waiting to be seen by a clinician
Laboratory technician	Performing a lab test	Returning a requisition that is not completed properly or adequately
Nurse	Assessing or providing treatment to a patient	Double-documenting on computer and paper

One objective of healthcare improvement activities is to maximize the time that healthcare workers spend doing value-added activities while reducing the number of barriers to efficiency that result in non-value-added activities. When developing healthcare indicators, targets, and analytics that monitor and evaluate value, include both value-added activities and non-value-added activities. Examining just one type of activity or the other will not provide a complete picture of performance. For example, one measure of performance is a patient's time with a physician (considered to be value-added). If a physician is spending more value-added time with patients but this activity is resulting in an increased time *between* patients, which may result in fewer patients being seen per day, this performance change may not have the desired net effect. Effective use of analytics can help to ensure that improvements in one aspect of quality and value do not have a negative impact on other areas.

> **Tip**
>
> Consider both value-added and non-value-added activities when designing analytics for quality and performance improvement.

Improving a System

HCOs fit the classic definition of "system," which is a "group of interacting, interrelated, or interdependent elements forming a complex whole."[6] Healthcare consists of many types of organizational units that range from major facilities such as hospitals to physicians' practices. Most healthcare facilities themselves consist of many departments, units, programs, services, and administrative functions within a single facility. And some HCOs consist of *many* individual facilities.

In addition to the myriad departments, services, and facilities within an HCO, it is necessary to take into account the many ways in which an HCO needs to measure quality, and how these quality measures are to be used. Even top-performing HCOs are very unlikely to achieve high quality in every aspect of their performance. And due to many dynamic environmental variables such as changing demographics, patient needs, and staffing, a high-performing HCO may experience a gradual (or sudden) deterioration in performance if its policies and workflows are not kept up to date or are not robust enough to accommodate such changes.

The complexity of healthcare demands that a robust approach to measuring quality be followed. As discussed above, it is entirely possible that "improvements" in one area of healthcare can actually negatively

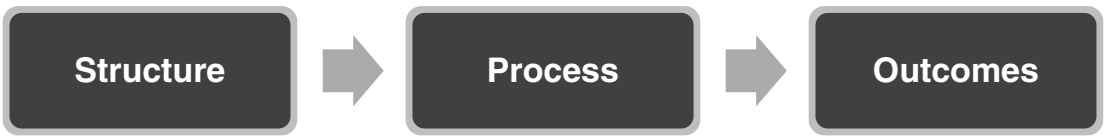

FIGURE 4.1 Three Components of Healthcare Quality Measurement

impact care in another. For this reason, healthcare quality and performance must be looked at from multiple perspectives; one approach is to consider healthcare from the perspectives of structure, process, and outcomes.[7]

As Figure 4.1 illustrates, these three elements—structure, process, and outcomes—form a continuum of quality measurement. Ultimately, "process measures must be linked to outcomes if they are to be effective measures of quality."[8] Patient outcomes (and other quality measures) depend on which processes and workflows are performed, how efficient and effective they are, and how well they are performed. The structure of an HCO (that is, the management, policies, and resources) will determine the organization's ability to innovate and to adopt and sustain the most efficient and effective processes and workflows possible. Without all three types of measures, only an incomplete evaluation of quality is possible within an organization.

STRUCTURE The "structure" of healthcare includes what are considered to be relatively stable aspects: healthcare delivery, including the various tools, technologies, and other resources available; the physical environment/surroundings in which the providers of healthcare work; and the overall organizational features (such as policies and management), all of which can promote high quality and optimal performance or hinder it.

Although the extent and impact of structural elements such as "leadership" and "policies" can be challenging to quantify and link to processes and outcomes, structural elements that can be quantified can be very useful. Structural elements that fall into the latter category include:

- Number of funded intensive care unit (ICU) beds
- Specialty trained physician coverage in ICU
- Number of CT scanners and their availability

Structural information is very often used to provide context to other healthcare performance data. For example, increases in lab test turnaround times that occur during certain times of day or certain days of the week may in fact be due to structure-related issues such as a reduced number of technicians. Structure-related measures help when comparing performance between units or sites. For example, two emergency departments may see similar numbers of patients in a day and experience similar lengths of stay,

but if one hospital is operating with fewer beds or more physicians, that information is important to consider.

PROCESS Processes are the various activities performed by healthcare providers and the interactions between healthcare providers and patients (and/or their family members) in the course of providing medical care to the patient. Processes are very often where HCOs begin with quality and performance improvements. There are several reasons for this. First, processes can be relatively easy to measure. Traditionally, QI activities would consist of time-and-motion studies where key time intervals in a process could be measured. These measurements would form baseline performance data, against which improved processes could be measured.

Healthcare information technology now makes the collection and analysis of time-and-motion data much more convenient. Many clinical systems (such as electronic medical records [EMRs]) capture well-documented patient trajectory data throughout a healthcare encounter. Table 4.2 provides examples of the type of data that can be used for analysis of processes likely available on EMRs and other electronic clinical systems.

Tip

When developing analytics for performance monitoring and QI, be sure to include relevant structure, process, and outcome measures.

TABLE 4.2 Examples of Process Data

Process	Process Data
Emergency department registration	Time of arrival at emergency department Time of registration start Time of registration completion Registration clerk name/ID
Patient X-ray	Time X-ray test requisted Type of X-ray requested Clinical provider requesting X-ray Time of porter arrival for pickup Name/ID of porter Time patient leaves department for X-ray Time of X-ray start Time of X-ray completion X-ray room used Name/ID of X-ray tech Time patient returns to department Time X-ray images available for viewing

For More Indicators

There are indicator sets published by various governmental and other healthcare-related agencies. These indicators are constantly evolving as information systems and needs of healthcare change. Please visit this book's web site, http://HealthcareAnalyticsBook.com, for links to the most current healthcare indicator sets, such as the Healthcare Effectiveness Data and Information Set.

OUTCOMES An outcome is an individual, quantifiable endpoint that is focused on the patient. Examples of types of outcomes include:

- Morbidity
- Mortality
- Readmission
- Length of stay

As the results of care, outcomes are an endpoint of a treatment or other process and typically are what is of main concern to the patient. According to Porter, health outcomes should:[9]

- Include health circumstances most relevant to patients
- Cover both near term and longer term
- Consider risk factors or initial conditions to allow for risk adjustment

When developing analytics for quality measurement, be sure that all the necessary and appropriate outcomes are considered. Keep in mind that a set of outcomes exist for any medical condition or primary preventive care. Because healthcare is complex, some outcomes may even be in conflict with one another and therefore need to be weighed against one another.

Structure, Process, and Outcomes

Consider the example of a hospital surgical unit when putting these three aspects of quality together. Elements of the structure include the number of surgeons, nurses, and operating rooms, plus the various technologies available, and administrative and medical policies under which the providers must practice. The process elements are those that measure percentage of on-time starts. Finally, examples of outcome measures include the rate of critical occurrences and the mortality rate from surgery.

When reporting structure, process, and outcome data over the same time period, be aware of the risk associated with lagging indicators. A lagging indicator is one that shows a response at some time after a situational or systemic change. For example, suppose improved hospital discharge processes result in patients getting home from hospital sooner; process indicators will show lower hospital lengths of stay shortly after implementation. Shorter hospital stays, however, may result in some patients being discharged too early who may need to return to the hospital; the recidivism rate, an outcome measure, will also show an increase, but likely after some time period, given that rates of recidivism are relatively low and would take time to manifest in the data. Because of this, the change in the outcome indicator may not be apparent until some time after the process indicator shows a change. This is why it is important to continue to monitor both process and outcome indicators after an improvement activity, to ensure that positive process changes and resultant positive outcomes are sustained, and that any hint of increased negative outcomes is detected.

Overview of Healthcare QI

Most HCOs are continually striving to improve quality out of both desire to become better and necessity (because quality is a constantly moving target). The environment in which HCOs operate is in a continual state of flux, with many issues that must be faced, including:

- External challenges (such as regulatory changes and financing issues);
- Internal challenges (including human resource management);
- Changing needs of patients (due to an aging and/or increasing population); and
- Technology (that can be both practice-changing and lifesaving but may also be expensive).

This constantly changing environment requires HCOs to be always adapting, innovating, and improving, because what worked just fine yesterday may be considered irrelevant or obsolete tomorrow. But what does "improving healthcare" mean, and what does it require? And are all changes and innovations necessarily improvements? How can we tell?

Healthcare QI has been described as "better patient experience and outcomes achieved through changing provider behavior and organization through using a systematic change method and strategies."[10] Healthcare QI can also be considered as "systematic, data-guided activities designed to bring about immediate improvement in health care delivery in particular settings."[11]

What is important about healthcare QI is the focus on patient experience. After all, the patient is the primary customer of the healthcare system, and the only reason the system exists in the first place. Patients should not be viewed as passive "recipients" of healthcare but rather as individuals who can and should expect high-quality service and care. The statement above notes that healthcare improvement is brought about by "changing provider behavior and organization" and recognizes that it is the providers of healthcare that must improve their processes and activities to help ensure a better patient experience. Finally, the statement recognizes that change in provider behavior and organization requires "a systematic change method and strategies"—that the changes required do not and cannot occur without a concerted effort to identify what needs to be changed and a structured approach to bring about that change.

Using Systematic QI Methodologies

If QI requires a systematic change method, what methods are the most successful HCOs engaged in to achieve high levels of quality?

Many, if not most, successful HCOs employ an established improvement or management methodology. There are many of these approaches used in healthcare today, including Lean, Six Sigma, total quality management, constraints management, and numerous variants (such as Lean Six Sigma). Although these frameworks differ in their philosophies, tools, and methods, they are similar in that they provide a structured approach for improving quality and performance within a complex organization.

For More Information

Please visit this book's web site, http://HealthcareAnalyticsBook.com, for links to more resources and references about the QI methodologies mentioned in this book.

How Information Guides Improvement Activities

One commonality of all healthcare quality efforts is their requirement for *information* in order to be successful. Modern healthcare improvement requires accurate, timely, and readily available information through almost every phase of a quality and performance improvement initiative. The use of analytics helps to distill data into information that is relevant for a given improvement initiative and usable by QI teams to gauge effectiveness of their efforts.

One of the benefits offered by analytics is the capability to augment management reports and dashboards with deep insight into past, current, and even future performance. Some of the insight available from analytics tools includes determining if processes are in control or not (from a statistical process control perspective), determining if changes over a period are merely random variation or in fact statistically significant, and predicting what future performance might be.

One reason that some healthcare improvement initiatives fail is the lack of initial baseline assessment and ongoing evaluation and follow-up. Interestingly, there is a tendency to assume that changes introduced into healthcare processes, workflows, and systems actually will have the desired effect, and that changes in quality or performance can be monitored with the same reporting mechanisms with which performance deteriorated in the first place. This is not the case.

Analytics can help determine if changes detected in performance indicators are merely due to chance, or represent actual (and sustained) change. Changes in performance indicators (both negative and positive) need to be communicated to leaders, quality facilitators, and frontline staff in a timely manner. This timely intelligence is important so that midcourse corrections to workflows can be implemented, if necessary, or to confirm that changes are having the desired effect.

Without the relevant and rapid analysis and feedback that is possible with business intelligence and analytics, evaluations are often performed too late to allow for effective midcourse corrections. If poor performance is not detected in time, it is possible for additional poorly designed processes to become ingrained within a unit, department, program, or entire enterprise. Without a robust system in place to evaluate the impact of changes to processes, the true effect of such changes can never be known.

Tip

It is a basic tenet of QI that you can't improve what you don't measure.

Common QI Frameworks in Healthcare

Many of the current causes of healthcare inefficiency have evolved over time through the adoption of ad hoc process changes, workarounds, and decisions based on gut feeling, not evidence. In fact, many of the workarounds impeding quality today were likely at one time lauded as heroic measures demonstrating a "can-do" attitude, but now only contribute to the tangled web of inefficiency and waste.

To achieve quality and performance improvement requires careful planning, methodological change, and persistent follow-up and evaluation. The discipline required to follow a structured QI approach is one of the most challenging cultural changes for an HCO to overcome. Healthcare professionals pride themselves in being action-oriented problem solvers; such behavior, when misdirected, is how much of the inefficiency gets introduced into healthcare in the first place.

To overcome haphazard improvement efforts and stubborn barriers to improving quality, many HCOs are turning to proven QI frameworks or methodologies to provide the disciplined approach required to understand the scope of a problem, to develop and implement solutions, and to evaluate outcomes of the changes.

A QI framework provides the tools, methods, and management philosophies required to drive improvement efforts and to achieve the desired improvement goals of the organization. QI activities typically are led by an experienced facilitator, and participants include knowledgeable subject matter experts, some of whom are experienced with QI initiatives and others with no such experience. QI teams tend to be assembled for a specific project (requiring specific subject matter expertise), and disbanded as projects are completed and other teams form up for new initiatives.

There are many QI frameworks used within healthcare. Some are proprietary to an individual or corporation, some are homegrown within a HCO, and some are generally in the public domain (although some proprietary "flavors" of several public-domain methodologies exist). Many of the most common QI frameworks have their genesis in other industries, such as manufacturing and aerospace, and have since been adapted for use in healthcare.

Using quality frameworks that have been proven in other industries has allowed the healthcare practitioners of these quality methodologies to learn from what has worked well elsewhere and decide upon approaches that will likely have the greatest impact on and probability of success in healthcare. For the purposes of this book, three of the QI methodologies commonly used in healthcare today will be discussed:

1. Plan-Do-Study-Act (PDSA)
2. Lean
3. Six Sigma

See Table 4.3 for a high-level summary of these QI methodologies.

There are many considerations that HCOs account for when deciding upon which of these QI methodology to use. QI methodologies are not one-size-fits-all, and the decision of which methodology to use is situational and dependent on several factors. For example, PDSA might be well suited

TABLE 4.3 Comparing Common Improvement Methodologies

Methodology	Approach to Improvement	Process Overview
PDSA	Conducting experiments and testing improvements iteratively on a local, small-scale basis.	Plan Do Study Act
Lean	Eliminating waste, improving flow, maximizing value-added and minimizing non-value-added activities.	Identify value Identify value stream Flow Pull Perfection
Six Sigma	Reducing variation and eliminating deviation in processes.	Define Measure Analyze Improve Control

for implementing a new patient scheduling process but might be inadequate for an initiative to reduce hospital-acquired infections, which may require a methodology with more analytic and process design rigor.

Many volumes have been written that cover each of these methodologies in complete detail. Within the limits of this book, only the essentials of each methodology are presented with the intent of illustrating how different methodologies can work in concert to address the problems of healthcare. This section will also discuss how analytics can be applied to improve how information is consumed by QI teams and other stakeholders working to improve healthcare quality and performance.

The following sections will look at how the PDSA, Lean, and Six Sigma improvement methodologies are used in healthcare, describe some of their key features, and discuss how analytics can play an important role in improving the capabilities of teams using these methodologies to plan better projects and to perform more in-depth and more accurate evaluations.

Plan-Do-Study-Act

PDSA is a common approach for improving processes in healthcare (and other industries). Also known as Plan-Do-Check-Act (PDCA), the basic premise is to encourage innovation by experimenting with a change in process, studying the results, and making refinements as necessary to achieve and sustain desired outcomes. PDSA is considered a staple of healthcare QI; for example, PDSA is a central tenet of the United Kingdom's National Health Service QI framework.[12]

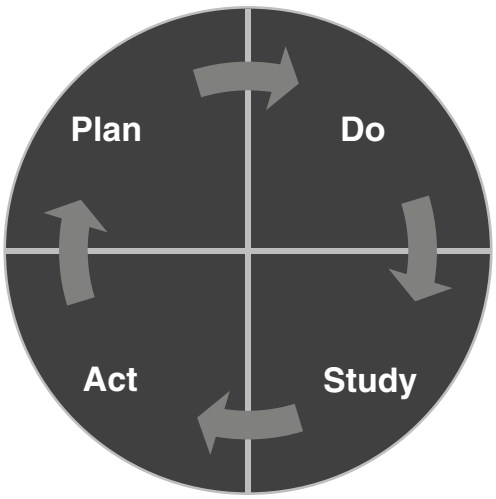

FIGURE 4.2 Plan, Do, Study, Act (PDSA) Cycle

PDSA begins, as do all QI activities, with a clearly defined goal. That is, the problem being addressed must be clearly defined, and the desired outcomes should be established as targets. Once these are in place, the PDSA cycle, as illustrated in Figure 4.2, proceeds as described next:

1. **Plan.** Start by planning the changes to a process that are to be implemented and tested.
2. **Do.** Proceed with carrying out the plan and making the desired changes to the specified process.
3. **Study.** Review the impact and outcomes of the implemented changes. What were the results of the process changes; were the anticipated outcomes achieved?
4. **Act.** Determine if the changes can be implemented as is, or if further cycles are necessary to refine the approach.

HCOs can utilize the PDSA approach as a stand-alone approach, or within other QI methodologies. For example, during Lean Rapid Improvement Events (where teams spend focused time experimenting with ways to reduce waste and inefficiency), teams may conduct several PDSA cycles throughout the event as new processes are tried, evaluated, and improved.

PLAN During the PDSA "Plan" phase, ensure that the problem is well defined and desired outcomes have been decided upon. Having a clear problem statement or project aim helps to maintain the team's focus on what is to be accomplished. To be effective, improvement aims should be framed in time-specific and measurable terms that define which specific populations of patients are going to be affected.

Appropriate metrics need to be decided upon by the time the planning phase is completed. Effective metrics are what the PDSA teams use to see if a change actually occurred. Metrics help to answer the question, "How will we know that a change is an improvement?" and the measures should be directly related to the improvement aim statement or the objective of the PDSA.

When defining the metrics for a PDSA cycle, ensure that the data used for establishing the impact either is already available or it will need to be somehow obtained. HCOs with comprehensive EMR (or other clinical systems) in place will likely be able to leverage existing data to measure performance. Organizations without the benefit of preexisting data sources will need to consider how to capture the data required. This plan to collect data needs to include who will be responsible for the data capture, how it will be captured, when it will be captured, and of course, what it is that is going to be manually captured.

Tip

Don't limit your PDSA (or any other QI initiative) efforts only to those areas and/or processes for which there is available electronic data. Although manual collection of data may seem anachronistic (especially when mentioned in a healthcare analytics book!), manual collection in many cases is not prohibitively cumbersome (requiring only a few data points collected each day), and may lead to real performance improvements. Process changes likely to yield significant results with a reasonable effort—"low-hanging fruit"—may be located in processes or areas of healthcare that have not undergone the sometimes intense scrutiny associated with having installed an EMR system.

DO The actual implementation of and experimentation with process changes occurs during the PDSA "Do" phase. In addition to making changes to processes and procedures, data collection and initial analysis occur during this phase. If manual data collection is required, that is done with the frequency and on the appropriate form specified in the data collection plan.

If electronic data is available, initial evaluation of this data should include checking to ensure that the metrics and reports defined and utilized for the initiative are sensitive to the changes being made in the process. In other words, determine whether the right things are being measured in the right way.

During this phase of a PDSA cycle, information can be communicated to project team members and stakeholders via project dashboards and regular reporting. Early analysis of data is critical in order to implement midcourse changes early in a project. Such midcourse corrections may be necessary if metrics and other data are not sensitive to the changes being made, or if changes being made are not having the desired effect—whether because the outcomes are not as strong as desired, or because the changes are having a negative impact.

STUDY The "Study" phase is where the bulk of the analysis occurs in a PDSA cycle. At this point in the cycle, QI teams will analyze the data in more detail to determine whether a change has occurred, and what the magnitude of the change actually is. In PDSA cycles, run charts and statistical process control charts are commonly used to monitor trends in performance and to detect changes in outcomes. It is also common to use statistical testing to detect changes in performance. For example, a *t*-test or an ANOVA might be an appropriate statistical test to detect whether a change is statistically significant (that is, whether the observed results are likely to have occurred purely by chance). In fact, both the charting and statistical approaches can be used in a complementary fashion to identify whether an improvement has indeed occurred. See Chapter 9 for a discussion of statistical and control chart principles.

ACT The last step in a PDSA cycle is "Act," where a decision is made about what to do next based on what is learned in the Study phase. There are three general outcomes of a PDSA cycle:

1. The change is successful—targets and goals have been met; no further testing required.
2. The changes are promising—process is closer to achieving goals and targets, but further revisions and experimentation are necessary.
3. The changes are not successful, and are not promising—a different approach to addressing the problem is necessary; different opportunities or approaches should be pursued.

In the event of a successful change that is meeting performance targets, the project team has identified a solution to a quality or performance issue, has utilized available data and analytics tools to determine that the changes were successful, and has achieved the desired outcomes. In the event of a successful PDSA, the work is not immediately over. To maintain momentum and ensure that the changes are sustained, the team must develop and implement a long-term process monitoring and evaluation plan. Ongoing monitoring is used to alert the HCO if process performance begins to deteriorate. If deterioration is caught early,

actions can be taken to reverse it and maintain optimal performance levels.

SUMMARY OF PDSA PDSA cycles are perhaps the most commonly used QI approach in healthcare. Many nurses and other clinical providers are familiar with PDSA, having been taught it in nursing or medical school, and with many HCOs having adopted PDSA as a standard QI approach. PDSA can be a powerful tool that healthcare QI teams can use to address issues of importance. One common complaint of PDSA, however, is that PDSA cycles tend to be too localized—that is, engaging exclusively in PDSA may result in HCO fixing many little problems while still not addressing greater overall issues.

Lean

Lean is a proven QI methodology with a successful track record in healthcare. Although largely developed in other industries, and perhaps made most famous in the automobile production industry as the Toyota Production System, Lean nonetheless has been gaining ground in healthcare as a QI methodology.

Some healthcare practitioners seem to be biased against Lean because of its roots in manufacturing—that somehow by adopting Lean we are viewing healthcare as no more than an assembly line. Nothing could be further from the truth, given that Lean is focused on maximizing value for the patient and reducing inefficiencies and waste in the delivery of healthcare.

The Lean Enterprise Institute, one of the leading organizations in the promotion of Lean in healthcare, states that Lean is "a set of concepts, principles, and tools used to create and deliver the most value from the customers' perspective while consuming the fewest resources and fully utilizing the knowledge and skills of the people performing the work."[13] Another way of looking at Lean is that "Lean thinking helps to identify the least wasteful way to provide better, safer healthcare to patients—with minimal delays."[14]

At its root, Lean is a systematic process of identifying and eliminating waste and evaluating improvements. A common misconception that many healthcare professionals have of Lean, however, is that it used only to find ways of "doing more with less," that is, to streamline processes only eventually to eliminate clinical or other staff positions. This opinion tends to erect barriers, because most healthcare professionals already feel they are working as hard as they possibly can and that they already make do in less than ideal conditions and with fewer than ideal resources.

What many healthcare practitioners don't realize is that by reducing waste and inefficiencies in healthcare processes, Lean *improves* the work environment by reducing and eliminating barriers to providing safe and

effective care to patients. The bottom line is that Lean helps to *reduce* the chaos and overworked feelings of healthcare providers by finding them *more* time to focus on the good work they already do and provide *more* value for the patient.

An important concept of Lean is the *value stream map* (VSM). Similar in concept to other forms of process mapping, VSMs identify both the amount of time that each step in a process takes and the amount of waiting time that occurs between steps in a process. VSMs invariably illustrate how most of the time a patient spends within a healthcare facility is actually spent waiting for the next step in a process to occur.[15] From the patient's perspective, this is wasted time and not value-added.

Lean has at its core the philosophy of identifying the least wasteful ways to provide value to patients; to support this philosophy, there are many tools associated with Lean—the benefit of its having evolved through many industries over the last several decades. The tools are commonly used by Lean practitioners to structure QI activities, to identify root causes of problems, and to develop and communicate standard work, among other tools. Although there are many tools associated with Lean, successful Lean initiatives require more than simply using a collection of tools.

The Tools of Lean

Please visit this book's web site, http://HealthcareAnalyticsBook.com, for links, resources, and references about the many Lean tools available.

The two major components of Lean in healthcare are a management system and a set of tools. Because Lean requires strong organizational support from the top on down in order to be successful, the management system exists to ensure that the corporate culture essential to Lean is in place. Lean management tools help build organizational commitment to innovation and experimentation, promote the ideals of providing value to patients, and reduce the fear of a failure in the name of learning. The Lean management system provides a framework for effectively guiding improvement activities from initial project conception and problem identification through to evaluation and sustainment while keeping the focus on providing value to the patient.

THE FIVE PRINCIPLES OF LEAN There are five key principles specific to Lean that practitioners adhere to on improvement initiatives: specify value, identify the value stream, flow, pull, and perfection.[16] These five principles help HCOs to identify and eliminate waste and efficiency within their processes,

and to redesign the processes to maximize flow and value. These principles of Lean are described next from a healthcare perspective:

1. **Specify value.** Value derived from a process must always be defined from the end customer's perspective and in relation to a specific product or service. In healthcare, the primary customer is the patient, but many other customer relationships exist (such as a physician being a customer of the hospital laboratory).
2. **Identify the value stream.** Map all the steps that are required in order to deliver the product or service to the customer. For example, mapping an elective surgery value stream would involve defining all process steps (including time intervals and other critical variables) from when a decision is made to book a surgery to the time the surgery is performed.
3. **Flow.** Once a value stream has been mapped out in detail, the next step is to identify all wasteful (or non-value-adding) steps in the process such that all remaining value-adding steps flow with a minimum of interruptions, errors, and delays.
4. **Pull.** After flow is improved, it can be further enhanced by implementing a "pull" system based on patient need/demand. With a well-functioning pull system, diagnostics such as lab and imaging are always available when the patient requires these diagnostics (not at the convenience of the service provider), or when hospital admissions from emergency occur quickly after the need for admission is identified, not after some delay-inducing screening process.
5. **Perfection.** As waste and inefficiency are removed from the value stream, and as the proportion of value-added activity increases, return to the first step and continue until no waste exists.

These five principles are fundamental to the Lean approach to improving healthcare quality and performance. The iterative nature of these principles underlies the commitment that Lean requires to the ongoing pursuit of perfection, and that Lean is a journey that HCOs embark upon. The term "Lean Thinking" is used because all staff should at all times be identifying inefficiencies within their scope of work and thinking of ways to reduce or eliminate that waste.

THE EIGHT WASTES OF HEALTHCARE Always examining healthcare processes in the relentless search for waste and inefficiencies can be an extremely daunting task. To the uninitiated, even knowing where to begin can be a challenge. Because of this, the different types of waste (*muda* in Japanese) have been conveniently grouped into eight categories. These categories provide healthcare QI teams a valuable framework with which to more easily identify waste and inefficiencies within processes, and hence to identify more easily

TABLE 4.4 Summary of the Eight Wastes of Healthcare

Waste	Description
Unnecessary motion	The many physical steps needed to gather equipment, confirm instructions/orders, and organize the treatment space to care for the patient.
Unnecessary transportation	Excess movement of people (patients), supplies, forms, and information throughout a facility.
Defects and errors	Time spent doing something incorrectly, inspecting for errors, or fixing errors.
Waiting	Time spent waiting for the next event to occur or the next work activity.
Inventory	Any supply in excess of the absolute minimum requirements necessary to meet customer demand.
Processing waste	Extra effort that adds no value to the service being provided from the patient/customer point of view. Can occur when the patient is unnecessarily queried or reassessed by multiple providers.
Overproduction	Doing more than what is needed by the patient, or doing it sooner than is required.
Unused human potential	Any situation in which people are not utilized to the utmost of their skills/ability to add value to processes.

opportunities for improvement. Table 4.4 lists the eight wastes in healthcare, and provides a brief descriptive example of each.

SUMMARY OF LEAN The Lean approach of methodically identifying and removing waste from clinical processes, combined with a framework for identifying *muda* and the many tools available for problem solving and process optimization, is a very powerful toolset that many hospitals and other HCOs have used to obtain significant quality and performance improvements.

An analytics challenge associated with Lean is that data from clinical systems rarely explicitly captures value-added/non-value-added time and data associated with waste. For example, in the clinical systems I have seen, there has never been an entry field for documenting unnecessary motion. Analytics teams must work with process and subject matter experts to identify proxy measures that can be used to estimate some of these values. For example, time intervals between processes such as assessment and X-ray may be used as a proxy measure for waiting. When system data is clearly not available, it may be necessary to manually observe processes for a time to manually document critical process-related data. It is important that a lack of data never be used as an excuse to not undertake a QI initiative.

Six Sigma

Six Sigma is another QI methodology that is used in healthcare. In fact, Six Sigma is often used together with Lean to provide a rigorous QI approach. Six Sigma was originally developed in 1986 by Motorola as a set of tools and strategies for improving processes, but was arguably made famous by General Electric after it won the Malcolm Baldrige National Quality Award, one of the most prestigious awards for achieving quality, in 1988.

Whereas the goal of Lean is to eliminate waste while improving value to the customer, the approach taken by Six Sigma emphasizes the use of information (or management by facts) and statistical analyses to rigorously and routinely measure and improve an organization's performance, practices, and systems. With this approach, the goal of Six Sigma is to reduce the occurrence of defects or errors from their current level within an HCO to the Six Sigma standard of 3.4 defects or errors per million opportunities (or DPMO). To put this in perspective, some estimates are that a typical HCO has an error rate between 2,700 and 45,500 (3 and 2 sigma) errors per million opportunities.[17]

Six Sigma has many variations and has been adopted by and integrated into a wide variety of organizations in myriad industries. Although Six Sigma may vary in how it is utilized within an organization, it has several defining factors that all implementations should have in common. Most Six Sigma initiatives can be considered to have the following five elements in common:[18]

1. **Intent.** Six Sigma initiatives are undertaken with the intent to achieve significant improvement in a short time period.
2. **Strategy.** Six Sigma can be applied throughout an HCO as a corporate strategy for improvement, but can also be applied where appropriate at the tactical level on individual projects.
3. **Methodology.** Although a few Six Sigma methodologies exist, the most common is DMAIC (Define, Measure, Analyze, Improve, and Control).
4. **Tools.** The Six Sigma methodology consists of numerous tools. These fall into categories, including requirements gathering (Kano's model), statistical analysis (*t*-test and ANOVA), and experimentation. Some tools were designed for Six Sigma, while others (like most of the statistical methods) have been adopted into the methodology.
5. **Measurements.** Three of the most common measurements used in Six Sigma are DPU (defects/errors per unit), DPMO (defects per million opportunities), and Sigma level.

As mentioned above, perhaps the most common Six Sigma methodology used in healthcare is DMAIC, which stands for define, measure, analyze, improve, and control (see Figure 4.3).

FIGURE 4.3 Six Sigma DMAIC Process

The five phases of the Six Sigma DMAIC methodology constitute a structured and rigorous approach to identifying opportunities for improvement. The DMAIC methodology is described in more detail in Table 4.5.

The five stages of DMAIC are effective because they are rigorous and must be followed in the prescribed manner. Achieving Six Sigma levels of performance requires significant changes to occur in a process, and therefore Six Sigma is not something that can realistically be undertaken on a part-time basis—it takes a real commitment on the part of management and project teams to make Six Sigma work. Six Sigma is the most statistically intensive of the three methodologies discussed in this section; because of the various statistical and other analysis tools and techniques associated with it, there are training and certification programs such as Green Belt or Black Belt that enable Six Sigma practitioners to learn about and understand

TABLE 4.5 Six Sigma DMAIC Methodology

Stage	Description
Define	Clearly identify and state the problem or issue that is the focus of the QI activity, and outline the scope of the project. Determine what are the critical requirements of and key benefits to the customer. Agree on which process is to be improved, and on the plan to achieve those improvements.
Measure	Review all available data and measure the extent of the quality or performance problem (defects, errors, deviations) and obtain baseline performance information.
Analyze	Study the root cause(s) of the problem and develop potential solution alternatives based on the root cause. Tools include the Ishikawa (or fishbone) diagram for determining root causes and FMEA (failure modes and effects analysis).
Improve	During this phase, alternative processes are developed to help achieve the required outcomes. These possible alternatives are evaluated based on potential impact on the outcome, with the selected improvement demonstrating (via statistical analysis) the highest likelihood of achieving "breakthrough performance."
Control	During this phase, the project team ensures that improvements are sustained by taking ongoing measurements and conducting ongoing communications, reviews, and training on the new process.

these various tools and apply them appropriately. See Chapter 9 for a summary of several of the statistical and graphical analysis techniques that are commonly used with Six Sigma.

Working with QI Methodologies

By no means are PDSA, Lean, and Six Sigma the only improvement methodologies that are effectively used in HCOs. But these and the other methodologies all recognize one basic fact: healthcare improvement is nearly impossible without a structured, comprehensive, and robust methodology to identify and rank improvement opportunities, map out and improve processes, and evaluate outcomes. Many HCOs that are struggling with healthcare quality are doing so because they are not approaching healthcare improvement in a methodical way.

The benefit of having multiple improvement methodologies from which to choose means that HCOs can find the tool that best matches the needs of a particular type of quality or performance problem. The challenge, of course, is determining what that best fit is. The further challenge for analytics is to deliver on the information needs unique to a methodology.

It is also true that all serious improvement methodologies require data throughout the entire project life cycle—from deciding what the improvement priorities are to knowing when to turn attention to other issues. The true value of analytics is in providing the practitioners of structured QI methodologies with solid evidence and deep insight not only into *how* healthcare is performing, but *why* it is performing the way it is.

Notes

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