Chapter 2
Basics of Quality Improvement

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Executive Summary

The Institute of Medicine (IOM) defines quality of care as “the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” [1]. According to the Agency for Healthcare Research and Quality (AHRQ), “Quality improvement (QI) is the framework we use to systematically improve the ways care is delivered to patients. Processes have characteristics that can be measured, analyzed, improved, and controlled” [2]. In today’s healthcare field, an increasing focus is placed on medical errors, cost-effective medicine, public reporting, and pay for performance. As a result, payers and patients have turned to QI as a strategy and framework to address specific concerns within the current healthcare system. Crosby suggests that poor quality not only has a negative effect on patients but also squanders resources that could be used to treat other patients [3]. Therefore, internal QI is vital to the ability of a healthcare organization or practice to fulfill many goals including, but not limited to, maintaining the fiduciary relationship between the physician and the patient, enhancing medical care and care delivery, simplifying and streamlining procedures, reducing costs, increasing patient and provider satisfaction, and enhancing workplace morale and productivity. External QI is crucial for physician education, licensure and certification, benchmarking, accreditation, and health policy formulation.

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This chapter introduces quality management theories and practices that have evolved over the past 40 years and highlights some of the themes that have marked progress within the field. It also addresses the policies, philosophies, and processes that characterize the QI field today.

Learning Objectives

Upon completion of this chapter, readers should be able to:

- Describe the history of QI in the field of healthcare
- Describe the purpose and philosophy of QI
- Describe the tools, methods, and strategies for successful QI in healthcare
- List the key evidence-based QI initiatives that affect patient outcomes

The History of the Healthcare Quality Management Movement: Past to Present

In 1914, a surgeon named Ernest Codman developed one of the earliest initiatives in healthcare quality: challenging hospitals and physicians to take responsibility for the outcomes of their patients [4]. He called for a compilation and analysis of surgical outcomes and recorded pertinent data (patient case numbers, preoperative diagnoses, members of the operating team, procedures, and results) on pocket-sized cards which he then used to study outcomes.

Following Codman's early efforts, the next several decades focused primarily on evaluating poor outcomes and departures from standards, commonly referred to as quality assurance or quality control. This method focused on identifying deficient practitioners and mandating "improvements" (e.g., negative incentives, weeding out recalcitrant clinicians who refused to change). This narrow focus did not acknowledge the contribution of other organizational characteristics to QI such as leadership, resources, information systems, communication patterns among teams, or the patient's perception of quality.

In the 1960s, Avedis Donabedian created the structure, process, and outcome paradigm for assessing quality in healthcare [5]. This paradigm had such a profound influence that he is often thought of as the modern founder and leader of the quality field. His work influenced practitioners to identify various methods to enhance patient outcomes in the broad areas of structural, policy, and organizational changes as well as process change and patient preferences. These advances helped establish the systems approach to healthcare quality and its studies.

Quality as a business imperative evolved in the factory setting through specialization, mass production, and automation. In *Economic Control of Quality of Manufactured Product*, Shewhart points out that the goal should not be inspection and specifications but to minimize variation in processes and to focus on customer needs [6]. Influenced by his work with Shewhart, Deming recognized quality as a primary driver for business and communicated these methods to Japanese engineers and executives, which ultimately contributed to the tremendous successes in Japan in the 1950s and for years thereafter. Perhaps Deming's best-known contribution to American industry is a set of management principles that are applicable in large or small organizations and in any business sector [7]. Deming's 14 Points constituted a second conceptual development that both followed and extended the Donabedian model. Quality management was redefined as not just a technical, clinical exercise but also as an issue of culture and values, psychological climate, and leadership—it provided another model for the improvement process.

Deming's 14 Points for Management

1. Create constancy of purpose towards improvement. *Think long-term planning, not short-term reaction.*
2. Adopt the new philosophy. *Management as well as the workforce should actually adopt this philosophy.*
3. Cease dependence on inspection. *If variation is reduced, there is no need for inspection since defects (errors) will be reduced or eliminated.*
4. Move towards a single supplier for any one item. *Multiple suppliers mean variation.*
5. Improve constantly and forever. *Focus on continuous quality improvement.*
6. Institute training on the job. *Lack of training leads to variation among workers.*
7. Institute leadership. *This draws the distinction between leadership, which focuses on vision and models, and supervision, which focuses on meeting specific deliverables.*
8. Drive out fear. *Management through fear is counterproductive and prevents workers from acting in the organization's best interests.*
9. Break down barriers between departments. *Eliminate silos. All departments are interdependent and become each other's customers in producing outputs.*
10. Eliminate slogans and exhortations for the workforce. *It is not people who make most mistakes—it is the process in which they are working.*
11. Eliminate management by objective. *Production targets encourage shortcuts and the delivery of poor-quality goods.*
12. Remove barriers to pride of workmanship. *This leads to increased worker satisfaction.*
13. Institute education and self-improvement.
14. The transformation is everyone's job.

In the 1980s and 1990s, the work of Crosby, Deming, and Juran became well known in manufacturing across the United States [3, 7, 8]. This work brought attention to systems design, process controls, and involvement of the entire workforce. Many executives who served on hospital and health system boards started using these concepts to push medical quality leaders to look beyond the boundaries of clinical quality assurance. The boards were encouraged to consider all aspects of the healthcare organization as targets for improvement—from leadership style and behavior to the presence of information system support and collaboration between departments and disciplines. Clinical quality management was now seen as part of total quality management (TQM), which emphasizes that all members of the team possess a thorough understanding of the process and the knowledge of specific tools to assess and improve processes [9]. *Continuous quality improvement* (CQI), an important part of TQM, emphasizes the opportunity for improvement through continuous effort in every aspect of the organization's operations.

The philosophy of TQM includes the following set of management principles:
CQI: a philosophy of continuously seeking improvement
Innovation: meeting customer needs in a whole new way
Quality into daily work life: integrating management principles into employee daily life
Strategic quality planning: the influence on long- and short-term planning [9]

Concurrently, during the 1980s and 1990s, various stakeholders (e.g., purchasers, regulators, patients, advocates) began to call for a more open examination of the quality of care. During these decades, healthcare professionals experienced a gradual erosion of autonomous quality control efforts. Accrediting bodies, such as the National Committee for Quality Assurance (NCQA) and the Joint Commission, as well as organizations like the National Quality Forum (NQF), became increasingly involved in the collection and assessment of quality data across the nation.

In 1998, Chassin and Galvin characterized the problems of overuse, underuse, and misuse in medicine [10]:

Overuse: The potential for harm from a health service exceeds the possible benefit.

Underuse: A health service that would have produced favorable outcomes was not provided.

Misuse: A preventable complication occurs with an appropriate service.

They also called attention to practice variation in medicine and to the suboptimal patient outcomes associated with this variation [10].

In 1999, Kohn, Corrigan, and Donaldson estimated that at least 75,000 people die from medical errors every year [11]. This number was revised in 2013 by an evidence-based estimate of patient deaths associated with hospital care, based on a weighted average of four studies, which suggested that greater than 400,000 people die from medical error related to hospital care annually [12]. Under the editorship of Kohn et al., the IOM published *To Err Is Human: Building a Safer Health System* [11]. This report identified the systems that must be developed to decrease the number of medical errors in the United States. In a second report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, the IOM defined the state of the quality problem, offered recommendations for improvements, and outlined specific targets that would contribute to nationwide improvements [13] (see "Quality Measurement Framework" in Chap. 3).

During the 2000s and 2010s, quality improvement became increasingly important and an accepted practice in the medical field, utilizing accountability measures such as quality metrics designed to improve transparency in the payment for care, the delivery of care, and patient care overall [14]. Additional changes seen during this period included the use of big data and data analytics for quality improvement analysis as well as a shift in fee structure from fee-for-service toward value-based payment [15]. Also during this time, the development of formal quality leadership and management roles expanded to include offices such as chief quality officer, director of patient experience, and chief patient experience officer [16, 17].

The Purpose and Philosophy of Quality Management

The purpose and philosophy of quality management has evolved from an orientation toward policing (i.e., finding "bad apples" among primarily excellent physicians, nurses, and clinical teams) to a focus on the use of quality management as a tool for continuous development of high performance. Quality management can be thought of as having three aspects:

1. A means of accountability for the use of clinical and physical resources in the care of patients
2. An effort to continuously develop and improve the services provided to patients by care teams throughout the organization and the community
3. A mechanism to improve the clinical outcomes of patients as defined by the patient and the healthcare system

Because the focus of quality management has broadened, quality management programs currently tend to target both clinical and organizational structures and processes that lead to improved outcomes.

Modern quality management leaders are systems thinkers, attending to both operating- and strategic-level issues that concern quality. These quality management leaders put patients first, use data and information to examine and respond to problems, and rely on the participation of the entire workforce. They constantly seek changes that will co-produce improvement in a continuous cycle. Although outside regulators may check on the quality of care, the concerns of outsiders are dwarfed by the insiders' commitment to CQI of patient care systems and the outcomes they produce.

Case Study • • •

Using Continuous Quality Improvement to Decrease Mortality from Coronary Artery Bypass Graft Surgery

Using collaboration and CQI, the Northern New England Cardiovascular Disease Study Group, a voluntary regional consortium, achieved a 24% decline in mortality from coronary artery bypass graft (CABG) throughout the region [17]. This group included all cardiothoracic surgeons, interventional cardiologists, nurses, anesthesiologists, perfusionists, administrators, and scientists associated with the six medical centers in Maine, New Hampshire, and Vermont and one Massachusetts-based medical center that support CABG surgery and percutaneous coronary interventions. Training in CQI, benchmarking, and continued monitoring of outcomes allowed institutions to learn from one another. There were 293 fewer deaths (n = 575) than the 868 expected in the post-intervention period (mid-1991 through early 1992). Major improvements in hospital outcomes have occurred in relation to improving coronary stenting technology. Variability in practice patterns across the different practices was a major stimulus to enhance quality of care across all sites.

Implementing a Quality Improvement Project

Clinical QI aims to enhance implementation of evidence-based medicine into clinical practice and to inform quality measurement with evidence-based process measures linked to outcomes. Improvement projects often rise to the surface because of an adverse event or a patient or provider complaint, so there may not always be an opportunity to choose an improvement project. However, in instances when projects can be prioritized, reviewing potential improvement projects against the criteria depicted in Fig. 2.1 may help identify the best QI projects to undertake first. In general, one would prefer projects that fit in quadrants I or II and would avoid those with low impact.

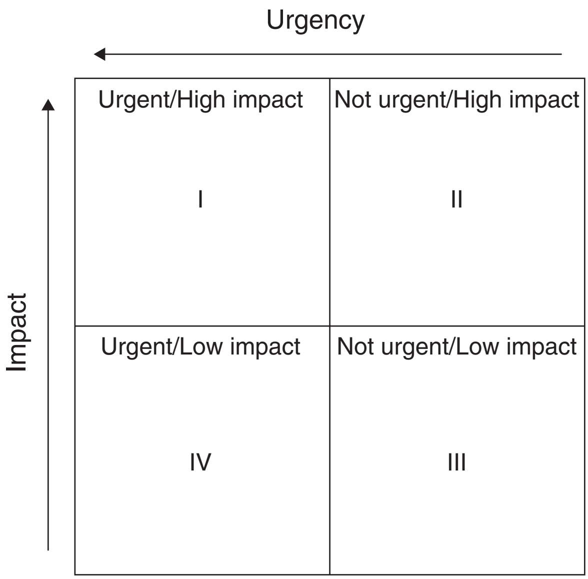


Fig. 2.1 Quadrant to help prioritize QI projects. From Bennett KE, Wichman R, Bentrock N et al. "Choosing a QI Project," Project Process Prioritization, Rochester, MN: Mayo Clinic Division of Engineering, September 1999; used with permission of Mayo Foundation for Medical Education and Research, all rights reserved

Tools for Quality Improvement

Process Mapping

Regardless of the improvement methodology used, once a QI project is chosen, a systematic process is key to guiding project implementation. Process mapping is a fundamental, yet often overlooked, step that is crucial to understanding an existing clinical or system process. Process mapping involves studying the entire process through various techniques including photography or videotaping, observation ("fly on the wall"), interviewing, field notes, and role-play as necessary. The process map can then be depicted using flow charts.

Flow Charts

These charts allow for identification of the alignment of processes that must be followed in the QI project. They identify the beginning and the end of the process and how one part of the process is dependent on another. Figure 2.2 is an example of a flow chart.

Matrix for the Use of Flow Charts
What does this method do?

- Allows a team to identify the actual flow or sequence of events in a process.

Why use this method?

- Shows unexpected complexity, problem areas, redundancy, and unnecessary loops and reveals areas where simplification and standardization may be possible.
- Compares and contrasts the actual versus the ideal flow of a process to identify improvement opportunities.
- Allows a team to come to an agreement on the steps of the process and examine which activities may impact process performance.
- Identifies locations where additional data can be collected and researched.
- Serves as a training aid for understanding and completing the process.

How do you effectively use this method?

- Identify the boundaries of the process.
- Clearly define where the process under discussion begins and ends.
- Team members should agree on the level of detail they must show on the flow chart to clearly understand the process and identify problem areas.

Cause-and-Effect (Fishbone) Diagram

Another common tool used in QI projects is the cause-and-effect diagram, also referred to as a fishbone or Ishikawa diagram, which can be used to enhance the QI team's ability to map the full range of possible root contributors to the desired outcome. A fishbone diagram is a graphical representation of relationships among the fundamental variables on which the group will focus when initiating improvement action (see Fig. 2.3). The diagram is used to expand the group's purview and to begin to generate consensus on targets for action. It is commonly used to analyze sentinel events and is described in more detail in Chap. 4.

Brainstorming and Affinity Diagrams

The technique of storyboarding grew out of the film and cartoon industry; Disney Studios perfected it to an art form. In planning and organizational work, storyboarding is more properly called an affinity diagram. The process begins with brainstorming, during which every participant writes ideas about addressing a given issue on separate cards and mounts those cards on a large corkboard or similar display (the storyboard).

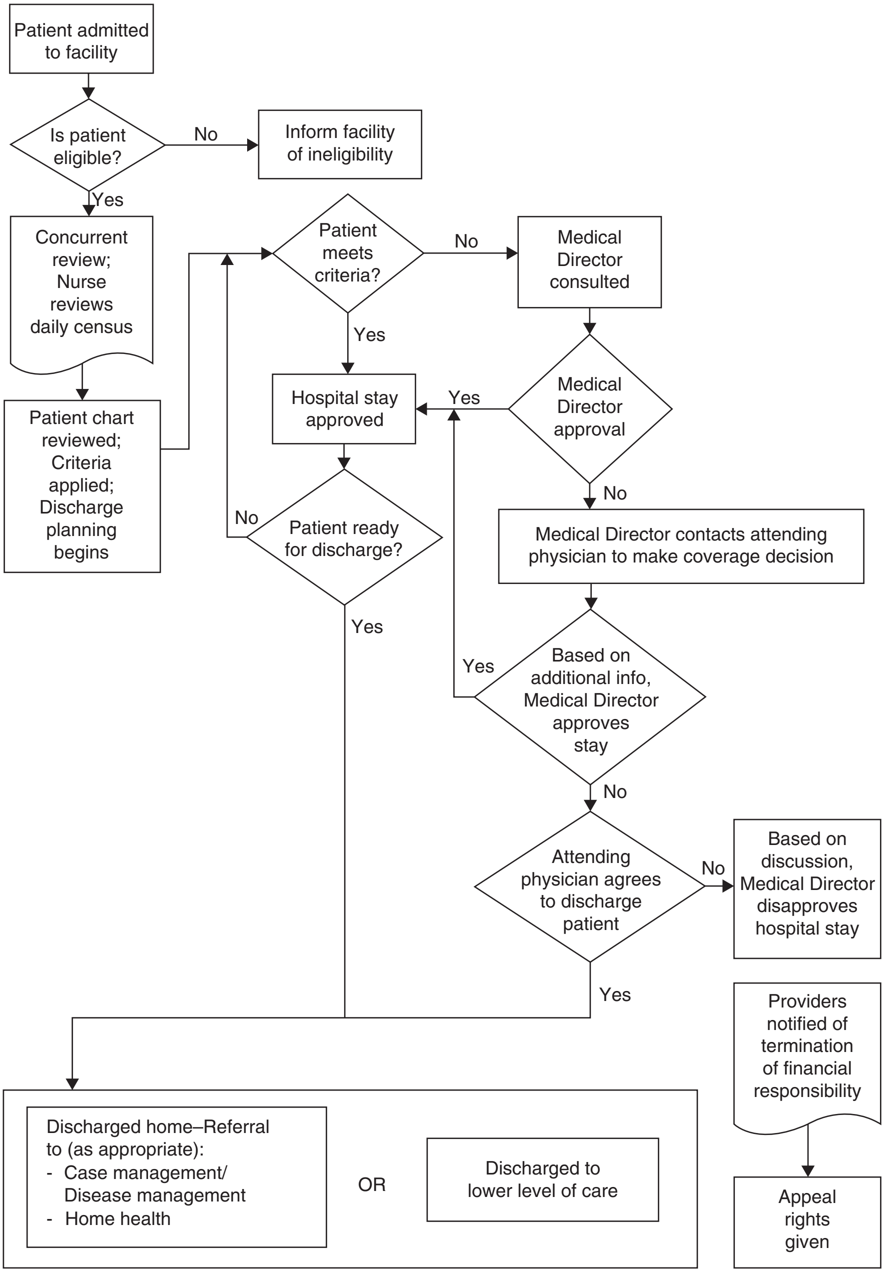


Fig. 2.2 Example of a flow chart for admission

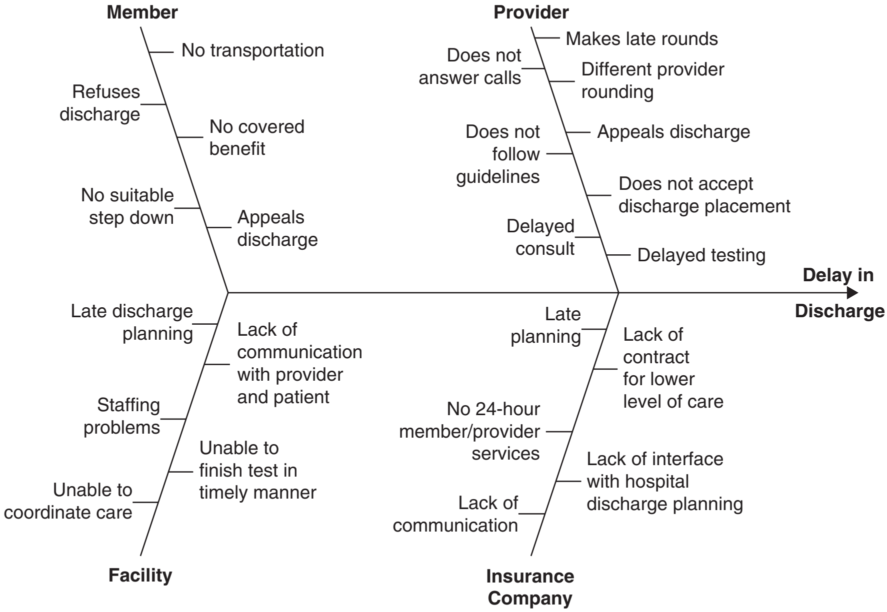


Fig. 2.3 Example of a fishbone diagram illustrating late discharge from a hospital

Creating Great Ideas by Brainstorming

What does this method do?

- Provides a way to creatively and efficiently generate a high volume of ideas on any topic by creating a process that is free of criticism and judgment.

Why use this method?

- Encourages open thinking and teamwork.
- Involves all team members.
- Allows team members to build on each other's creativity and maintain a unified goal.

How do you effectively use this method?

- For clarity, state the question to be discussed and write it down.
- Allow everyone to offer ideas without criticism!
- Write each idea down, visible to all team members.
- Review the list of ideas for clarity and discard duplicates.
- Participants may build on the ideas of others.

During the ensuing discussion, the ideas are grouped according to subject matter—hence the term affinity diagram. Further discussion enables the participants to rearrange the groups into clusters and identify subject headings and causes, symptoms, impacts, or side effects of the original issue. The affinity diagram that results from the brainstorming session is typically used at the beginning of a QI project or process. If affinity diagramming occurs later in the process, when individuals or group members are identifying actions for addressing immediate problems, the diagram will most likely contain alternatives that the group members have identified as actions to take.

Gathering and Grouping Ideas in an Affinity Diagram
What does this method do?

- Allows a team to organize and summarize ideas after a brainstorming session to better understand the essence of a problem and possibly reach breakthrough solutions.

Why use this method?

- Encourages creativity by all team members at all phases of the process.
- Encourages creative connectivity of ideas and issues and allows breakthrough solutions to emerge naturally (even on long-standing issues).
- Encourages participant ownership of results.

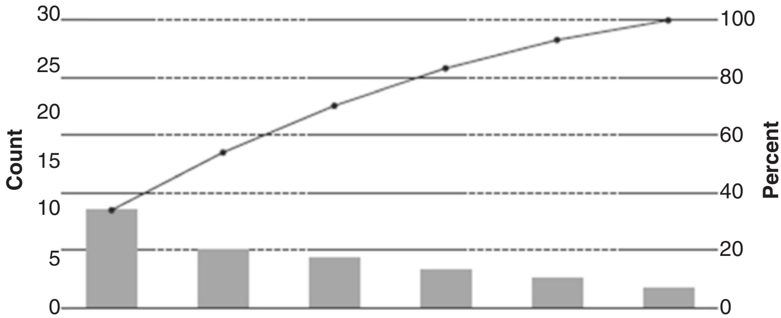
How do you effectively use this method?

- Phrase the issue under discussion in a clear and complete sentence.
- Brainstorm at least 20 ideas and issues and record each on sticky notes.
- Sort ideas into related groups of five to ten ideas.
- Create a summary or header cards using the consensus for each group.

Pareto Chart

Once themes and clusters of potential causes of a lack of quality in an area of care are noted, contributing factors must be identified. Without inspecting the data, managers may assume that all causes contribute equally to poor quality or that one or more causes are most prominent. Pareto diagrams, often expressed as bar graphs, help to show the relative contribution of various causes to the problem addressed (see Chap. 4). Figure 2.4 presents a Pareto chart that was developed to help a provider group examine its late discharges from a hospital.

Using a Pareto Chart
What does this method do?



Defect	Procedure Delay	No Step Down Unit	Physician on Call Does Rounds	Lack of PM Rounding	Patient Refuses Discharge	Family Does Not Show Up
Count	10	6	5	4	3	2
Percent	33.3	20.0	16.7	13.3	10.0	6.7
Cumulative %	33.3	53.3	70.0	83.3	93.3	100.0

Fig. 2.4 Example of a Pareto chart to examine reasons for delayed discharge from a hospital

- Expends efforts on problems that offer the best possible improvement by showing their relative frequency or size in a descending bar graph.

Why use this method?

- Helps a team to focus on causes that will have the greatest impact if solved.
- Based on the Pareto principle: 20% of the sources cause 80% of any problem.
- Helps prevent "shifting the problem," i.e., the "solution" removes some causes but worsens others.

How do you effectively use this method?

- Decide which problem you want to know more about.
- Categorize the causes or problems that will be monitored, compared, and ranked by brainstorming or with existing data.
- Choose the most meaningful unit of measurement, such as frequency or cost.
- Choose the time period for the study.
- Collect the key data on each problem category either in "real time" or by reviewing historical data.
- Compare the relative frequency or cost of each problem category.
- List problem categories on the horizontal line and frequencies on the vertical line.
- Interpret the results: The tallest bars indicate the largest contributors to the overall problem.

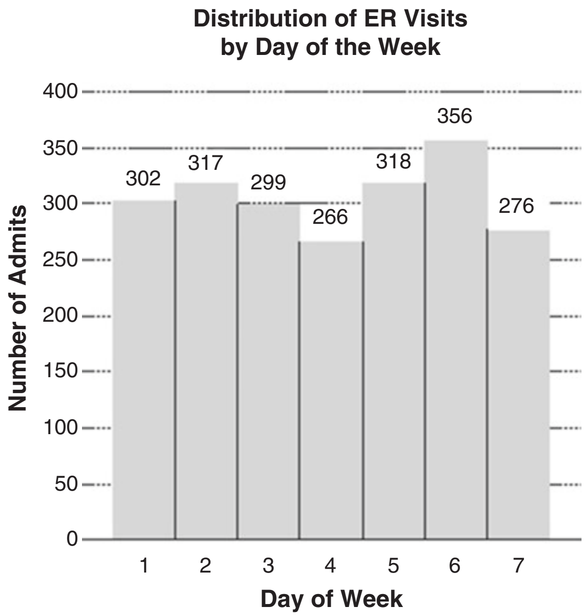


Fig. 2.5 Example of a histogram showing the number of ER visits per day of the week

Histogram

The *histogram* can help elucidate the reasons for a variation by depicting the frequency of each value of the quantitative variable (see Chap. 4). For example, the first step in understanding the reasons for variation in hospital discharge times is to choose a sample time span, perhaps a 2-week period, and to count the number of patients who were discharged each hour during that period. The values can then be graphed on a histogram (see Fig. 2.5).

Using a Histogram to Achieve Process Centering, Spread, and Shape
What does this method do?

- Aids in making decisions about a process or product that could be improved after examining the variation.

Why use this method?

- Displays measurement data in bar graph format, distributed in categories.
- Displays large amounts of data that are not easily interpreted in tabular form.
- Shows the relative frequency of occurrence of various data values.
- Depicts the centering, variation, and shape of the data for easy interpretation.
- Helps to indicate if the process has changed.
- Displays the variation in the process quite easily.

How do you effectively use this method?

- Gather and tabulate data on a process, product, or procedure (e.g., time, weight, size, frequency of occurrences, test scores, GPAs, pass/fail rates, number of days to complete a cycle).
- Calculate the rate of the data by subtracting the smallest number in the data set from the largest. Call this value R.
- Decide about how many bars (or classes) to display in the eventual histogram. Call this number K. This number should never be less than 4 and seldom exceeds 12. With 100 numbers, K = 7 generally works well. With 1000 pieces of data, K = 11 works well.
- Determine the fixed width of each class by dividing the range, R, by the number of classes, K. This value should be rounded to a "nice" number, generally a number ending in a zero. For example, 11.3 would not a "nice" number, but 10 would. Call this number I, for interval width. The use of "nice" numbers avoids strange scales on the x-axis of the histogram.
- Create a table of upper and lower class limits. Add the interval width to the first "nice" number less the lowest value in the data set to determine the upper limit of the first class.
- The first "nice" number becomes the lowest lower limit of the first class. The upper limit of the first becomes the lower limit of the second class. Adding the interval width (I) to the lower limit of the second class determines the upper limit for the second class. Repeat this process until the largest upper limit exceeds the largest data piece. You should have approximate classes or categories in total.
- Plot the frequency data on the histogram framework by drawing vertical bars for each class. The height of each bar represents the number.
- Note the frequency of values between the lower and upper limits of that particular class.
- Interpret the histogram for skew and clustering problems.

Bar Chart

A *bar chart* is similar to a histogram, except that the variable of interest is not a quantitative measure, such as discharge time, but rather a categorical variable, such as a department within the hospital. Bar charts are commonly used to illustrate comparisons, such as the number of patients discharged before or after 11:00 a.m. for each of several hospital services, and may help identify departments that require further attention. As with histograms, bar charts are especially useful for diagnosis and evaluation. A bar chart that displays the number of laboratory tests performed by a physician group by month is shown in Fig. 2.6.

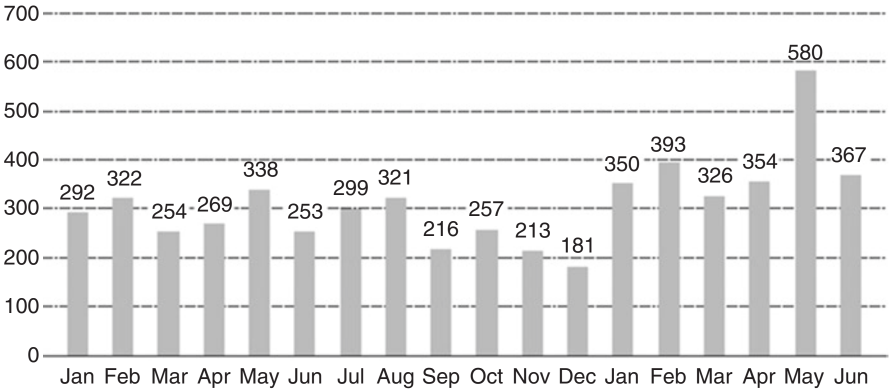


Fig. 2.6 Example of a bar chart showing number of lab tests performed by month

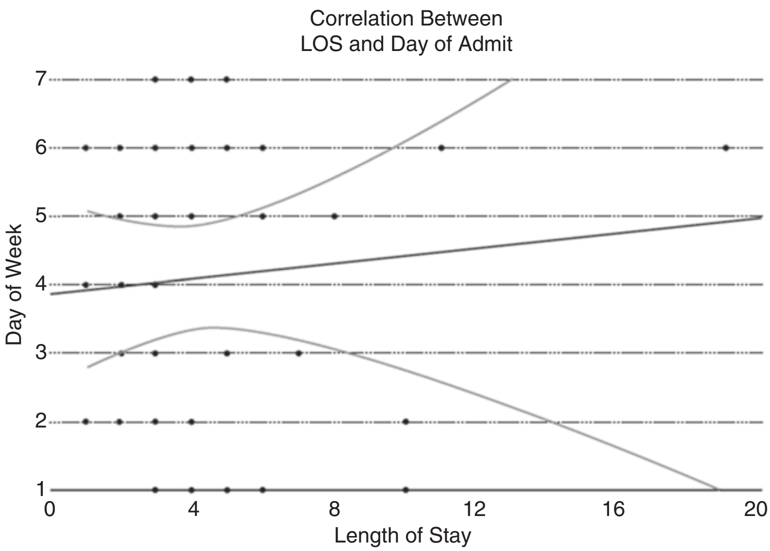


Fig. 2.7 Example of a scatter diagram showing correlation between length of stay and day of admission

Scatter Diagram

The *scatter diagram* in Fig. 2.7 shows the relationship between length of stay (LOS) and time of discharge and examines whether there is a pattern to this relationship; if so, the QI team could then investigate whether the pattern was controllable.

Using a Scatter Diagram to Measure Relationships Between Variables
What does this method do?

- Analyzes and identifies the possible relationship between the changes observed in two different measurements.
- Interpret the data to determine if any pattern or trend emerges, noting positive or negative correlation.

Why use this method?

- Provides the data to confirm a hypothesis.
- Depicts both visual and statistical means to test the strength of a potential relationship.
- Provides a good follow-up to a cause-and-effect diagram to determine if more than a consensus connection exists between causes and the effect.

How do you effectively use this method?

- Collect the data (50–100 paired samples of related data) and construct a data sheet.
- Draw the x-axis and the y-axis, and plot points corresponding to these measures for each observation.

Statistical Control Chart

Processes typically have two kinds of variation, normal variation that occurs under normal conditions and abnormal variation that occurs under unusual circumstances, and often can be traced to a cause. A *statistical control chart* represents continuous application of a particular statistical decision rule to distinguish between normal and abnormal variations. Statistical control charts have been widely used to control quality in the management process. The use of a statistical control chart is further explained in Chap. 3.

Methods for Quality Improvement

While there are several methods for quality improvement, we will focus on the three that are most commonly used in healthcare. Each has common elements and varies slightly for different settings, all eventually leading to testing and change. Principles from multiple different methodologies are used for the same project, making their differences less relevant and drawing on their commonalities and symbiosis (e.g., use of Sigma-Lean methodology) [18].

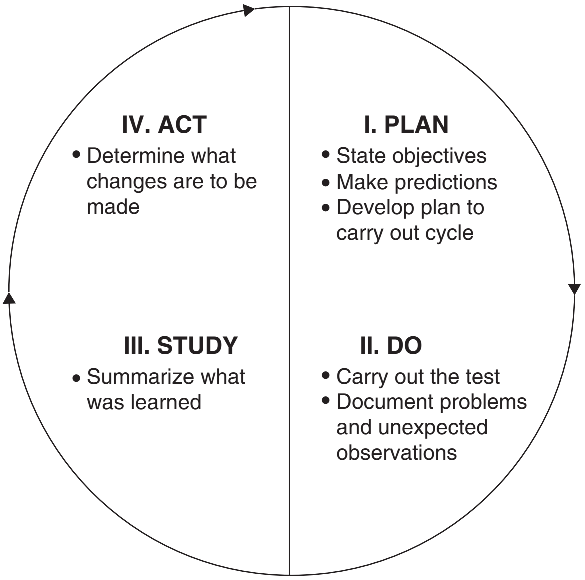


Fig. 2.8 The PDSA or Shewhart cycle. Republished with permission of John Wiley & Sons, from *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*, by G.J. Langley et al., 1996; permission conveyed through Copyright Clearance Center, Inc.

Plan, Do, Study, Act Methodology

The process of Plan, Do, Study, Act (PDSA) is also referred to as the Shewhart cycle. It involves a trial-and-learning methodology, whereby a hypothesis or suggested solution for improvement is made and tested on a small scale before any changes are made to the whole system [19]. The process entails a logical sequence of four repetitive steps, shown in Fig. 2.8.

During the Plan stage of the cycle, the areas in need of QI are identified. These can be high-cost, high-volume, high-risk areas or areas in which outcome results are not as good as the organization would like. During this part of the cycle, Nolan's three-question model [20] is often used to determine the aim for the project, establish measures, and select what changes should be made.

The first question in Nolan's model, "What are you trying to accomplish?", helps define the goal or aim of the project. The aim of the project should be time-specific and measurable. The second question, "How will you know a change is an improvement?", guides the selection of appropriate measurement tools and methodologies. The measures chosen should be quantifiable and should demonstrate if a specific change actually leads to an improvement. Finally, Nolan's third question, "What changes can you make that will result in an improvement?", generates improvement ideas. The changes that are most likely to result in improvement are chosen and tested through the PDSA cycle.

The Do part of the cycle entails implementation and documenting problems and unexpected observations. The Study portion of the cycle involves collecting data from the Do part of the cycle and then producing information from those data. The final stage of the cycle, Act, involves determining whether the intervention produced improved outcomes as reflected in the information. If the intervention did

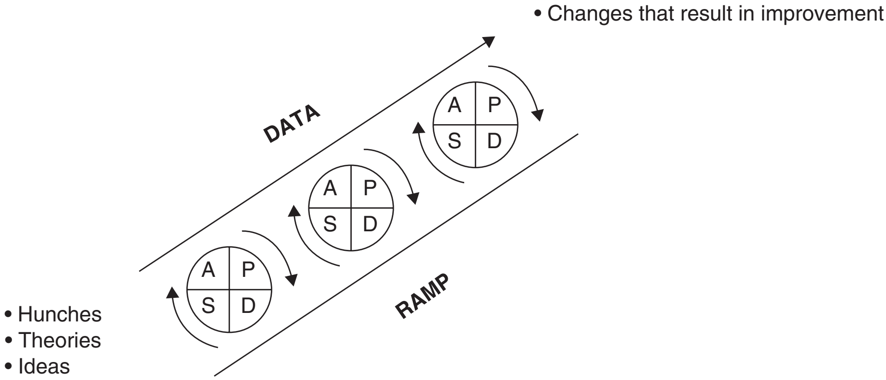


Fig. 2.9 Ramp of improvement: a sequence of multiple PDSA cycles. Republished with permission of John Wiley & Sons, from *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*, by G.J. Langley et al., 1996; permission conveyed through Copyright Clearance Center, Inc.

produce improved outcomes, it may be continued to determine whether improvement can be maintained. If it did not produce improved outcomes, the cycle begins anew, and a new intervention is tried. The process is carried out over a course of small cycles, which eventually leads to exponential improvements, displayed in Fig. 2.9. The tools of data analysis and presentation described previously are used at one or more points in this problem-solving process.

Six Sigma

Sigma is the 18th letter of the Greek alphabet and the symbol for standard deviation. It is now utilized in service and healthcare organizations.

The aim of Six Sigma is to reach a level of quality that resides in the six standard deviations of average performance, resulting in an error rate of 0.0003% or about 3.4 defects per million opportunities; at this stage, the process is virtually error-free (99.9996%) [21].

Six Sigma uses data to identify quality problems, potential quality problems, and areas for improvement. The Six Sigma approach concentrates on customer-driven measures and acceptable quality and relies on data-driven process improvement. Six Sigma is achieved through a series of steps (akin to the PDSA cycle) identified as define, measure, analyze, improve, and control (DMAIC). Six Sigma is generally instituted by practitioners, known as Six Sigma Black Belts, who have been trained in the use of the proper analytic tools to address quality problems. A certified Black Belt understands and effectively employs DMAIC, demonstrates team leadership, understands team dynamics, and is able to assign team member roles and responsibilities appropriately.

The first step of the DMAIC model entails the definition of the problem, the project parameters, and the establishment of an improvement objective. In the second step, measure, the measurement of each of the process steps is conducted, and data is collected. In the third step, an analysis of the collected data is performed to test a hypothesis about key process factors. In the fourth step, the process is improved by conducting a pilot test. In the final step of the cycle, the process is controlled by implementing the process improvement and continuously working to monitor and sustain the process.

For Six Sigma efforts to be successful, senior management must support them. These efforts cut across operational lines, use the most talented people in the organization, and move them into new areas. The Six Sigma concept has become popular in healthcare organizations and is useful for processes that are repeated in large numbers (e.g., laboratory tests, radiological procedures).

Case Study • • •

Use of Six Sigma to Reduce Process Variations and Costs in Radiology

The Commonwealth Health Corporation (CHC) in Bowling Green, Kentucky, is a not-for-profit integrated delivery network that includes three medical centers and one extended care facility with over 2000 employees. Six Sigma was implemented within the Radiology Department in early 1998. Department members were trained in the Six Sigma approach, and participants achieved Green Belt status. At the completion of projects, Green Belts progressed to Black Belts and then to Master Black Belt status. As a result, the Radiology project reduced wait times for patients, generated faster turnaround times for radiology reports, and increased productivity. CHC's team managed to increase throughput by 25% while using fewer resources and decreasing costs per radiology procedure by 21.5%. In total, radiology cost per procedure decreased from $68.13 to $49.55 for over 100,000 procedures a year, resulting in a $1.65 million cumulative savings. In addition, errors in magnet resonance imaging (MRIs) decreased by 90% resulting in a cost savings of $800,000 within the 18-month period [22].

Lean

Lean methodology is used to accelerate the velocity and reduce the cost of any process by removing any type of activity that absorbs resources and yet creates no value (also known as muda) [23]. Perhaps the most noted and benchmarked "lean" organization is Toyota Manufacturing of Japan. Several healthcare systems have used Toyota's process (also called the Toyota Production System [TPS]) to improve healthcare quality in their organization [24].

One of the common terms used in Lean is Kaizen, a Japanese word meaning *good change* which refers to gradual and orderly, continuous improvement [25]. Kaizen is essentially a rapid, relatively low-cost, simple, team-based approach to improvement. A Kaizen Blitz or a Kaizen event is an intense process for introducing rapid change into a work unit or organization using the ideas, motivation, and energy of the people who do the work. The general principles and approaches behind Kaizen are very useful in healthcare quality improvement strategies. Kaizen is implemented through practices that help employees propose their own ideas and solutions to problems with the goal of striving for perfection through employee involvement, creating solutions for problems, and effectively sustaining results over time [26].

Lean thinking improves process outcomes by removing non-value-added processes including the waste of overproduction and underproduction (e.g., smoothing day-to-day variations in radiological procedures), waste of inventory (e.g., excess patient IV pumps in storage), waste of rework rejects (e.g., poorly done lab tests), waste of motion (e.g., repeating several steps to obtain clinical data from a medical record), waste of waiting (e.g., patients waiting for appointments), waste of processing (e.g., decreasing steps in the emergency department admission process), and waste of transporting (e.g., unnecessary transfer of patients between patient care units). In addition, lean processes line up value-creating steps in the best possible sequence in order to deliver services or products just as the customer needs them and in just the manner the customer requested. One of the most commonly used tools is called value stream mapping, whereby the process is depicted in a physical graph in order to identify wasted effort or steps that do not add value for the customer.

The three QI methods discussed in this chapter are summarized and compared in Table 2.1.

Table 2.1 Comparison of three improvement methodologies

	PDSA	Six Sigma	Lean
Process steps	Plan, do, study, act	Design, measure, analyze, improve, control	Eliminate non-value-laden steps, eliminate defects, reduce cycle time
Improvement focus	Rapid cycles of improvement toward identifying optimal process improvement	Eliminate defects, customer-centric	Enhanced efficiency, elimination of non-value activities, variance reduction, and reduced cycle time. Product "flows" when the customer wants and needs it
Ideal use	A target project is chosen for improvement; time and resources are limited	A target project is chosen for improvement and resources are available. The project consists of an activity that is repeated with high frequency	Process efficiency is the focus Process can be clearly defined and is laden with non-value activities
Supports/tools for success	Environment for testing, prototyping, and piloting of ideas	Statistical process control charts, analytical tools, Six Sigma experts (i.e., black belts, green belts)	Value stream mapping, value analysis, Kaizen events

Commonly Used Quality Improvement Strategies

Most published literature suggests the use of multipronged approaches for successful QI as opposed to single interventions. Descriptions of commonly used QI strategies follow.

Academic Detailing

Academic detailing, also called *educational outreach*, employs trained providers (e.g., pharmacists, physicians) to conduct face-to-face visits to encourage adoption of a desired behavior pattern. Although academic detailing was originally conceived and proven effective as a one-on-one educational intervention, several studies have incorporated academic detailing principles in small group sessions. Academic detailing has been shown to be effective at enhancing provider knowledge and changing prescribing behaviors, although it has generally been proven ineffective at enhancing patient outcomes in a sustained fashion [27].

Opinion Leaders

Opinion leaders are members of the local system who are usually able to influence others, either on a broad range of issues or in a single area of acknowledged expertise. They do not always have leadership titles but generally have higher status among their peers and higher visibility. Peer feedback from local opinion leaders has been shown to have a modest effect on enhancing quality of care and has been used as part of multifaceted QI strategies in several institutions [28].

Audit and Feedback

This strategy entails the provision of a summary of the clinical performance of an individual provider, practice, or clinic to the respective entity. It is often done in conjunction with reports that contain anonymous performance rates of comparable clinics or providers. Based on the timeliness and type of feedback, this strategy has shown small-to-modest benefits in the improvement of targeted processes or outcomes, especially when combined with achievable benchmark feedback. In a study of diabetes patients by Kiefe et al., physicians were randomly assigned to receive either a chart review and physician-specific feedback or an identical intervention plus achievable benchmark feedback [28]. Odds ratios for patients of the achievable benchmark physicians versus comparison physicians were higher for influenza vaccination, foot examination, lipid control, and long-term glucose control measurement.

Reminder Systems

These interventions prompt providers to remember information relevant to a particular encounter, patient, or service. They are often effective when integrated into the workflow and are available at the point-of-care delivery. An example is the system of flagging charts of patients whose influenza vaccinations are due, which prompts the provider to remember and enhance the recommendation of influenza vaccination at the time of the visit.

Patient Education

Individual or group sessions to enhance patient self-management of disease were shown to have modest to large effects based on patient characteristics and conditions. These effects have been well studied, especially in the management of diabetes mellitus and chronic heart failure.

Case Management

Case management and disease management are described in detail in Chap. 7. They are well-studied QI strategies used to manage special populations who have specific diagnoses or who require high-cost or intensive services. These services are often centralized and involve the coordination of healthcare interventions and communication between members. This strategy has demonstrated a positive effect on enhancing quality of care for patients with chronic diseases.

Reengineering

Reengineering and process redesign consist of improving an existing process or system in such a way that allows expanded opportunities to be met or existing problems to be solved. This broadens the reach by allowing additional uses, generating lower costs, or delivering improvements in usability. Because of the nature of the process, this strategy has often yielded novel product or service innovations that go beyond the realm of improvement and result in the redesign of existing structures and processes. Examples are the use of telemedicine to enhance access to care in remote locations or convenient care clinics to enhance access and efficiency and to create new business models for healthcare service.

Incentives

This strategy is described in detail in Chap. 9. Financial incentives for achieving a certain percentage increase or target level of compliance with targeted processes of care have shown evidence of a positive relationship in the achievement of target goals. This concept has led to the current strategy of pay for performance. There is less evidence that negative incentives such as withholding of salary or year-end bonuses for not achieving target performance are an effective means of enhancing quality of care.

Quality Improvement Research

There is often confusion about whether a project is purely QI or research. In general, QI is used when changes need to be made to a local system for clinical management. In this case, the effects of rapid changes are studied using small samples and less rigorous documentation; this provides for rapid feedback to the system. A project is considered QI research if there is deviation from established good practices, the subjects are individual patients rather than systems or providers, randomization or blinding is conducted, the majority of the patients are not expected to benefit directly from the knowledge gained, and participants are subject to interventions that are not required in routine care.

There is limited understanding of the factors that truly make a QI project successful because systems changes often have multiple confounding factors, thus creating an urgent need for rigorous research in this area. It is especially important to know the costs of the intervention, any possible unintended "side effects" of the intervention, if the intervention contributed to improved patient outcomes in addition to improving the process, and if the overall effect of individual QI efforts actually enhances the quality of the entire system. As Perneger suggests, it is important to keep in mind that although quality improvement is the aim, not all change may be an improvement [29].

Study designs that may be useful in QI research include randomized controlled trials, controlled studies, pre- and post-intervention studies, as well as time series. Rigorous research designs become especially important when results are to be generalized or communicated externally and the impact of the change is potentially large.

Challenges to Successful Quality Improvement

Many organizations have encountered difficulties when implementing quality management. Barriers may be found in the organization's technology, structure, psychological climate, leadership, culture, and involvement in legal issues. A summary of each of these areas is given below.

Technology

Many organizations' quality managers have had to learn new quality management techniques while simultaneously building the information infrastructure needed to do the work. In many organizations, technologies designed for use in quality management are relatively new and require training and testing by the staff. Some technological innovations still await widespread diffusion due to a lack of necessary resources and change management necessary for implementation.

Structure

Some leaders have taken aggressive steps to put quality councils in place, recognize QI gains in public ways, and inject quality into performance requirements; however, these efforts are by no means widespread. How to structure the quality effort and how much visibility to give the quality initiative in the organizational structure are two barriers that often result in inaction.

Psychological Climate

The climate of the organization sometimes presents a barrier to two fundamental aspects of quality philosophy: openness to data sharing and teamwork. Quality management requires that the staff collect and analyze data and share the findings transparently in open meetings, yet the climate of some organizations is too closed for this type of exposure. In other organizations, teamwork is only an occasional proposition. Because QI depends on examining relationships and interdependencies across departmental boundaries and hierarchical levels, a lack of familiarity with this "boundaryless" movement may be a barrier.

Leadership

Just as leadership can support quality management, it can also obstruct it. Unless quality management has a clear and continuous commitment from the organization's leader, the quality effort is doomed. Frequently, the leader fails to adequately communicate the importance of the quality effort and its ongoing progress. The leader must constantly demonstrate visible support for the quality effort. Clinical and administrative staffs are keenly sensitive to any real or perceived wavering of support. As quality and value become more associated with payment by the Medicare Access and CHIP Reauthorization Act (MACRA) and the Medicare Incentive Payment System (MIPS), leadership will become more keenly focused on these topics.

Culture

In Deming's view, successful quality management requires building a supportive organizational culture [7]. Conversely, an organizational culture that has the following characteristics conflicts with the basic philosophy of quality management: decisions are made from the top down, the workforce is not empowered, communication tends to be closed (i.e., data are not openly shared), patients' interests are subservient to medical center objectives, errors bring blame-seeking and dismissal, and teamwork is thought to be unnecessary. Initiating quality efforts in a hostile environment is a doomed experiment. Unfortunately, many academic medical centers and large community institutions lack a history of a supportive culture for QI.

Legal Issues

An easy way to disable a quality program is to saddle it with legal implications. In such a climate, patients will not sign release forms, and the organization cannot legally ask for or disseminate information related to quality or safety. Because provider contracts do not specify that data can be requested, an organization's managers must be creative and innovative in moving these legal issues aside without harming the organization, its employees, and the patients who receive care.

Future Trends

The IOM reports heightened public and industry awareness of medical errors and quality issues in the healthcare system. Accrediting bodies and regulations have prompted healthcare institutions to enhance their QI and quality measurement initiatives to address these issues, resulting in a renewed interest in QI across the nation. Similarly, accrediting bodies of health profession education are increasingly interested in establishing competencies for upcoming graduates in the areas of QI and safety. This has resulted in a proliferation of curricula including the early involvement of trainees in QI efforts to enhance patient care.

Alternative Payment Models

In January 2015, the Department of Health and Human Services (HHS) tied 30% of payments in Medicare to alternate payment models (APMs) associated with quality or value. The aim is for almost all fee-for-service (FFS) payment to be tied to quality or value [30]. APMs include accountable care organizations (ACOs), bundled payments, and medical homes [30]. Additionally, recent changes made by the Medicare Access and CHIP Reauthorization Act (MACRA) (final ruling October 2016) yield incentives to providers participating in APMs. MACRA also combines incentives for providers participating in APMs and facilitating the new payment models, electronic health records (EHR), value-based payment, and current quality reporting into one system called the Merit-Based Incentive Payment System (MIPS) [30].

Accountable Care Organizations

Accountable Care Organizations (ACOs) were created under the Patient Protection and Affordable Care Act (PPACA) as a new payment model under Medicare. With ACOs, there will be pilot programs to extend the model to private payers and Medicaid. Proponents hope that ACOs will allow physicians, hospitals, and other clinicians and healthcare organizations to work together more effectively to both slow the growth of spending and enhance quality improvement [31]. The success of ACOs will depend in large part on whether the Centers for Medicare & Medicaid Services, doctors, private payers, and healthcare system leaders can work together to establish a tightly linked performance measurement and framework for evaluation. The goal of measurements and evaluations is to assure accountability to patients and payers and support rapid learning, timely correction of policy and organizational missteps, and broad dissemination of successful organizational and practice innovations [32].

Final Thoughts

Healthcare providers armed with knowledge of QI will be key to the success of such initiatives and shaping policy in this area, especially if they are supported by regulations that impose consequences to achieve compliance and accountability.

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Additional Resources-Further Reading

Agency for Healthcare Research and Quality. http://www.ahrq.gov
American College of Medical Quality. http://www.acmq.org
American Health Quality Association. http://www.ahqa.org
Centers for Medicare and Medicare Services: Quality Measure and Quality Improvement. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-.html
Foundation for Health Care Quality. http://www.qualityhealth.org
Health Resources and Services Administration. https://www.hrsa.gov/
Institute for Healthcare Improvement. http://www.ihi.org
Kaiser Family Foundation. https://www.kff.org
National Academies of Science, Engineering, Medicine: Health and Medicine Division. Quality and Patient Safety. http://www.nationalacademies.org/hmd/Global/Topics/quality-patient-safety.aspx
National Association for Healthcare Quality. http://www.nahq.org
National Committee for Quality Assurance. http://www.ncqa.org
National Quality Forum. http://www.qualityforum.org
Quality and Safety in Healthcare. http://www.qhc.bmjjournals.com
RAND Health. http://www.rand.org/health
The Joint Commission. http://www.jointcommission.org
Utilization Review Accreditation Commission (URAC). http://www.urac.org