Chapter 2
The Quality Cycle

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Abstract Due to the iterative pattern of quality improvement, numerous models have been developed that are referred to as quality cycles. Each model can offer unique advantages and disadvantages depending on the settings in which they are applied. The concept of cycles was foundational to the early quality efforts with the inception of the Plan-Do-Check-Act (PDCA) by Shewhart and Deming. Numerous variations based on this original model have been developed. As the sophistication of the processes that were being studied and improved increased, the models evolved into complex tools requiring special training and teams of individuals to implement and monitor. Each major quality cycle will be reviewed including the usual settings in which they can be most effective. Understanding these concepts allows evaluation and implementation of the methodology that is most likely to succeed in a particular setting.

Keywords Quality cycle • Plan-do-check-act • Lean • Six Sigma • Bridges to excellence • FMEA • Rapid cycle testing • Milestones • Breakthrough series model

The process of quality improvement is inherently iterative until a predetermined goal is reached. Following attainment of the goal, a monitoring process must be part of the plan to insure the process that was altered remains effective and maintains the desired outcome. As a result, models that have been developed to meet specific needs all rely on a cyclical process of evaluating the current state and describing an ideal future state; developing tools to implement the changes required; assessing the effectiveness of those tools and then repeating the process. This process has resulted in a number of quality cycle models being developed. A quality cycle model can range from a simple four step process to a much more complicated matrix methodology. It has evolved over the decades to meet the individual needs of the quality improvement process. As a result, it is important to know the various quality cycle models that are available and the strengths and weaknesses of each as it pertains to the quality improvement process that is being undertaken. Fourteen

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quality cycle models will be described in this chapter describing their implementation, specific applications, scope, size and special features (Table 2.1), five will be considered in greater depth.

Table 2.1 Comparison of quality cycle models

Quality cycle	Project scope	Project size	Special features
PDCA/PDSA model	Variable – narrow to broad iterative	Small to large	Basis of other models
API model	Scalability regarding complexity of issues; used to develop new models or improve old models	Variable model dependent on team/project size	Three questions added to PDCA cycle
FOCUS-PDCA model	Maximize performance of pre-existing processes	Small to large	Developed by Hospital Corporation of America; variation of PDCA
FADE model	Problem focused	Small	Variation of PDCA
LEAN	Reduction of inefficiencies and waste adversely affecting performance	Usually large and multi-step serial processes	Numerous tools developed to facilitate. Need trained staff to facilitate improvement process
Six Sigma model	Reduce variation in currently functioning processes	Usually large and complex projects involving numerous teams	Reduces variability in process resulting in reduced waste and inventory and improved throughput
FMEA model	Predict future product failures due to prior failures; usually applied to new designs and processes	Usually utilized in multi-step cross departmental processes	Analysis based on severity, likelihood of occurrence and ability to detect future failure
5S model	Individual process improvement	Individual	Easily accomplished with training
Rapid cycle testing model	Decreasing time for implementation of improvements	Small to large, more effective in smaller populations	Developed by IHI, serial overlapping improvement process
Breakthrough series model	Collaboration among organizations to promote broad scope change	Large projects	Developed by IHI; barriers to success are required transparency among organizations that may be competitive
Milestones model	Assessment of process most likely to succeed;	Small to large	Serial process requiring completion of a step before proceeding to next step
Meyer model	Analysis of quality improvement and disconnect between data measurement and improvement	Aimed at physician change – small to large group	Numerous strategies included to promote change

(continued)

Table 2.1 (continued)

Quality cycle	Project scope	Project size	Special features
Al-Asaaf model	10 step model encompassing QA, QI, QC and total quality management	Large scale	Unifies all the major concepts of quality measurement and improvement
Bridges to excellence model	New process development to assure ability to apply Six Sigma improvement methodology following implementation	Small to large	Design of a process to allow implementation of Six Sigma improvement tools

PDCA Plan-D-Check-Act, *PDSA* Plan-Do-Study-Act, *API* Associates in Process Improvement, *FOCUS* Finding-Organizing-Clarification-Understanding-Selecting, *FADE* Focus-Analyze-Develop-Execute, *FMEA* failure mode effect analysis, *5S* sort, straighten, shine, standardized, sustain, *IHI* Institute for Healthcare Improvement, *QA* quality assurance, *QI* quality improvement, *QC* quality control

The concept of a quality improvement cycle was first published by Shewhart in the mid-1920s. Deming utilized this tool extensively and as such, he is often credited with its inception [1]. The Deming/Shewhart tool is especially useful in healthcare applications due to the inherent knowledge base of the healthcare delivery model as well as its values and disciplines by those who are implementing quality improvement [2]. In all of the quality improvement cycles, each step is dependent on the preceding step in that there must be significant coordination and balance between all of the steps to ensure an affective outcome [3]. This is reflected in the concept of "for a process to be improved it must be able to be measured" and the corollary argument of "do not measure things that you do not want to or cannot improve". It is also important to note and one of the difficulties with quality improvement processes is that they tend to be unique to the setting in which they are implemented. A successful quality improvement cycle implementation may require an entirely different set of tools to be successful in an institution with a different culture, mission, vision and values. This has made the generalizability of a particular quality improvement mechanism difficult and a reason for skepticism on the part of the practicing clinician when approached to participate in these activities. To better understand the unique characteristics of each quality cycle, the different models will be examined independently with regard to their strengths, weaknesses and usual implementation settings.

Plan-Do-Check-Act or Plan-Do-Study-Act (PDCA/PDSA)

The basis of all of the performance improvement models or quality cycles has some relation to the original quality improvement concept of Plan-Do-Check-Act or Plan-Do-Study-Act (PDCA/PDSA). The "planning" phase of this cycle includes defining an objective for the improvement project followed by inquiry

into what the leaders think will happen during the process resulting in questions and projections. Having defined these two areas, a plan to carry out the cycle involving the necessary quality improvement team members, the goal of the project, a prospective timeline for major milestones in its accomplishment and the sites of implementation would need to be defined. The "doing" phase of the cycle is comprised of four major components: (1) Educating and training the staff who will be involved in the quality improvement process; (2) Developing a plan that allows implementation on a small scale or testing prior to broader implementation of the change; (3) Having implemented the small scale change, it is important to document any problems or unexpected observations that may occur during this phase of the change cycle; (4) Data generated from this small scale change project can begin to be analyzed using the quality control tools which are described in a later chapter. This completes the "doing" phase of the cycle. The third phase of the cycle entitled "Check/Study", includes an assessment and determination of the effect of the intervention with regards to the successful attainment of the goal or objective outlined in the planning phase. Detailed comparison of the results of the small scale change relative to predictions occurs during this phase. The lessons learned from the intervention are documented and shared with others as the team determines what changes are necessary for broad scale implementation. The final phase of the PDCA/PDSA cycle is "Act". During this phase organizational change is implemented depending upon the lessons learned during the prior three phases. Leadership will need to determine whether the plan can be implemented or if a second cycle is required to evaluate implementation of knowledge learned during the first cycle. Necessary changes to business processes will need to be implemented. Once implemented on a broad scale it is important to continue to evaluate the impact on quality improvement to identify any gaps in processes or performance of the initial intervention when more broadly applied within the organization. If further intervention is required due to the inability to obtain control of the process, the cycle can be restarted based upon the new knowledge obtained from the organization and implementation of the first cycle [4].

Associates in Process Improvement (API) Model

A variation on the PDCA cycle was the API improvement model. This model added three questions to the initiation and completion of the PDCA cycle. These questions were: what are we trying to accomplish, how do we know that the change results in improvement, and what change can we implement that will result in improvement? Focus on these three questions allowed scalability regarding the complexity of issues to be addressed through the improvement model. It additionally allowed variation based upon the size of the quality improvement team or whether this was to develop a new model or improve an old model of quality improvement [5].

"FOCUS"-PDCA Model

In the early 1990s, the Hospital Corporation of America formulated the next variation to the PDCA cycle. The key feature of this process was to maximize the performance of pre-existing processes. The preliminary steps leading up to the usual PDCA phase is the FOCUS acronym. In the focus acronym, "F" stands for finding a process that is in need of improvement. This includes defining the beginning and end of the process and determining who will benefit from the improvement. The "O" is for organizing a team of people knowledgeable regarding a process and should cross various levels of the organization. "C" is for clarification of current processes and the changes needed to achieve improvement. "U" is for understanding the potential for real causes of variation by measuring performance and whether or not the process to be improved is currently in a state of statistical process control. Finally, "S" is for selecting actions that are felt necessary to improve the process. Once these actions have been selected, the PDCA process can be implemented on those actions by the team that was identified [6, 7].

Focus Analyze Develop Execute (FADE) Model

The next variation on the PDCA improvement cycle is the FADE model developed by Organizational Dynamics. This was developed in early 2006. The methodology is more problem focused rather than systematic in its approach. The four phases are: Focus-choosing a problem and writing a statement to describe it; Analyze-learning more about the problem by gathering performance data; Develop-development of a solution and plan for implementing the solution; and Execute-implementing the plan and monitoring results with adjustments as necessary until success is documented [6].

LEAN Model

The LEAN model is specifically focused on reduction of inefficiencies which can adversely affect performance. This model originated in the Japanese automobile industry in the early 1990s. There is broad application of this methodology in healthcare in an effort to reduce waste within the healthcare system. Five principal areas of process improvement include value, value stream, flow, pull, and perfection. Value is defined as that which is important to the customers and ensures focus on their perspective, value stream insures all activities are necessary and valued to the process, flow implies the need for continuous processing throughout the value stream, pull signifies the drive for production due to demand and finally perfection is aimed at preventing defects and rework. There are eight

Table 2.2 Detailed steps in the LEAN process model

Step	Detail
1.	Definition of the performance problem from customer's perspective
2.	Examine current work procedures and diagram processes
3.	Gather improvement opportunities
4.	Identify root causes of the problem
5.	Develop proposed process diagram to address root causes
6.	Design an implementation plan for the change to include measures to determine success and a timeline

types of waste that were identified as part of the early LEAN work. These include unnecessary human movement, waiting for something needed to do your work, doing more than is necessary to meet requirements, poor quality work and rework to fix mistakes, excessive inventories resulting in resources that are waiting to be used, unnecessary movement of people, supplies and equipment in the process, products and services that customer's view as unnecessary to deliver the product and overproduction resulting in doing things that do not add value to the process.

The steps in a LEAN process include definition of the performance problem from the customers perspective as a first step (Table 2.2). Current work procedures are then examined and a diagram of the current process is created. This will help clarify the cause of the performance problem and provides the best information when described by those directly involved in the process. Improvement opportunities are gathered along with data to inform the team regarding the severity and frequency of the problem. As a result of the above, root causes of the problem can be identified and investigated. In response to the root causes that were identified, a proposed process diagram for a better way to do the work is evaluated and finally an implementation plan for the proposed new process is designed. This design includes measures to determine success as well as a completion timeline [6]. The LEAN process is very robust and designed to deal with complex system improvement throughout an organization. There is a broad spectrum of tools that are available to analyze and improve processes. There are numerous opportunities for specific training to acquire the skills necessary to fully utilize these tools as well as implement the Lean process in an organization.

Six Sigma Model

The Six Sigma model was developed in the 1980s and 1990s as a mechanism to reduce variation in business processes. It was initially implemented at Motorola and later refined by General Electric. It is quite popular in practice today with more than 20 % of recently surveyed physician executives utilizing this tool to improve healthcare performance. Reducing performance variability is the essence of a Six

Table 2.3 Detailed steps in the Six Sigma model

Step	Detail
1.	Defining the problem
2.	Measuring key aspects of current process
3.	Analyzing data from current process
4.	Implementing new processes
5.	Ensure control and improvement sustainability

Sigma quality improvement project. If successful, the defect rate should be less than 4 per 1 million opportunities. The five steps in a Six Sigma project include defining the problem, measuring key aspects of the process, data analysis, implementing improvements and finally ensuring control and sustainability of the improvement (Table 2.3). The process relies on three areas of emphasis which are: process variation control, an orientation towards results and the use of data to drive the process. Secondary effects of a uniform process derived from the implementation of Six Sigma are reduced waste, improved throughput and just in time inventory control [4, 6]. The Six Sigma process is very powerful in reducing variability and errors in processes. The process requires significant resources regarding data collection analysis and implementation of plans to correct error along with continuous reporting to ensure process change remains in place and there is no return to the prior practices.

Failure Mode Effect Analysis (FMEA) Model

Failure mode effect analysis is a mechanism to predict future product failure due to past failures [4]. This is usually reserved for evaluation of new designs and processes. The mechanism is primarily focused on the steps in a process that have the greatest potential for failure before that failure actually occurs. This results in a prioritization of failure modes based on severity, likelihood of recurrence and the ability to detect the potential for future failure. This is particularly helpful in the development of new processes within healthcare organizations given the multiple steps that could result in significant patient harm.

Five Steps (5S) Model

On an individual level there is a Japanese tool entitled 5S. The five steps allow a worker to implement change within their individual workplace to assure highest quality and productivity. The five steps are: sort, keeping only necessary items; straighten, arranging and identifying those items so that they can be easily retrieved; shine, keeping the workspace neat and clean; standardized, using best practice consistently; and sustained, maintaining current gains along with commitment to the

process [4]. Implementation of the 5S model is at the individual level and fairly easily accomplished with minimal training. As this methodology is more individual, maintaining the process relies upon the individual's initiative to maintain improvement.

Rapid Cycle Testing Model

The Institute for Healthcare Improvement (IHI) has provided two mechanisms for quality improvement in the clinical setting. The first of these is rapid cycle testing or fast cycle time. This is a process designed to shorten the time for improvement from months to days for new process implementation while building significant staff engagement in the new process. It is important to note that rapid cycle improvement is not aimed at shorter development schedules or doubling the speed of current work as this will only increase the number of mistakes and limit the number of short-lived successes. For a rapid cycle time process to be successful, it is necessary for an organization to be redesigned into multifunctional teams with highly visible and measurable timelines and accountability to each other. This process also requires excellent communication skills between the teams. Additionally to be successful, rapid cycle improvement requires highest level leadership support as the process is very resource intensive. To be most effective, rapid cycle improvement requires overlap between implementation of the first change and evaluation, analysis and development of a second change in the cycle. The second cycle then is implemented while the third cycle starts the evaluation, analysis and development of the third change in the process. This is an iterative process until the goals are met for the process change project [4, 8]. Rapid cycle testing can be highly effective in an organization that needs to adapt quickly to changes in the surrounding environment with regard to its basic processes. The methodology garners support from large numbers of staff due to significant involvement at some stage in the process change. It does require excellent communication skills among the teams if it is to be successful.

Breakthrough Series Model

The second methodology that was derived from IHI is the breakthrough series model. The principal focus of this model is collaboration between large numbers of organizations working together over a defined period of time to improve a specific area of performance. Different models of change can be implemented in each of the organizations and then best practices are shared across those organizations including lessons learned and barriers to improvement. Leadership is provided by the IHI along with national experts. The use of this model results in implementation of

widespread change affecting a larger population due to the broad collaborative nature of the team involved in developing the change. Barriers to success of this methodology include the need to openly share both successes and failures with other team members who may be in competitive markets, development of new communication models to share best practices across organizations, and the need for high level resources to accomplish and overcome these barriers [9]. The breakthrough series model affords the opportunity for collaboration across multiple organizations and thus affects change on a broader basis. Due to the need to build consensus regarding this change the process is not appropriate for those quality improvement initiatives that require more rapid implementation. Communication and sharing of information across organizations which are not used to this level of transparency can be a hindrance to its utilization.

Milestones Model

Also important in the clinical application of a quality cycle is the ability of an organization to evaluate its processes and measures to determine those which have the greatest opportunity for improvement. This is a more recent paradigm for evaluation developed by Lloyd and presented as seven milestones for an organization to be successful (Table 2.4). The seven milestones are: (1) Developing a measurement philosophy and involvement of measurement in the day-to-day functioning within the organization. A measurement of success in this milestone is that data is not being collected because you are told to but because someone wants to learn more about process variation within the organization. (2) Identifying the types and categories of concepts to be measured. This milestone ties the organizations strategic objectives to its quality improvement work. (3) Identifying specific measures for improvement. Specificity regarding the measure and ensuring appropriate data collection is an important part of this milestone. (4) Development of operational definitions of specific measures. It is important that an organization understands the definition to ensure consistent data collection and focus on a question for analytics. (5) The fifth step is to develop a data collection plan and gathering of the data. Many times the organization will fall into the predicament of utilizing current data because

Table 2.4 Detailed steps for the milestones for quality improvement model

Step	Detail
1.	Developing a measurement culture and incorporating into daily function
2.	Identify types and categories to be measured
3.	Identify specific measurements for improvement
4.	Develop operational definitions of the measures
5.	Develop and implement a data collection plan
6.	Data analytics using process control tools
7.	Develop and implement process improvement plans

it is easily available, however, not the most applicable to the question at hand. Specific data collection tools and resources to ensure adequate sampling and recording of the data is a necessary outcome from this step. This may require outside expertise to ensure consistency and reliability. (6) The sixth step in the process is data analytics including utilization of statistical process control methodology described in a later chapter and development of analytics for potential future processes. (7) The last step is the data collection necessary for the organization to develop plans regarding process improvement including implementation plans. This includes the investment in the resources for and the actual potential for execution of the process improvement [10]. The milestones model encourages an organization to address change in a serial manner. In order to progress to the next milestone, the requirements for all of the prior ones must be met. Although this can slow process, it insures success due to completion of each of the steps required to affect change.

Meyer Model

In a more specific model aimed at analyzing quality improvement and the disconnect between data measurement and improvement, Meyer proposes the following quality improvement cycle. The steps in the cycle include identification of an opportunity for improvement which leads to a plan for improvement followed by an intervention to the process. Outcomes from the intervention are then measured and compared to results that were available prior to the intervention or from other organizations. Based on the results from this comparison, further changes to the process are implemented and the cycle restarts with identification of new opportunities for improvement. As this cycle is principally based on physician change and quality improvement, Meyer additionally noted some representative strategies which could be applied. These included audit and feedback, use of regulations, focused incentives, behavioral interventions, the use of local opinion leaders and outreach visits to improve information, educational interventions including continuing medical education and self-instructed learning, and the use of information systems including reminder systems and computer decision support systems as mechanisms to affect improvement [3]. Many times a multifactorial approach with regard to application of the strategies is necessary for success.

Al-Assaf Model

In an effort to incorporate the concepts of quality assurance, quality improvement, quality control and total quality management, Al-Assaf developed a ten step quality management cycle. The first step is to plan for the process change, step 2 is standards setting, step 3 is communication of the standards, step 4 is monitoring the current process to insure it is in control, step 5 is to identify and prioritize opportunities for

improvement, step 6 defines the opportunities for improvement, step 7 identifies the team to work on opportunities for improvement, step 8 analyzes and studies the opportunity for improvement with data gathering and analysis, step 9 is choosing and designing a solution to address the problem and step 10 is implementation of the solution. Step 10 can lead to further cycles that can start either at step 1, 2, 3 or 4 depending upon the solution and its implementation plan. This cycle applies all four quality activities. In the early steps of the process quality assurance is addressed, quality control is addressed in step 4 and quality improvement in steps 5 through 10. Total quality management is addressed throughout the entire cycle. This cycle follows all aspects of quality improvement in modern healthcare organizations [11].

Bridges to Excellence Model

The most recent model for quality improvement was derived by General Electric and is a variation on its previously described Six Sigma methodology. GE realized that if it was to utilize Six Sigma methodology to minimize defects, improve quality and reduce cost that it would be imperative to design processes that would be amenable to Six Sigma analysis. This new design methodology when applied in healthcare was entitled Bridges to Excellence. The process involves five steps. The first is initiation during which the need is defined including the scope, timeline and resources necessary for success. The second step is to define those measures which are critical to quality and define the customer's needs. Examples of this include well-defined performance measures that are within the provider's control, thresholds that are attainable and the provision of accurate and comprehensive data. The third step in the process is to define program specifications including high level design and evaluation of the design. The fourth step is to develop detailed designs, evaluation of those detailed designs and development and verification of a control plan regarding the process once implemented. Finally, is executing a pilot program and analysis of the results from this pilot with implementation in full scale production along with future vision for the product. Important key elements to success include ensuring that the rewards for excellence are as meaningful as possible, that the program's administratively simple and that the implementation of new processes would not be disruptive to current successful processes [12]. The Bridges to Excellence program is unique in that it is designed to build a process that is amenable to the application of other quality improvement processes, such as Six Sigma. This is a powerful tool and serves as recognition of the importance of ongoing quality improvement processes for organizational success.

In summary, the process of quality and the cyclical nature of its improvement mechanisms have been in place for almost a century. There has been significant evolution in the processes over that timeframe given the increasing complexity of the systems and which will work whether it be manufacturing or the delivery of healthcare. Cardiac imaging, as will be noted in Chap. 4, is a complex process which should benefit significantly from application of the quality cycle methodology.

As healthcare workers in the field of cardiac imaging, it is important to understand how each of these quality cycle tools can help to improve the quality within each of our facilities. Those that have had the greatest success in healthcare applications have been evaluated in greater depth and include: FOCUS-PDCA, LEAN, Six Sigma, FMEA and the Milestones models. Evaluation of the relative strength, weaknesses, and resources necessary for success and potential outcomes will ensure the ability to select the correct quality cycle improvement tool when addressing a specific problem.

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