Quality Evaluation in Non-Invasive Cardiovascular Imaging

Peter L. Tilkemeier
Robert C. Hendel
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Editors
Peter L. Tilkemeier
Department of Medicine
Greenville Health System
Greenville
South Carolina
USA

Gary V. Heller
Department of Cardiovascular Medicine
Atlantic Healthcare System
Morristown
New Jersey
USA

Robert C. Hendel
Miller School of Medicine
University of Miami
Miami
Florida
USA

James A. Case
Cardiovascular Imaging Technologies
Kansas City
Missouri
USA

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Foreword

Quality: A Degree of Excellence

Quality. What does that word even mean? *"The standard of something as measured against other things of a similar kind; the degree of excellence of something." Oxford Dictionaries.*

In diagnostic testing, we can define quality as high value that leads to better outcomes for the patient tested.

But this does not happen by chance.

We have all seen those images, and perhaps more frequently, those reports of images, which are of low quality. They do not accurately represent the true state of the cardiac anatomy or physiology of the patient and cannot trustworthily guide further testing or management. The experienced referring physician may become less trusting of results, and may learn to adapt by layering tests, changing test referral patterns, or perhaps moving to more invasive testing strategies which they believe to be more definitive. The latter may increase costs and risks but also removes the potential diagnostic and prognostic benefit of non-invasive imaging.

In the USA, there is a move from volume-based to value-based purchasing of healthcare services. This transformation will dictate that 90 % of payments from Medicare will be related to quality measures within a few years of this printing. This includes mandatory laboratory accreditation for non-invasive imaging (as of 2012) and implementation of appropriate use criteria in decision support prior to ordering advanced cardiac imaging (as of 2017) in order to receive payments under the Medicare physician fee schedule.

This book is dedicated to increasing the level of quality in imaging by equipping the adaptable reader with the specific tools needed to navigate this sea change. Each area of non-invasive imaging has its own deep dive into how to improve quality. Whether motivated by our Hippocratic duty, medical liability concerns, or garnering fair payment for imaging services rendered, we all must strive for the highest level

of quality in imaging. We must set and maintain quality as that degree of excellence, communicating it and even perseverating on it until it is uniform, commonplace, and widespread.

Chicago, IL, USA Kim Allan Williams, MD

Preface

Quality management is a journey, not a destination.
~Thomas H. Berry, leader in quality management development

A common theme among multiple international societies and organizations involved in cardiac imaging has become apparent in recent years: quality, due to its impact on all phases of cardiac imaging. Quality in imaging clearly has importance in clinical practice, is essential for accreditation, and signifies a laboratory that places patient care first. Quality in cardiac imaging impacts directly on patient care and may affect outcomes in a variety of ways. How quality initiatives are implemented in hospitals, clinics, and imaging centers is unclear and guidance is needed for laboratory's medical and technical directors and hospital administrators with regard to the development of quality improvement programs. This book is designed to serve as an important resource describing the importance of quality in cardiovascular imaging and how best to optimize an imaging laboratory.

Quality Evaluation in Non-Invasive Cardiovascular Imaging is designed to help physicians, technologists/technicians, and administrators develop their own quality programs. Discussions of each of the major cardiac imaging modalities (including computed tomography, cardiac magnetic resonance imaging, positron emission tomography, single-photon emission computed tomography, and echocardiography) are provided in a structured format. The first section addresses important global perspectives of the importance of quality, its relationship to value in the evolving role of non-invasive cardiac imaging, and the important role that accreditation plays in assuring quality. The final section presents tools for the reader to develop a meaningful quality improvement program, assists in preparing for accreditation, and suggests benchmarks for reporting quality. The overarching emphasis on quality in this book is of vital importance as part of the quest to advance the role of non-invasive cardiovascular imaging as "gatekeeper" to more expensive testing procedures and interventions.

As editors, we felt it important to assemble a group of authors that shared our vision as well as clinical expertise in each of the imaging modalities. With the group of experts contributing to this handbook, we believe that this book will be a valuable

resource for all individuals interested in establishing high quality cardiac imaging services. Each modality-specific section is constructed of chapters addressing clinical applications of the imaging modality, appropriate patient and protocol selection and important elements for meaningful quality control and improvement programs addressing the needs for physician and technologist certification as well as laboratory accreditation. We anticipate that this book will serve as an important resource for the quality improvement activities in cardiac imaging laboratories and provide a day-to-day reference addressing quality issues as they may arise.

We invite you to begin on your quality improvement project for non-invasive cardiac imaging services and that Quality Imaging: A Handbook for Non-Invasive Cardiology will serve as a valuable resource in guiding you through that journey.

Greenville, SC, USA — Peter L. Tilkemeier
Morristown, NJ, USA — Gary V. Heller
Miami, FL, USA — Robert C. Hendel
Kansas City, MO, USA — James A. Case

Contents

Contributors

James A. Case, PhD Technical Director, Cardiovascular Imaging Technologies, Kansas City, MO, USA

Marcus Y. Chen, MD Cardiovascular and Pulmonary Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, USA

Cesia Gallegos, MD Department of Medicine, University of Miami Miller School of Medicine, Miami, FL, USA

Abhijit Ghatak, MD, MRCP Southwest Heart PC, Las Cruces, NM, USA

Linda D. Gillam, MD, MPH Department of Cardiovascular Medicine, Morristown Medical Center, Morristown, NJ, USA

Gary V. Heller, MD, PhD Department of Cardiovascular Medicine, Morristown Medical Center, Atlantic Healthcare System, Gagnon Cardiovascular Institute, Morristown, NJ, USA

Research Section, Intersocietal Accreditation Commission, Ellicott City, MD, USA

Robert C. Hendel, MD, FACC, FAHA, FASNC Cardiovascular Division Chief (Interim), University of Miami Miller School of Medicine, Miami, FL, USA

Steve W. Leung, MD Division of Cardiovascular Medicine, Departments of Medicine and Radiology, University of Kentucky, Lexington, KY, USA

Ryan Longmore, DO Department of Cardiology, Saint Luke's Hospital, Kansas City, MO, USA

Amgad N. Makaryus, MD, FACC, FACP, FASE, FSCCT Department of Cardiology, NuHealth, Nassau University Medical Center, East Meadow, NY, USA

Patty Reames, ARRT, CNMT, NCT, FASNC Practice Manager, Ohio State University Heart and Vascular Center, Bellefontaine, OH, USA

Ibrahim M. Saeed, MD, FACC, FAAP Saint Luke's Mid America Heart Institute Cardiovascular, University of Missouri, Kansas City, MO, USA

Sofia Shames, MD Department of Cardiology, Columbia University Medical Center, New York, NY, USA

Joseph Soltys, PhD MR Physics, Cardiovascular Imaging Technologies, LLC, Kansas City, MO, USA

Peter L. Tilkemeier, MD, MMM. Department of Medicine, Greenville Health System, Greenville, SC, USA

Seth Uretsky, MD, FACC Cardiovascular Fellowship Program, Atlantic Health System, Gagnon Cardiovascular Center, Morristown, NJ, USA

Part I
Overview

Chapter 1
The Importance of Quality

Peter L. Tilkemeier

Abstract Quality has evolved over the last five decades to a robust process assessing all aspects of the patient's, caregiver's, physician's and health system's experience and outcome. The importance of quality and the role it plays as we shift from volume to value based health care delivery systems is paramount. The quality process can be affected by all of those involved as well as the culture of the organization. Culture change can be an important part of ensuring high-quality outcomes. As health systems move from volume to value, imaging changes from a revenue center to an expense. Ensuring the highest quality outcomes from imaging, not just technically excellent images, but information that changes the delivery of healthcare at the patient level and affects satisfaction and morbidity and mortality will be essential.

Keywords Quality • Health care outcomes • Quality improvement processes

The quality improvement movement and medicine can be traced to the early 1900s when the Flexner report identified the lack of standardized requirements for medical schools. This initial standardization lead to the closing of a significant number of the medical schools at the time. In the late 1960s and early 1970s the work of Donabedian described the components of quality in terms of people, preferences, systems and effectiveness and the now familiar assessment paradigm of structure, process and outcome [1]. From this came the development of the ubiquitous quality assessment and quality assurance activities leading into the total quality management initiatives initiated by Toyota in the late 1980s. More recently, quality initiatives have been more centered around national initiatives such as the National Center for Quality Assurance (NCQA) and quality improvement efforts from the Center for Medicare and Medicaid Services (CMS). The current discussion is now one of changing the entire payment model for medicine from one of quantity to quality. Unfortunately, defining quality remains elusive due to the many different definitions and perspectives. Quality can be defined in many different ways. The definitions range from that

P.L. Tilkemeier, MD, MMM
Department of Medicine, Greenville Health System, Greenville, SC, USA
e-mail: ptilkemeier@gmail.com

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of the dictionary definition: (1) how good or bad something is (2) a characteristic or feature that someone or something has (3) something that can be noticed as a part of a person or thing: a high level of value or excellence [2]. To an individual perspective of "I know it when I see it" or as described by Deming, the father of the quality movement: (1) Quality is defined by the satisfaction of the customer; (2) Quality is dynamic and ever changing; and (3) To maintain a quality reputation, successful organizations must constantly adapt to change [3]. Depending upon the perspective of the person assessing, the definition of quality can vary widely. From a single patient perspective it may be exactly how something will affect them. From a physician perspective, quality can be measured as the effect on a single patient, multiple patients, their practice, or the group/hospital at which they practice. From an insurer perspective, the definition may look towards larger populations of patients and their overall outcome relative to a benchmark measures. Additionally, insurers may be assessing quality based upon the value of the care delivery which takes into account the cost necessary to achieve the quality measures [4].

The current emphasis on quality is driven by the poor performance outcomes noted in healthcare. Royer noted four drivers of the transformational change necessary if quality is to be improved. These are: (1) the lack of consistency in coordination of services among providers; (2) the high cost of care where prices and charges are unrelated to actual cost; (3) increasing physician dissatisfaction as physicians practice patterns become more guideline and protocol driven, and; (4) the current misalignment of vision with a focus on illness rather than wellness and volume rather than value [5]. In addition to these four drivers of transformational change in quality, other forces that are engaged in the marketplace include the increasing complexity of healthcare services and their delivery, customers and their knowledge, opinions, experience and other priorities. Furthermore, when taking a broader perspective, the cost and consequences of over use and inappropriate use and preventable errors enter into the equation.

One of the most important factors in limiting overuse, inappropriate use and preventable errors is a highly informed and engaged customer. Customer quality has been proposed as the third leg of the quality improvement effort [6]. Historically the quality improvement efforts have been focused around technical quality and service quality as defined by Berwick [7]. Technical quality has been defined as what the customer receives relative to what is known to be effective regarding the clinical or disease specific aspects of care and relates primarily to the healthcare provider. Service quality refers to the non-health aspects of care and the environment in which the care is delivered. It has been proposed that customer quality relates to those characteristics that the customer needs to effect improvement in the healthcare process, decision making and action to improve the quality of care delivered and received [6]. This conceptual scheme involves the customer in the delivery and decision making regarding their individual care. The use of the word "customer" can sometimes be sensitive as it relates to patients, however, in this setting many times the customer is not the patient. The customer can be a family member, a caregiver or a wellness visit patient and thus encompasses a much broader population than the use of the word patient alone.

Obtaining the highest level of quality of care delivery will require high levels of technical and service quality as well as high levels of customer quality. In order to achieve the highest level of customer quality three main attributes are necessary. These include a well-informed patient regarding knowing: (1) what and why to do; (2) how to do it and (3) the desire to do it [6]. Coaching a customer regarding these three major attributes will move the customer from a dependent stance to one who is interdependent and interacting effectively with all aspects of the healthcare delivery system. This important change in the paradigm of healthcare delivery will be necessary if we are truly going to affect the quality of care delivered.

Just as important as the empowered patient is to quality, the culture in which the care is delivered is essential. The first step in the necessary culture change to promote quality is one that is patient centric. In this model, provider convenience is relegated to a lesser importance. The major change in the perspective of the organizational culture that must be achieved are creating a safe and just culture within the organizational structure. Creating a culture of safety requires everyone in the organization to be practicing in a mindful and consciousness based manner while striving for perfection. This culture of mindfulness encourages the organization to be constantly evaluating workflow processes for any indications of a failure or hazard that may grow into an adverse event. If an organization is to obtain the high quality that will be necessary for the successful transformation of healthcare, it will be necessary to strive for perfection. Given the high volume with which healthcare organizations are functioning today, a small percentage error, are although seemingly acceptable, can lead to completely unacceptable population outcomes. It will no longer be acceptable to be good enough. Those organizations that hesitate in the process of quality improvement will soon find themselves passed by others that continue to strive for perfection. Thus an organization that was high performing becomes good while others strive for perfection and greatness [8]. For organizations to be successful and achieve this high functioning status, it will be necessary for them also to develop a just culture, characterized by a non-blaming quality improvement process [9]. This non-blaming process allows staff to report potential areas for improvement with the understanding that punitive measures will not be a result and requires civility on the part of all [10].

Those organizations which will be able to perform at the highest levels of quality are those that will include all of the tools mentioned as part of their quality initiatives to ensure a highly reliable and safe environment (Fig. 1.1). In addition to the utilization of the previously mentioned tools, understanding the importance of process improvement tools such as DMAIC: define, measure, analyze, improve and control; and their implementation in all aspects of the organization will be necessary to ensure quality outcomes. As part of this analysis, it is important to ensure that there is a continual return on investment as an organization strives to obtain perfection with regard to its quality. Most importantly, the return on investment is more than just a financial measure. As the organization is investing leadership, personnel, patient's and family's time and well-being, and the organizations dollars, the return on investment is important to be measured in other outcomes. These can include performance measures regarding the organization's mission, vision and values as well as goals outlined in the strategic plan from a leadership perspective. Second, patient satisfaction, well-being

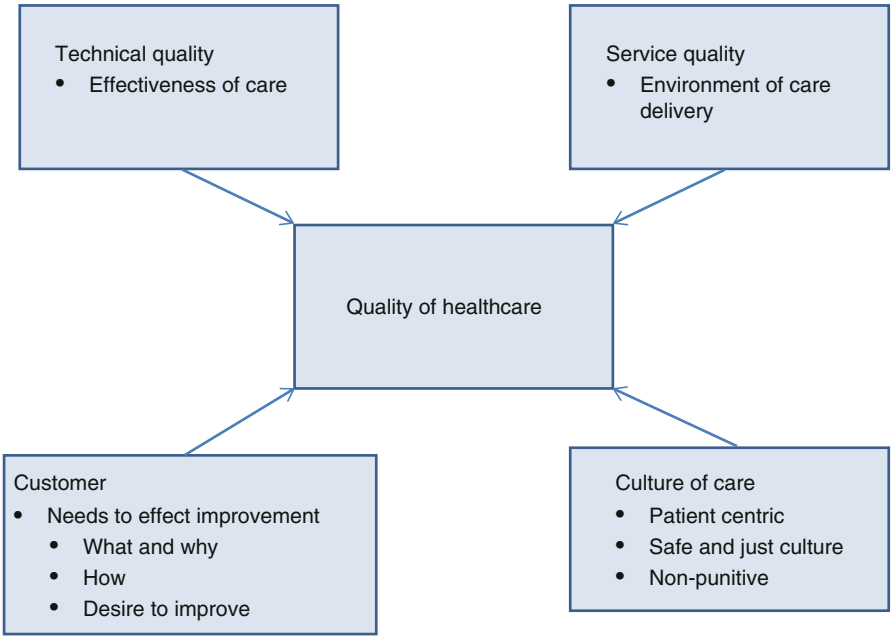

Fig. 1.1 Conceptual diagram outlining the four major components influencing quality in healthcare

and clinical outcomes from a patient and family perspective are important measures of success. Finally, financial outcomes given the financial resources that are invested in an effort to achieve the outcomes should be evaluated [10].

Therefore, quality is becoming central to everything that we will be doing in healthcare especially with regard to imaging. Developing tools and processes that allow us to continually improve, empowered patients and caregivers, and that have definable, measurable and comparable outcomes that allow assessment of organizational performance will be essential moving forward. If these are all done correctly patient, physician, insurer, regulatory agencies and large populations will all benefit [11]. The implications for imaging are significant. Quality of services delivered will become paramount, as imaging will become an expense rather than a revenue center as we move from volume to value. Determining the quality of an imaging study will no longer be determined only by the technical quality of the images but in terms of downstream care and health events such as functional status, quality of life, and reductions in morbidity and mortality [12].

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Chapter 2
The Quality Cycle

Peter L. Tilkemeier

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

P.L. Tilkemeier, MD, MMM
Department of Medicine, Greenville Health System, Greenville, SC, USA
e-mail: ptilkemeier@gmail.com

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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