Performance Improvement CME:

A Practical Introduction & Toolkit
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Performance Improvement CME and Self-Assessment: A Practical Introduction

Performance Improvement CME (PI-CME)

PI-CME is a learning format that teaches basic quality improvement skills in the context of assessing the learner’s performance in a given area of practice. PI-CME participants plan and implement improvements based on this assessment, and then, as part of the activity, evaluate the effects of those improvements on practice. While PI-CME incorporates quality improvement principles, no previous experience with quality improvement is required to engage in the activity. Likewise, no particular “style” of quality improvement is required to fulfill the requirements of the format. PI-CME developers are encouraged to incorporate the language and techniques of their organization’s quality improvement culture into the design of activities.

All too often, quality improvement and education are pursued as separate activities, and quality improvement experts and educators work in an isolated manner without reference to the other’s expertise. While collecting and analyzing data are key to PI-CME (the quality improvement component), the participant often must learn something new (the educational component) in order to improve his or her practice. PI-CME consciously combines both quality improvement and education.

We anticipate that this guide will be used primarily by educators. For those who would like to learn more about the history of quality improvement in healthcare, please refer to the article “Quality Improvement: A Context for PI-CME” in the Appendix.

The following discussion pertains to the development of physician-oriented PI-CME modules. A PI-CME module is a predesigned activity that can be used by an individual learner who finds it relevant to his/her setting, and may accommodate individual learners in multiple settings.

Another model that is eligible for PI-CME is the hospital and health system quality improvement model. This model allows PAs participating with other colleagues in a formalized quality improvement project within a work setting, such as a hospital, health system or clinic, to seek approval for the project so that PAs who participate can receive PI-CME credits. This model is supported by the application entitled “Institution-Based QI Project.” The hospital and health system quality improvement model is discussed in a separate section.

The Physician-Oriented PI-CME Model

In 2005, the American Medical Association (AMA), American Academy of Family Physicians and the American Osteopathic Association all approved PI-CME as a newly recognized format for CME credit. This format involves a one-cycle performance improvement process, which has served as a model for many of
the modules developed by physician certification boards, known variously as performance improvement modules (PIMs), practice performance modules (PPMs) or performance in practice (PIP) modules. While this is a useful and normative model, it does not exhaust the possibilities of what a PI-CME could be. The basic three-stage model is as follows:

**Stage A:** Learning from current practice performance assessment

Assess current practice using identified performance measures, either through chart review or some other appropriate data collection mechanism. Participant must be actively involved in the analysis of the collected data to determine the causes of variations from any desired performance and identify appropriate intervention(s) to address them.

**Stage B:** Learning from the application of performance improvement to patient care

Implement the intervention(s) for improvement based on Stage A, using suitable tracking tools. Participants should receive guidance on appropriate parameters for applying intervention(s).

**Stage C:** Learning from the evaluation of the PI-CME effort

Reassess and reflect on performance in practice measured after the implementation of the intervention(s) in Stage B by comparing the assessment done in Stage A and using the same performance measures, and reflect on performance in practice after the implementation of the intervention(s) in Stage B by comparing the assessment done in Stage A and using the same performance measures any practice, process and/or outcome changes that result from conducting the PI-CME activity.¹

This PI-CME model assumes at least one quality improvement cycle. It has become the normative model but does not exhaust the possibilities of how PI-CME could be designed. Variations could include requiring more than one improvement cycle, or institutional group participation models.

In its simplest form, PI-CME is a structured learning format composed of the following components:

A. Selecting a suitable target for improvement and collecting data about performance
B. Evaluating current performance and formulating and implementing a plan to improve
C. Evaluating the results of interventions after a suitable time and reflecting on the experience

While the model requires one quality improvement cycle, many projects involve multiple cycles, and some are continuous. The minimum requirement for AAPA Category 1 PI-CME is that the participant complete at least one quality improvement cycle. However, multiple cycles may make sense if the process being examined involves an activity that is repeated multiple times at high volumes.

It is important to consider consulting a healthcare quality improvement expert when developing PI-CME activities. These professionals can assist in identifying appropriate measures, devising effective data collection strategies and selecting processes for improvement. Also, remember that this is an educational
endeavor. Participants may need new knowledge or skills in order to improve their practice.

This is where the traditional educator plays an essential role. As you reflect on the nature of the measures you have chosen, consider the knowledge, competence or performance-related needs that may underlie poor performance for each of the measures, and identify appropriate educational content and resources related to each.

**Measures**

At the heart of performance improvement is the ability to benchmark one’s performance against a standard of performance in order to define any gaps that may exist.

In many cases, you will find that national organizations have developed measures that will be useful in your efforts. These may be called “performance measures” or “quality measures.” While there may be subtle differences in meaning depending on the perspective of the developer, for the purposes of this discussion, these are synonyms.

Measures are often derived from evidence-based guidelines and come in four general types:

- **Process Measures**, sometimes called “accountability” measures, look at how often a recommended healthcare intervention has been performed within the context of the targeted population. An example of a process measure would be whether or not patients with diabetes have a documented A1C test recorded in the chart within the past 12 months.

- **Outcome Measures** reflect the overall result of healthcare and actual patient outcomes. An example of an outcomes measure would be the percentage of patients with diabetes whose A1C < 7 percent. This outcome reflects overall management of diabetes. Multiple factors contribute to achieving an optimal outcome in addition to clinician performance, including how care is organized and delivered, and the engagement of the patient in managing his or her own care.

- **Structural Measures** focus on a system’s capacity to deliver care and the conditions under which the care is delivered. Structural measures consider factors, such as information technology infrastructure (i.e., electronic health records, registry functions, electronic prescribing), staff (number, qualifications), facilities and policies.

- **Balancing Measures** examine the extent that an attempt to improve one part of the system might inadvertently affect other parts of the system in a negative way. Balancing measures are chosen because of their close relationship to the process targeted for improvement. For instance, a team implementing a protocol to reduce venous thromboembolism that includes the use of low molecular weight heparins may decide to track the incidence of heparin-induced thrombocytopenia (HIT) to balance concern that increased use of heparin products may produce higher rates of HIT. Likewise, a team implementing a basal/bolus insulin administration protocol to improve inpatient glycemic control may track hypoglycemia to balance concern that the use of basal insulin may increase the rate of overnight hypoglycemia.
While outcome measures are the most robust and ultimately the most meaningful, they are also the most complex, and introduce factors that may not be within an individual clinician’s control. Factors that fall outside the clinician’s or team’s control include a patient’s adherence to therapy and advice on lifestyle modification.

The use of a variety of measures can give a fuller picture of the process of care. The fact that a patient with diabetes receives a periodic A1C test (process) does not guarantee an appropriate response (performance) from the clinician, but the clinician is more likely to appropriately intervene than if the test was not performed. Clinical policies that define how lab tests are routed through the clinic for review and clinical algorithms (structural) may define the norms of what a clinician will do with the information. Outcome measures are often chosen because they, in many ways, reflect the effectiveness of the whole process.

A useful library of performance measures can be found at the National Quality Measures Clearinghouse site, housed within the Agency for Healthcare Research and Quality's (AHRQ) overall website: http://www.qualitymeasures.ahrq.gov/.

In addition to providing one of the most comprehensive collections of measures—the National Quality Measures—the site also contains a wealth of educational materials on quality measures and how to use them.

Another useful set of measures has been produced by the Physician Consortium for Performance Improvement (PCPI) and hosted on the AMA website http://www.ama-assn.org/ama/pub/physician-resources/physician-consortium-performance-improvement.page.

**Anatomy of a Measure**

A well-described measure usually has a numerator and a denominator, and defines denominator exceptions.

**Numerator:** The number of patients who meet the measure

**Denominator:** The number of patients who are eligible for the measure

**Denominator Exceptions:** Patients otherwise eligible for a measure but excluded from the analysis for a valid reason (Explicit reason is stated)

Example:

**Measure:** Percentage of patients aged > 50 years who have either received a screening colonoscopy or have been referred for one

**Numerator:** Patients over the age of 50 who have either received a colonoscopy or have received a referral for colonoscopy

**Denominator:** All patients over the age of 50
**Denominator Exceptions:** Eligible patients who were offered colonoscopy but refused, or patients for whom colonoscopy is contraindicated

**Calculating Performance**

To calculate your performance for a measure, use the following formula: 

\[
\text{Measure Performance} = \frac{\text{Numerator} - \text{Denominator exceptions}}{\text{Denominator}}
\]

The result will be expressed as a percentage of compliance with the measure.

**When No Measures Are Available**

Measures have been developed in many areas of medicine. However, there are still many areas of interest where measures have not yet been developed. While it is always preferable to use measures that have been developed by organizations or by individuals with specific expertise, you may want to develop measures on your own. Some guidelines for developing your own performance measures are found in the Appendix. If you need to develop measures, you may want to seek the advice and assistance of a colleague with special expertise in quality improvement and/or assessment.

**Designing a PI-CME Activity: Key Issues**

**Identify a Target for Improvement**

Healthcare organizations must prioritize how they will invest limited resources. When selecting a target for improvement, it is always good to think about who cares about an issue and why. The following factors should help you select targets for improvement that are both high-priority for the healthcare organization and for the PAs practicing in it.

- Does the process have a direct link to the quality of patient care?
- Is the process of interest to an external regulator or payer (i.e., Joint Commission, National Committee on Quality Assurance, the Centers, Centers for Medicare and Medicaid Services, insurance company, etc.)?
- Does the PA practicing in this setting have some level of influence over the factors that contribute to the outcomes being considered?

Choosing something related to the quality of care increases the likelihood that others will consider the potential project important and will support it. Choosing something that is already of interest to outside stakeholders increases the likelihood that the organization may already be collecting data related to the issue and already has improvement efforts underway that you may be able to join. The relevance to PA practice is the final and probably the most important criterion. The PI-CME requirement is about involving PAs in improving their practice, not about creating mindless busywork.
It is not necessary for the PA to have total control over a process for the activity to be an important and relevant performance improvement opportunity. PAs are trained and often work in a team-based environment. Leading a team-based improvement initiative supports the PA’s professional development by providing the opportunity to demonstrate leadership and showcase skills that the team finds valuable. A PA-led quality improvement project may also be an opportunity to involve other team members, and thereby, foster a deeper level of teamwork.

Investigate the Feasibility of Data Collection

Consider where you will get data. Data may come from a number of sources:

Paper Charts:
A chart abstraction tool is developed to ensure standardized data are collected from patient charts related to the measures you are assessing. Data for assessment of both process and outcome measures can come from chart review.

Electronic Health Records:
Automated reports are generated from electronic patient charts. Many reports are generated and distributed to clinicians and administrators. These reports can identify areas that need improvement. But often, electronic health records (EHRs) don’t collect the data needed or in a manner that is useful for performance assessment. Information technology experts may be necessary to produce appropriate reports. Data for assessment of both process and outcome measures can come from electronic health record review.

Administrative/Claims Reports:
Claims data help with tracking process measures. For example, you can tell how often a lab report was billed and for which patients. This will assist in assessing the practice’s overall compliance with process measures. Data for outcomes measures are generally not available through administrative data.

Registries:
Disease or patient registries are collections of secondary data related to patients with a specific diagnosis, condition or procedure. It allows for easy analysis of patient care across the practice. Registries can be built in complex technology platforms or may be as simple as a spreadsheet.

When working with patient data, it is important to remember your ethical and legal obligations to ensure the security of protected health information. The Privacy Rule in the Health Insurance Portability and Accountability Act (HIPAA) defines protected health information as “individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral or paper) by a covered entity or its business associates, excluding certain educational and employment records.” A best practice is to collect data in a way that ensures that it is de-identified (i.e., all elements that would reveal a patient’s identity are removed.) You may want to seek the guidance of your organization’s
compliance officer to ensure that the methods you are using are compliant with HIPAA and with your organization’s policies for safeguarding the confidentiality of protected health information.

Consider Data Requirements

When data collection is relatively easy, and perhaps, automated, examining all patients with a specified definition (diagnosis, procedure, age, etc.) or all instances of a given activity during a specified time frame will give the most accurate picture of your practice. However, if data collection requires manual abstraction of data from patient charts, you may want to consider using a sampling method. Rather than looking at every qualified patient or every occurrence of an activity during a specified time period, a sample is chosen to “represent” the overall process or practice.

If this were a research endeavor, a statistician might calculate the size of the sample that would be required to represent the overall process accurately. But because this is quality improvement rather than research, a more practical standard that balances the validity of the sample size with the feasibility of data collection may be applied. When choosing your sample size, consider how comfortable you are with the defined sample as being representative of how you manage a particular type of patient or perform a specific task. Useful feedback, rather than statistical validity, is the standard.

Short of the statistician’s research-based calculation, there is no hard-and-fast rule about what constitutes an adequate sample. However, there are some norms from physician PI-CME that are useful to consider. PI-CME activities approved by the American Board of Family Medicine for the Maintenance of Certification program that require chart abstraction tend to require data from 10–20 patient charts. Those approved by the American Board of Internal Medicine tend to require between 25–30 charts. Whatever sample size you choose, be prepared to provide a reasonable rationale for why it was chosen. Keep in mind that the sample should be sufficient to provide the PA with some practical insight into how he/she (or organization or team) performs on each measure.

Sampling Strategies

When sampling rather than using the full population dataset, there is always the danger of biasing the sample. A number of techniques are used to reduce the possibility of bias. These include specifying a certain number of consecutive cases, specifying random samples or specifying all occurrences within a given time period. The following are examples of sampling strategies that are intended to reduce bias:

- **Consecutive Cases:** The last 10 consecutive patients seen in the office with a primary diagnosis of type 2 diabetes
- **Full Data Set:** All admissions during the month of October
- **Random Selection:** A random selection of 15 patients with a diagnosis of heart failure seen during the second quarter of last year
Consider How You Will Collect Data and Calculate Measure Compliance

For PI-CME activities that have the potential to involve a great number of participants and have robust funding, a number of software developers have created applications designed to be hosted in the “cloud” that provide convenient ways of facilitating data collection, automating measure calculation, summarizing data for the learner and generally facilitating the process for learners. However, the software platforms are costly and require staff involvement to oversee the production of the module. If you are developing a PI-CME activity that you believe will meet the needs of a broad audience and can attract funding, please contact AAPA staff for assistance.

For most activities, a “low-tech” approach will serve well, but will require you to spend a little more time thinking about how you will collect data and calculate measures.

One approach is to prepare a spreadsheet in an application like Excel. Someone with a certain level of sophistication in the use of spreadsheets could set it up so that there is a data entry tab, and another tab with summarized data and calculated measures. We have provided an example of what this sort of data collection sheet could look like. <<insert link to document>>

Deciding how you will collect data is another factor that you might want to give some thought. If a measure sets the standard for blood pressure < 150/90 mm Hg, the simplest way to approach it would be to make it a dichotomous variable by asking the question: “Was the patient’s blood pressure less than 150/90 mm Hg?” and giving the participant the opportunity to record a “yes” or “no” response. A more sophisticated (and complicated) approach would be to ask the participant to record both the systolic and diastolic blood pressure values (continuous variable) and use a formula to calculate whether or not it was < 150/90 mm Hg. While this adds a level of complexity, it also adds some richness in terms of what can be done with the data. With actual blood pressure values, you could calculate mean blood pressure, or look at how many patients fell between 140/90 mm Hg and 150/90 mm Hg, or examine diastolic and systolic blood pressure separately. Remember that how you collect data may limit the types of analysis you are able to perform, so consider these decisions carefully.

Another factor to consider, as you structure how data will be collected, is how you will maintain the confidentiality of protected health information. Ensuring that you are not asking for information that would reveal a patient’s identity is a good practice. Many activity developers ask participating learners to assign a code to each patient that is known only to the learner, but would allow the learner to audit the data back to the patient chart if the data needed to be re-checked for any reason.

If you use the spreadsheet strategy, consider how you will summarize the data for the participants in a way that is useful to them. Consider a “dashboard” approach. You can also use the data to support a graph or a chart that will make a participant’s performance clear to them.

Additional Considerations for Baseline Data Collection

In addition to asking participating learners to collect patient-care level data, you may want to consider also
asking them some questions about the resources and structure that surround the current way that care is delivered. Often, strategies for improvement center around how the delivery of care is designed, and asking relevant questions about practices and resources that support best practices in a given setting may be very useful for focusing the attention of participating learners on potential improvement strategies.

The questions may be focused around established best practices or care models that support best practice. One might ask if the organization has a clinical registry or ask questions related to attributes of the patient-centered medical home. One could also ask about current clinical policies and practices. Are specific individuals charged with performing certain routine tasks? Are there follow-up mechanisms to track specialty referrals or missing labs? Does the current pattern of practice allow or specify the delegation of some tasks to other team members?

**Facilitating Improvement**

After establishing a baseline of performance, participating learners develop and implement a plan for improvement (Stage B). While strategies for improvement may be obvious for many learners, others may need guidance. Often, it is helpful to provide a list of generic improvement interventions related to specific measures addressed by the activity. A basic outline for an improvement plan would include the following:

- **Area of Focus**: What process or outcome do you want to improve? Is there a particular area of the problem that you would like to focus on? Are you able to express it as a goal statement? Is it explicitly related to one or more of the measures?
- **Specific Plans**: What exactly does the learner plan do in practice? Will others be involved, and if so, in what capacity?
- **Timeline**: Over what period of time will the participants work on implementing the project? When will the planned changes be reassessed?

**Stage C: Evaluating the Improvement Effort and Reflecting on the Process**

The final phase of a PI-CME project is to evaluate one’s improvement efforts by applying the same measures used in Stage A to a time period that would reflect the improvement efforts, comparing the Stage C results with Stage A results. Sampling methods should be the same as in Stage A, but not the same patients’ data. You are looking for overall practice improvement, not necessarily the improvement of individual patients. Some evaluations and reflection questions that may be considered include the following:

- Did the baseline data cause surprise?
- Were planned changes to practice effective in improving performance?
- If improvements were not realized, what were the likely barriers that may have prevented improvement?
- What changes were made, and should they be retained?
- What has this experience taught the participant about his/her approach to care, and how can it be applied to other areas of practice?
Once the improvement cycle is completed, participants are eligible for credit, but the improvement should not end. Ongoing quality and performance improvement should become a routine part of practice.

Endnotes


4. Codman, Ernest A. A Study in Hospital Efficiency. (1916). Boston, Mass.: Privately printed


15. Institute for Healthcare Education. The breakthrough series: IHI’s collaborative model for achieving breakthrough improvement. 2003. Available at www.ihi.org

Quality Improvement: A Context for PI-CME

In order to understand PI-CME, it is helpful to have a basic understanding of quality improvement in healthcare. The following is a short history of the quality movement in medicine and how many of the basic concepts of quality improvement have emerged and developed over the last century.

The history of healthcare quality improvement in the United States begins with the efforts of the surgeon Ernest Codman (1869-1940), who began to track his own surgical outcomes on “end results” index cards and followed the patients for more than a year. He is considered to be the first physician to systematically examine the outcomes of his own care, and he urged healthcare organizations to take more responsibility for outcomes. He was instrumental in founding the Hospital Standardization Program within the American Board of Surgery that later evolved into The Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations. Among his other legacies are the establishment of the first mortality and morbidity conference at Massachusetts General Hospital and the first tumor registry.

Codman’s approach involved setting standards, examining deviations from standards, and evaluating poor outcomes. Frustrated by the resistance from the medical establishment of his day, Codman founded his own hospital, and true to his own rigorous methods he analyzed the outcomes of 337 patients discharged from his hospital between 1911 and 1916, cataloguing 123 errors and publishing them at his own expense. Codman’s approach with its focus on deviation from standards and examining poor outcomes led to an approach known as “quality assurance” or “quality control.” This approach tends to focus on identifying poorly performing individuals and intervening with them to either eliminate them from the system or to help them improve. While this approach represented a huge improvement over the previous ad hoc approach, it is criticized for not recognizing the importance of leadership and organizational factors.

Avedis Donabedian (1919-2000) is considered to be the founder of modern medical quality management and contributed the framework of “structure, process, and outcome” that is still central to how medical quality is analyzed. In this model, “structure” includes the context within which care is delivered including facilities, equipment and staff. “Process” includes all of the actions that go into delivering healthcare including diagnostic procedures, treatments and preventive services. “Outcome” refers to the effects of healthcare on patients and includes their health status, behavior and satisfaction. The quality measures that we use today are classified within Donabedian’s framework.

During the 1980s and 1990s, techniques used by W. Edwards Deming (1900-1993), Joseph Juran (1904-2008) and others in the industrial development of post-war Japan began to be applied in healthcare. This approach focused on systems rather than on individuals. While organizational leadership and capacity are emphasized, the overall approach is interdisciplinary and de-emphasizes hierarchy by making improvement “everyone’s business.” The approach makes use of a number of tools that are used to analyze processes, discover the causes of variation and error, and to monitor performance. Two terms associated with this overall approach include total quality management (TQM) or continuous quality improvement (CQI).
Patient Safety

During the late 1990s and the early 2000s there was a renewed emphasis on the safety of healthcare in the United States. The Institutes of Medicine published two influential reports: “To Err is Human: Building a Safer Health System”\textsuperscript{7} and “Crossing the Quality Chasm: A New Health System for the 21st Century”\textsuperscript{8} that examined the issues related to healthcare quality and safety, and made policy recommendations to improve the situation.

“To Err is Human” recommended:

- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety
- Identifying and learning from errors by developing a nationwide reporting system that is public and mandatory, and by encouraging healthcare organizations and practitioners to develop and participate in voluntary reporting systems
- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups and group purchasers of healthcare\textsuperscript{5}

“Crossing the Quality Chasm” articulated that quality healthcare should have the following characteristics:

- **Safe**—avoiding injuries to patients from the care that is intended to help them
- **Effective**—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively)
- **Patient-centered**—providing care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions
- **Timely**—reducing waits and sometimes harmful delays for both those who receive and those who give care
- **Efficient**—avoiding waste, including waste of equipment, supplies, ideas and energy
- **Equitable**—providing quality that does not vary because of personal characteristics such as gender, ethnicity, geographical location or socioeconomic status\textsuperscript{6}

In 1998, Chassin and Galvin contributed another useful framework for examining the use of healthcare interventions:

**Overuse:** When a medical intervention is used in a situation where the risk of harm outweighs any potential benefit
**Underuse:** When a service that could have resulted in an improved outcome is not provided

**Misuse:** When an intervention is provided inappropriately, causing harm

A common example of overuse would be prescribing antibiotics for upper respiratory ailments that are more likely to be caused by viruses than by bacteria. A common example of underuse would be the failure to provide recommended immunizations. An example of misuse would be prescribing a medication to a patient for whom there is a documented allergy, or clear contraindication to the prescribed medication. Another way of thinking about “misuse” is to consider it to be a synonym for error.
Methods for Quality Improvement

Many organizations have chosen a particular approach to quality improvement. The choice of method or “style” of quality improvement helps an organization to develop a common language and culture of improvement. The choice of a particular method depends on an organization’s size, focus and infrastructure. To a large extent, these methods tend to overlap more than they differ, but it is useful to have a basic understanding of the differing methods no matter which is chosen by a given organization.

PDSA/PDCA (Plan, Do, Study, Act)

PDSA, also known as the Shewhart cycle or the Deming circle, is probably the best-known and most widely used improvement model in healthcare. While named for Bell Laboratories quality engineer Walter Shewhart (1891-1967), it was popularized by W. Edwards Deming. PDSA is sometimes also referred to as “the model for improvement.” The model assumes that changes are planned and tested on a small scale before they are implemented system-wide. The cycle is described as follows:

- **Plan**: Define objectives, make predictions, plan implementation.
- **Do**: Carry out a test, and document problems and unexpected observations.
- **Study (Check)**: Summarize what was learned during the test.
- **Act**: Modify the plan to address discrepancies between expected and actual results and prepare for another test.\(^{10}\)

PDSA is often represented graphically as a circle with four quadrants and arrows on the outside indicating that the process repeats. PDSA/PDCA does not require a great deal of infrastructure to support it, and it is suitable for use in small systems, and for processes that involve small numbers of interactions.

Six Sigma

Six Sigma was developed at the Motorola Corporation in the 1980s, and its name refers to a level of precision in manufacturing that is considered to be “defect-free” (accurate to the sixth decimal). It was popularized in the 1990s when Jack Welch introduced it into GE.

Six Sigma relies on customer-defined measures of quality and depends heavily on data and statistical methods. The process is facilitated by experts certified as “Black Belts” for their mastery of statistical analysis tools. Compared with PDSA/PDCA, Six Sigma requires substantial organizational commitment, and it is best
employed to address issues related to large systems. Six Sigma has its own embedded analysis sequence known as DMAIC, which stands for the following:

- **Definition**: Define the problem to be addressed.
- **Measurement**: Data is collected about each step identified in a process.
- **Analysis**: Data that have been collected are analyzed to test a hypothesis related to key process factors.
- **Improvement**: The process is improved and tested in a pilot.
- **Control**: The improved process is continuously monitored to sustain improved performance.\(^{11}\)

**Lean**

“Lean” methodology is associated with Toyota and involves identifying and eliminating any step that absorbs resources without creating value for the customer. A major emphasis of Lean is identifying and eliminating waste. The Lean approach de-emphasizes hierarchy and focuses its energies on gaining insight from, and involving the people who actually do the work. Among the tenets of Lean are the following:

- Questioning current practices
- Choosing progress over perfection
- Correcting mistakes as soon as they are discovered
- Discovering root causes by asking “why?” five times
- Gathering input from many sources rather than relying on experts
- Using the wisdom of frontline employees\(^{12}\)

Lean is a team-based approach that can move relatively quickly and at low cost. Because of the focus on waste, the application of Lean principles to healthcare is especially useful in addressing areas where overproduction or underproduction might be an issue, such as staffing where there is variability in demand for services, waste of materials through excess inventory, unnecessary or redundant steps, or wait times.
Lean Six Sigma

Increasingly, Lean and Six Sigma are being combined into a hybrid model known as “Lean Six Sigma.” This approach adds the Lean focus on waste elimination to the Six Sigma DMAIC quality process. Like Six Sigma, Lean Six Sigma requires certified experts to facilitate the process and is therefore expert-driven and resource-intensive.¹³

FADE

The FADE process is a process improvement sequence that is part of Organizational Dynamic’s Quality Action Team approach to total quality management. FADE has much in common with PDSA and DMAIC, in that it represents a sequence of activities related to analyzing and improving a process. The FADE Sequence is as follows:

- **Focus**: Define the process to be improved or the process to be addressed.
- **Analyze**: Collect and analyze data to establish baselines, identify root causes and point toward possible solutions.
- **Develop**: Develop action plans for improvement, including implementation, communication and measuring/monitoring.
- **Execute/Evaluate**: Implement the action plans and implement an ongoing measuring/monitoring system to ensure success.¹⁴
IHI Collaborative Model

The “Breakthrough Series” collaborative learning model was developed in the mid-1990s by the Institute for Healthcare Improvement (IHI) as a model for accelerating improvement in specific areas by bringing together teams from different hospitals, clinics or systems to work on improving a specific clinical issue.

Members of the collaborative typically meet during three face-to-face “learning sessions” separated by “action periods.” Faculty facilitators introduce a “change package” consisting of measures and interventions that may be useful in improving the healthcare process that serves as the focus. During the process team members learn about current best practices, improvement techniques and tools. During the action periods, they implement elements of the “change package” in their respective practice environments, and collect data. Faculty coaches interact with collaborative members during these action periods by email and conference call, and teams issue monthly reports to report progress and hold one another accountable. During subsequent learning sessions, teams discuss barriers encountered and formulate strategies for overcoming them.

The IHI uses the PDSA model, and collaboratives generally last for 12-15 months. The IHI model is more of an intervention strategy rather than a specific quality improvement model in and of itself.\textsuperscript{15}
Guidelines for Developing Performance Measures

The following are some basic steps recommended by Rubin and colleagues\textsuperscript{16} that are helpful in the process:

1. **Define your audience.**

   Who will care about and potentially use the data that you produce? Clinicians? Administrators? Payors? Patients? Does the process have high enough volume to measure?

2. **Define the clinical area and impact.**

   How does what you would like to measure impact outcomes? Is it related to increased mortality, morbidity or cost?

3. **Identify your resources.**

   Do you have access to expertise in measurement, the clinical area, users of the process?

4. **Select the aspect of care or process criteria.**

   Is there strong scientific evidence that the process is related to important outcomes? Is it feasible to gain access to data? Are PAs able to influence the process? Is there evidence of variability in performance or evidence of substandard care in this area?

5. **Write the measure specifications.**

   - Define the unit of analysis (Patient? Clinician? Frequency of activity? Clinic? Hospital?).
   - Define the indicator:
     - Dichotomous measure: the answer is either “yes” or “no,” i.e., “was X service provided?”
     - Continuous measure: can be averaged such as “time to event”—What was the average time between when a patient registered in the ED until he/she saw a provider?
   - Define the intended sample and any exclusions.
   - Define where you will obtain data and how it will be collected:
     - How will you reduce the possibility of error or bias?
     - Will you use a sampling strategy? If so, what size sample is needed to adequately represent the whole? How will the sample be collected? Random sample? Consecutive cases?
• Specify how data will be collected.

6. **Perform a pilot test.**

   • A test performed on a small sample can reveal unanticipated problems that may require a revision in how a measure is defined or the data collection strategy.

   • Test for reliability and validity:
     
     o **Reliability:** Is the measure reproducible? If I repeat the same measure will it produce the same result?

     o **Validity:** Does it accurately measure the domain being assessed?

   • Tests of reliability:
     
     o **Inter-rater reliability:** the differences among evaluators

     o **Internal consistency:** variation among items that should produce similar results

     o **Test-retest reliability:** differences when the same person repeats the same measure at two different points in time

   • Tests of validity:
     
     o **Confirmation that the scores produced through the measurement instrument are linked to important outcomes**

     o **Demonstration that the scores can differentiate between good and bad quality**

     o **Confirmation that the measure represents something that is important to the users of the measure**

7. **Specify how the measure will be scored.**

   • What constitutes acceptable performance?

   • How will the data be analyzed and reported?