Quality Improvement is the Science of Process Management

Identifying and implementing Processes of Care within your hospital will help transform your organization, improve healthcare processes, quality outcomes, remove waste, and deliver the best value to the patient. It will help focus on interventions that improve quality and safety through translating evidence into practice.

Leadership and Change Management go hand in hand with Process Improvement and will change your existing culture and help your leadership focus on identifying, advancing and synthesizing hospital wide clinical pathways for successful implementation, adaptation and sustainability of process improvements in healthcare processes.

Our Team Approach will get the clinicians involved and have them own their department's processes to identify, streamline, and improve the applications of human factor engineering and ergonomics in development of information technology and understand the clinical staff psychology for patient safety, improved workflows and improve care delivery. Get your peers to envision and embrace a new future.

Accreditation will give your hospital the framework and guidance to bridge gaps, reduce the variances of care, accelerate the adoption of guidelines, update old protocols, identify and streamline interlinked processes, and makes changes that will result in quality improvement. The benefits to the facility that accomplishes accreditation are many. They can include streamlining patient throughput, resulting in a reduction in the time it takes for patients to receive treatment, and decreasing costs by providing efficient and effective care that is void of duplication and waste. Process Improvement allows for consistent training and education, improves patient satisfaction, decreases liability exposure and improves work performance.

American College of Cardiology's Suite of Cardiovascular Data Registries help hospitals further measure and improve the quality of care they provide. The National Cardiovascular Data Registry consists of eight hospital-based registries and two outpatient registries.

The often repeated adage, "If you cannot measure it, you cannot improve it" applies. The ACC registries offer the most relevant data elements and metrics, actionable reports, voluntary public reporting and other opportunities to do even more with your data through quality improvement programs. NCDR registries cover a wide range of clinical topics and cardiovascular procedures, with each registry featuring standardized, evidence-based data elements and definitions. Options for data collection vary based on your setting.
Metrics

Metrics are simply measurements. Measuring something allows you to know where you have been and where you are going. Measuring provides a method of determining whether or not a project is going in the right direction and when the goal has been reached. This process of deciding what will be measured and when these measurements meet established goals is called "metrics."

Histogram

Histograms are another method of looking at variation by looking at the frequency the data is distributed. They are bar charts that display this data distribution, using the number of times the data points appear in each bar. In this manner, they show how consistently a process meets its goals. For instance, if your goal is to achieve a ten minute ECG interpretation from the time the patient enters the ED, you would gather all your times for a given period, categorize them into sections or into individual times depending on the size of the sample, and plot each time within the category.

Histograms can tell you what your distribution or variation looks like and whether or not your data contain any outliers.

The example below looks at 22 door-to-ECG times.

The benefits to the facility that implements process improvement initiatives are many. They include streamlining patient throughput, resulting in a reduction in the time it takes for the patients to receive treatment, and decreasing costs by providing efficient and effective care that is void of duplication and waste. Process Improvement allows for consistent training and education, improves patient satisfaction, decreases liability exposure and improves work performance.
In this example, 22 door-to-ECG times were measured and categorized into blocks of time.

- 6 times the door-to-ECG time was 11 minutes - the "mean"
- 4 times the door-to-ECG time was 10 minutes and 4 times the door-to-ECG time was 12 minutes
- 3 times the door-to-ECG time was 9 minutes and 3 times the door-to-ECG time was 13 minutes
- 1 time the door-to-ECG time was 8 minutes and 1 time the door-to-ECG time was 14 minutes

The process of obtaining the ECG appears to be in control with little variation. We know this because, with a controlled process you would see that most times are close to the average with fewer times occurring the further you get from the average.

Now there is an opportunity to improve the process because it appears to be well controlled, or done in a consistent manner each time.

*Although 22 ECG times were used for the above example, larger numbers are typically more helpful in determining whether or not variation exists in a process.*
Pareto Chart

Pareto charting uses the "80/20" rule to target the problems you need to work on by helping you identify the largest contributor to those problems. According to the Pareto principle, 80% of the problem is caused by 20% of the steps. Using this principle can help highlight the biggest issues, or "low hanging fruit" so that you can better target your resources. The example below uses the Pareto Chart to determine why the team, when called in after hours, takes longer than 30 minutes to reach the lab, the goal for the facility. Each case surrounding team activation is examined, and the reason for the delay is plotted on the Pareto Chart.

A total of five reasons were found for the delay, but bad weather appears to be the overriding cause. Understanding this fact enables a facility to work on a solution that targets the major cause of this delay. In this case, requiring the on-call team to stay within the facility when bad weather is expected and providing them a sleeping area should improve response times.

Flowcharting

Flowcharting is the method used to determine how a process works by requiring an intense look at the current process, breaking down each step, and asking whether or not this step can be improved or deleted.
When a flowchart is created and a process is improved, the flowchart may be used to teach new staff members, many of whom are visual learners, how the process should be carried out. Posting the flowchart in areas where process steps occur allows for frequent visualization and reduces the possibility that variation will occur.

1. **Define the boundaries of the process**, where you will start and where you will end, and then begin to map the process. Mapping requires you to identify the big steps within a process, thereby directing you to the individuals needed to help create the more detailed version. This is the aerial view. For example, a flowchart illustrating the triage process from the time a patient enters the ED until the patient's initial ECG may look like this:

![Flowchart of triage process](image)

2. **Gather together the right people.** The people who work with the process are essential to help define the process. By interviewing the different people involved, you may find that the process is done differently by different staff members and during different shifts, weekends, and after hours. Variations in carrying out each task will be important to know going forth when process improvements are to be implemented.

3. **Remember, a flowchart is a graphic representation of a process** from beginning to end. Certain symbols are used to designate the steps of the process as they occur sequentially. For the purpose of accreditation, only eight basic symbols are necessary:

- Rectangle, designating an activity or activities
- Diamond, designating a decision that must be made
- Circle, designating an on-page reference
- Five-sided "home plate," designating an off-page reference
- Oval, designating the start or end of a process
- Arrow, connects symbols and indicates directionality
Delay, designating a delay in the process
Document, designating a document created in the process

5. The following illustration is an example of a flowchart of the process of EMS responding to a 911 call through delivery of the patient to the ED, using many of the symbols listed above.

When completed, the flowchart should be reviewed by others involved in the process who may not have been part of its creation. Observe the process while comparing what you see with what is on paper. When you are sure the flowchart is accurate and the process itself is being done in a consistent manner, you can begin to think about ways to improve the flow. Always keep in mind that if flowcharting properly, there will be many drafts before a final product is reached.

Additionally, in the true spirit of process improvement, even when completed the process itself should be continually critiqued for better and more efficient ways to perform the task. This will, of course, result in continual flowchart changes.
Relationship Flowchart

Much like the flowchart, the relationship flowchart shows sequentially the steps in a process. Unlike a flowchart, it also shows who or what department is responsible for carrying out each step. The same flowcharting conventions are used but the sequential steps are separated by role or department. In the following example, a simple relationship flowchart attempts to demonstrate the process surrounding both a walk-in and EMS patient with symptoms of ACS. Although in this example there is not a great level of detail, it is still possible to look at the various roles within this process to further define responsibilities and overlap between departments. For example, if the registration clerk is the first point of contact for the walk-in patient, he or she may be responsible for recognizing that a patient is experiencing symptoms of ACS. If the registration clerk is not properly trained, this could be a critical source of delay as valuable time may be lost if this type of patient is registered or sent to the waiting area before receiving treatment.
Variation

Every process contains variation. No two ways of performing a task are always the same. People have their own styles, their own interpretations of a process, and their own ways of carrying out the process. Some variation is normal, expected, and cannot be changed. This normal variation can actually be measured. Variation outside of the range of what is considered normal, also known as "abnormal" variation, needs investigation. It is this type of variation within a process that makes it difficult to successfully implement change. Abnormal variation must be identified and either eliminated if a "bad" variation, or incorporated into the process if found to be beneficial.
It is also important to understand "normal variation." For instance, when measuring door-to-balloon time with an average of 90 minutes, the measured times will not all be 90 minutes. Some may be 80 minutes and some 110 minutes. This does not mean that the staff with the 80 minute timeframe does a better job than those with 110 minutes. These time differences may all be part of the normal variation based upon a 90 minute average. A control chart will help identify both normal and abnormal variation.

Control Charts

If we don't monitor our processes, the variation mentioned earlier will creep in beyond that which we would normally expect and throw these processes out of control. When a process is not well controlled, making improvements becomes complex. In this case, there are just too many different ways of accomplishing a goal, and trying to implement one method of doing so will be very difficult. For change to be successful, it is necessary to ensure that the process being changed is being done in the same manner by everyone involved. It is only then that the outcome will be predictable and have the effect that is desired.

Control charting is an excellent method of identifying variation within the process. These charts use mathematical calculations to identify whether the variation is normal or abnormal. When this variation is identified and addressed, the process is ready for change. If day and night shifts are practicing differently, what process should be changed? If, on one occasion, the ECG was misplaced causing a longer than normal door to ECG time, should the entire process be changed? It would be better to remove that one data point and recalculate the average. Only if you repeatedly identified a lost ECG machine would you show a process in need of change.

The following illustration is an example of a control chart. Note that the control chart displays the average, 16.5 minutes, and an upper and lower control limit. Any data points that fall around the average in a "non-random" manner, or that fall outside of the upper and lower control limits, could indicate a process that is not well controlled. For instance, it would not be normal for one data point to be below the line and the next above the line, repeating in this fashion for a number of times. If these non-random data points represented different shifts, it could mean that day shifts and night shifts had two different ways of doing something. Data points that fall in a "random" manner are considered normal variation, or that amount of variation that will normally occur if a process is in control. Note in the example that there is one data point outside of the control limits. As previously stated, in addition to looking at non-random patterns, there
is a need to look at those data points that fall outside the upper and lower control limit. Statistically speaking, one would expect almost all data points to occur within plus or minus three standard deviations from the average (the upper and lower control limits, or UCL/LCL). This data point deserves a second look as it is outside of those parameters, indicating that some variation crept in and caused this out of control behavior.

One important point to remember regarding the selection of a control chart to identify variation is that processes change over time. In order to see what a certain process is doing presently, you need to get as close to the process as possible and have at least 15 data points before constructing the chart. For instance, you would not choose 15 ECG times done over the past six months. In the course of six months, the process of obtaining an ECG may have changed many times. Staffing differences, age of the equipment, etc., all could produce variations. It would be better to select the last 15 ECGs that were done. This sample is closer to the process you need to understand, the one that must be addressed. Control charts that span long periods of time can certainly show improvement in a process but do little to identify variation that is currently occurring. If you are doing 36 primary PCIs for STEMI each year, that would amount to only three per month. Control charting over the year will display trends up or down with a recalculation of the average but may not be as effective in showing current process variation given the long span of time in which the data were collected.
Root Cause Analysis

Essentially, this method of analysis takes you to the core of the problem. It is not a specifically defined methodology and thus, can be accomplished in a number of ways including the following popular but simple technique of using "The Five Whys." This method of determining the root cause of a problem was originally developed by Sakichi Toyoda and was later incorporated into the manufacturing process in the Toyota Motor Corporation. The following example demonstrates the Five Whys in action to help solve a simple issue.

**Problem: Our chest pain patients are being walked from triage to the ED**

- **WHY?** - We can't find a wheelchair
- **WHY?** - They are never put back after use.
- **WHY?** - Staff hide the wheelchairs so they are available when their patients need transported.
- **WHY?** - There are never enough wheelchairs.
- **WHY?** - The current supply of wheelchairs has deteriorated and was taken out of service.

**Solution: Budget for more wheelchairs**

By drilling down five times, it is likely you may find a simple solution to a common problem by determining the root cause of the problem.

Other types of Root Cause Analysis include the FMEA (Failure Mode and Effects Analysis) and the Ishikawi, or Fishbone Diagram. FMEA is a powerful analytical tool that allows examination of steps within a process to anticipate what may go wrong so that preventive measures can be taken prior to the unwanted occurrence. The Ishikawi, or "Fishbone" Diagram, looks at a current process, and isolates the steps within the process, helping to look for methods of improvement.

Focus + PSDA

Process improvement teams benefit from having a common framework for thinking about the improvement process. One popular approach is the FOCUS-PDSA model, defined as follows:
FOCUS

- Find a process to improve.
- Organize a team that understands the process.
- Clarify what is currently known about the process.
- Understand the causes of variation within the process and what is acceptable variation, and attempt to uncover the root cause of the problem.
- Select the method of improving the process and start the PDSA.

Facilities should first determine what they wish to accomplish, such as improving overall door-to-reperfusion times. The next step is to organize a team that is familiar with the process and supports the need for change. Look at the variation within the selected process and if it is not "normal variation" as previously discussed, attempt to eliminate or incorporate this variation so that the process is being done by everyone in a consistent manner. Try to identify process steps that cause delays, the "root causes" if possible.

This is a good time to refer to the flowchart, breaking down the total process into manageable steps with potential for improvement. When a root cause is identified and selected for process improvement, it is time to move to the PDSA cycle and implement the plan.

**PDSA (Plan Do Study Act), PDCA (Plan Do Check Act), Shewhart Cycle, Deming Cycle**

These titles/acronyms are all synonymous for the four-step model used to bring about process change. It is arguably the most recognized method of identifying an opportunity for change, implementing this change, and then continually monitoring the change for success, thus ensuring continuous improvement. Typically depicted as a circle, it is a recognized method of testing what has been identified as an improvement opportunity.

When the changes are selected, it is time to use the PDSA cycle to "Plan" the change, try it out ("Do"), "Study" the results, and "Act" on what was discovered during the implementation.

**Terms**

**Affinity diagrams**: A diagram that organizes a large number of ideas by finding relationships between them. The information is then gradually structured from the bottom up into meaningful groups. From there you can clearly "see" what you have and
then begin your analysis or come to a decision.

**Average:** The sum of all the values in a set of data divided by the number of values in the set. For example, if the values are 3, 5, 7, and 9, then the average would be 6 (total of all numbers ÷ 4).

**Basic flowchart:** A flowchart that shows the sequence of steps in a job or process. It can have different levels of detail.

**Cause-and-effect diagram:** A tool that is used for identifying and organizing possible causes of a problem in a structured format. It is sometimes called a "fishbone" diagram.
because it looks like the skeleton of a fish.

Centerline: The middle line on a control chart or time plot. It represents either the average or median value of the data.

Check sheets: Forms used to collect data by making tally marks to indicate the number of times something occurs. Check sheets help standardize the data that are collected and the data collection process.

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Common cause: A cause of variation that is inherent to the process.

Control Charts: A time plot that has a centerline and statistical control limits added. There is an upper control limit and a lower control limit. These limits allow you to quickly detect specific types of changes in a process.
Control limit: A line on a control chart that indicates either the upper or lower range of the common cause variation within a process. It is also called the "statistical control limit."

Cost-added only step: A step in a process that is not essential for producing the product or service. It is carried out because defects, errors, or omissions do occur or because we worry that defects, errors, or omissions might occur.

Cumulative line: A line that can be added to a Pareto chart. It shows how much, or what percentage, of the problem comes from the largest categories.

Data: Clearly defined measurements of characteristics. They are most useful when collected for the purpose of monitoring or improving a process.

Data point: A single measurement, count, or observation.

Deployment flowchart: A flowchart that shows the detailed steps in a process and which people are involved in each step. (Also see relationship flowchart.)

Detailed flowchart: A flowchart that breaks the sequence of steps in a job or a process into detailed substeps.
DMAIC: The methodology used in Six Sigma - define, measure, analyze, improve, and control.

Dot plot: A type of frequency plot that uses dots to show how often values occur in each interval. It shows the shape or distribution of the variation in the data.

80/20 rule: A principle that offers the belief that, in many situations, roughly 80% of the problems are caused by only 20% of the contributors. (Also see Pareto Principle.)

Error proofing: Implementation of fail-safe mechanisms to prevent a process from producing defects. (Also known as poka-yoke). The philosophy behind error proofing is that it is not acceptable to make even a very small number of defects, and the only way to achieve a goal is to prevent defects from happening in the first place.

Failure Modes and Effects Analysis (FMEA): A step-by-step approach for identifying all possible failures in a design, process, product, or service. "Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects,
especially ones that affect the customer, and they can be potential or actual. "Effects analysis" refers to studying the consequences of those failures.

**5S System:** A tool used in Lean Thinking. The idea is that a messy workplace, desk, or manufacturing cell makes it hard to find things, easier to get distracted, and more prone to accidents or mistakes. The 5 S’s stand for: sort - sort needed and unneeded items; set in order - arrange things in their proper place; shine - clean up the workplace; standardize - standardize the first three S's; and sustain - make the 5's part of the job.

**5 Step Process for Data Collection:** A process that ensures the collection of meaningful data and includes 1) clarification of data collection goals, 2) development of operational definitions, 3) planning for data consistency and stability, 4) beginning data collection, and 5) continuous improvement of measurement systems.

**Flowchart:** A picture of the sequence of steps in a process. Different steps or actions are represented by boxes or other symbols. Common types of flowcharts include basic, opportunity, and deployment.

**Frequency plot:** A graphical tool that shows the shape, or distribution, of the data by showing how often different values occur. This picture makes it easier to see what is happening with the data and to identify some types of process problems. (See histogram.)

**Gantt chart:** A Gantt chart is a graphical representation of the duration of tasks against the progression of time. It is a useful tool for planning, scheduling, and monitoring a project's progress.
Graph: A picture of data.

Histogram: A type of frequency plot that uses bars to show how often values occur in each interval. It shows the shape or distribution of the variation in the data.

Horizontal axis: the labeled straight line at the bottom of a graph that runs from left to right, or horizontally. It is also called the X-axis.

Improvement tools: Data collection and analysis tools used to better understand and more quickly solve problems.

Kaizen (Japanese for "improvement"): A Japanese philosophy that focuses on continuous improvement throughout all aspects of life. When applied to the workplace, Kaizen activities continually improve all functions of a business, from manufacturing to management and from the CEO to the assembly line workers. By improving standardized activities and processes, Kaizen aims to eliminate waste. Key elements of Kaizen are quality, effort, involvement of all employees, willingness to change, and communication.

Lean: A process improvement methodology that originated from the Toyota Production System (TPS). It focuses on improving efficiency by removing waste. Lean has come to mean any effort to do more with less and has become interchangeable with the term waste reduction. The five basic steps are identify value, define value stream, determine flow, define pull, and improve process.

Lean Six Sigma: A blended methodology that incorporates both Lean (focus on
process flow and waste reduction) and Six Sigma (focus on variation reduction). Six Sigma uses statistics to understand variation. Lean uses visuals such as flowcharting and value stream mapping to understand the process flow.

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<thead>
<tr>
<th>Program</th>
<th>Lean Thinking</th>
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<tr>
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<td>Variation is waste</td>
<td>Non-value add is waste</td>
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<td>Application</td>
<td>Define Measure Analyze Improve Control</td>
<td>Identify value Define Value Stream Determine Flow Define Pull Improve Process</td>
</tr>
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<td>Math-Statistics</td>
<td>Visualization</td>
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<td>Focus</td>
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<td>Process flow focused</td>
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**Lower control limit (LCL):** A value, represented by a line on a control chart, that specifies the lower limit of the results of common cause variation. Data points that fall below this value provide signals of special cause.

**Matrix diagram:** A graphical tool that shows the connection or correlation between ideas or issues in the form of a table (matrix). A relationship is indicated at each intersection of rows and columns as present or absent.

**Mean:** The arithmetic average of a list of numbers. (See average.) Example: Door to ECG times of 2, 3, 4, 8, 8. The mean time is 5 minutes.

**Median:** The numerical midpoint of a list of numbers. It is found by rank ordering the values and locating the number that in rank is halfway between the beginning and end. If there are an odd number of values, the median is the middle value; if there are an even number of values, the median is the average of the middle two values. Example: Door-to-ECG times of 2, 3, 4, 8, 8. The mean time is 4 minutes.

**Metric:** A measured variable that is tracked and can be used to detect errors or variation and make improvements.

**Mode:** The value that occurs most often in a list of numbers. Example: Door-to-ECG times of 2, 3, 4, 8, 8. The mode time is 8 minutes. A set of data can have more than one mode.

**Non-value-added steps:** Activities that do not contribute to the product or the process
and should therefore be eliminated. Non-value-added steps are waste.

**Operational definition:** A precise description that tells how to get a value for the characteristic you are trying to measure.

**Opportunity flowchart:** A detailed flowchart organized to separate steps taken when things go right from steps taken when things go wrong.

**Pareto chart:** A graphical tool that helps break a big problem down into its parts and then identifies which parts are the most important.

**Pareto Principle:** A principle that states that, in many situations, a small number of...
causes account for most of the problems, while most of the causes account for only a few of the problems. (Also see 80/20 rule.)

**PDSA (Plan Do Study Act), PDCA (Plan Do Check Act), Shewhart Cycle, Deming Cycle:** Titles/acronyms for the four-step model used to bring about process change. It is arguably the most recognized method of identifying an opportunity for change, implementing this change, and then continually monitoring the change for success, thus ensuring continuous improvement. Typically depicted as a circle, it is a recognized method of testing what has been identified as an improvement opportunity.

**Process:** A series of linked steps necessary to accomplish work. A process turns inputs, such as information or raw materials, into outputs such as products, services, and reports.

**Pull:** A production system characterized by smaller batches, quick responses to customer demand, and smooth product flow. Originating from the famous Toyota Corporation, pull production is a process that aims to arrange an organization so that customer preference or orders are what cause materials to be "pulled" through a system.

**Range:** The difference between the lowest and highest values in a list of numbers. Example: Door-to-ECG times of 2, 3, 4, 8, 8. The range is 6 minutes. The range tells you something about how spread out the data is. Data with large ranges tend to be more spread out.

**Relationship flowchart:** A flowchart that shows the detailed steps in a process and who is involved in each step. Each of the people or groups involved in a process is listed across the top of the chart, and the steps are arranged in the columns of the people who carry them out. (Also see deployment flowchart.)
Root cause: The deep, underlying cause of a problem in a process or system.

Run charts: Graphs of data over time.

Scatter diagram: A graphical tool that shows the relationship between two variables also referred to as scatter plot.
Six Sigma: Six standard deviations from mean Sigma is the Greek letter used to represent standard deviation in statistics. Six Sigma methodology improves an existing process by constantly reviewing and re-tuning the process. To achieve this, Six Sigma uses a methodology known as DMAIC (define, measure, analyze, improve, and control). This methodology focuses on improving process capability by reducing variation.

Special cause: A specific or assignable cause of variation that is outside of the normal variation in a process. It is signaled by a data point falling outside of the upper control limit (UCL) or lower control limit (LCL), or by one of several defined patterns on a control chart or time plot.

Stratification: Dividing a whole group of data into subgroups (strata) to see whether the data are different for different subgroups. This helps focus efforts on those factors that have the most impact on the problem.

Time plot: A graph of data in time order. It helps identify any changes that occur over time.
**Time-ordered data:** Characteristics that are measured, counted, or observed and recorded in the chronological order in which they occur.

**Top-down flowchart:** A flowchart that shows both the major steps in a process and the next level of substeps.

**Upper control limit (UCL):** A value, represented by a line on a control chart, that specifies the upper limit of the results of common cause variation. Data points that fall above this value provide signals of special causes.

**Value-added step:** A step in a process that is essential for producing the product or service at the current level of technology.

**Value stream mapping:** A Lean technique used to analyze the flow of materials and information currently required to bring a product or service to a consumer.

**Variable:** The characteristic(s) that you are measuring.
Variation: Differences among measured values in a process.

Vertical axis: The labeled straight line at the side of a graph that runs up and down, or vertically. It is also called the Y-axis.

Work-flow diagram: A tool for collecting data on how work flows through an operation. The path of the work is recorded on a schematic of the workplace.

Value chain: A chain of activities. Products pass through all activities of the chain in order and at each activity the product gains some value. The chain of activities gives the products more added value than the sum of added values of all activities.