



NCC Pediatrics Continuity Clinic Curriculum: **PCMH 3: Patient Safety and Quality** *Faculty Guide*



Goals & Objectives:

Upon completion of this module, the learner should be able to:

- Understand the uses for **fishbone diagrams** (cause and effect diagrams).
- Apply the “**5 whys**” technique to identify the root cause(s) of a medical error.
- Design a multidisciplinary team to drive quality and safety measures.
- Describe the leader’s role in quality improvement and patient safety.

Pre-Meeting Preparation:

Please do the following:

- Read PIR article “Core Principles of Quality Improvement and Patient Safety”
- Watch the 5-minute video “[Cause and Effect Diagrams](#)” on the Institute for Healthcare Improvement web site

Conference Agenda:

- Discuss Case 1
- Discuss Quiz

Extra Credit:

- [IHI Open School](#) - more than 30 free courses available in patient safety, quality improvement, leadership, and patient-centered care. CME and MOC Part 2 credit available; also offers certificate program in basic quality and safety. Courses are in digestible 15- to 40-minute blocks. FREE just by emailing your request to info@ihi.org.
- [AAP EQIPP](#) - Takes the worry out of completing quality or process improvement projects! The course leads you through, step-by-step, and produces most of your charts and statistics automatically. Free to AAP members and eligible for both CME and MOC Part 4 credit. Includes a short course in basic QI.
- [Lean Six Sigma](#) - Philosophy of improvement that values reduction in waste and process variation. Three industry-level certification courses are available at WRNMMC. For more information, contact [Dana Koester](#). Also see [Quality Directorate](#), [TeamSTEPPS](#).
- [ABP Content Specifications for PI/QI/Patient Safety](#) – 1.5% of the ABP exam involves Quality Improvement and Patient Safety (page 76).

Core Principles of Quality Improvement and Patient Safety

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Education Gap

Despite proven results in industry, quality improvement and safety implementation lags in the health care arena. Improving patient safety and quality of care requires an understanding of leadership, teamwork, system design and function, change motivation, and a scientific/statistical approach to assessing whether changes are leading to improvement.

Objectives After completing this article, readers should be able to:

1. Understand the importance of leadership in creating a culture of safety and quality improvement in the health care system, with an emphasis on reducing blame and improving learning.
2. Use tools such as process maps and fishbone diagrams to identify weaknesses in systems that may contribute to errors or suboptimal quality of care.
3. Effectively use multidisciplinary teams in driving quality and safety efforts.
4. Utilize both extrinsic and intrinsic motivation in individuals to elicit acceptance of changes to their practice and procedures.
5. Use a rational, scientific approach to implementing changes and assessing the results of those changes in the context of system variation.

CASE PRESENTATION

AUTHOR DISCLOSURE Dr Bartman has disclosed no financial relationships relevant to this article. Dr McClead has disclosed that he receives research grant funding from the Cardinal Health Foundation related to adverse drug event reduction and neonatal abstinence syndrome management and that, at the time of writing this article, he served as a board member for the March of Dimes Ohio Chapter.

At 2 AM on July 2, a pediatric intern enters room 4 of the emergency department (ED) to see his next patient. He encounters 4-year-old Aiden, whom his parents report has not been feeling well for a few days. In addition, they report decreased oral intake. Aiden is communicative but listless. His extremities are cold, he has delayed capillary refill, and he has weak pulses. His heart rate is 140 beats per minute and blood pressure is 80/50 mm Hg. The intern decides that Aiden is dehydrated and submits electronic orders for the nurse to place an intravenous line, draw blood for a complete blood cell count and blood culture, and administer a bolus of 10 mL/kg of normal saline. Expecting that these events will take some time, he leaves the room to discuss the case with an

attending physician but discovers that she is currently in another room with another patient. To be efficient, he decides to begin working with his next patient and to return to Aiden in 30 to 60 minutes. Forty-five minutes later, a code is called in room 4, and he returns to find the boy being intubated and receiving chest compressions. Aiden is subsequently admitted to the PICU but soon dies of septic shock.

KEY PRINCIPLES OF PATIENT SAFETY

Patient safety and quality of care are intertwined, as demonstrated in the case presentation. Typically, we think of quality in health care as providing the best clinical outcomes and safety as not harming the patient, but poor quality care can be riddled with errors and unsafe acts. Over the last few years, the concept of aiming for “zero” preventable harm has taken hold in many pediatric institutions. The journey to “zero” requires application of 3 key principles of patient safety: development of a safety culture, staff accountability, and institutional transparency. In a safety culture, staff receives error prevention training, exhibits certain safety behaviors, and employs safety tools that are typically associated with high-reliability organizations such as the nuclear power industry, railroads, and commercial airlines. As a culture of safety and accountability evolves, hospital staff increasingly uses voluntary reporting systems to identify opportunities to improve patient safety. Transparency, both internally and externally, allows hospital staff to see the results of their safety focus.

At our academic institution, serious preventable patient harm has decreased 68% since 2009, serious safety events and harmful medication errors are down 85%, 41% of stage 3 and 4 decubitus ulcers have been eliminated, and the unadjusted mortality rate is down 25%, which is well below the severity-adjusted mortality rate. We calculate that these efforts have eliminated 200 preventable deaths from 2009 through 2013 based on our pre-2008 rates. (1) We employed several specific interventions to achieve these milestones. We created a preventable harm metric that focuses on the number of patients harmed and not a rate. (2) A structured error prevention training program was given to all 10,000 employees, followed by audits of the use of safety behaviors and tools. We became transparent by posting key quality data on our public Internet and hospital intranet sites and established a patient-centered quality and safety strategic plan that hospital staff could understand and articulate. (3) Finally, a robust cause analysis process and event classification system was crucial to our success. Of note, we believe these interventions would not have been effective without the attention of executive leadership.

THE IMPORTANCE OF LEADERSHIP IN CREATING A CULTURE OF SAFETY IN THE HEALTH CARE SYSTEM

A hospital or practice seeking to dramatically improve patient safety needs leadership that can create a sense of urgency to drive transformational change within the organization. Visionary leaders have unique characteristics. Like all leaders, they begin with a vision of what can be. Their vision “emanates from their passion, values, ethics, and etiquette.” Their “vision clears the clutter and makes the path free of obstacles.”(4)

Visionary leaders also can articulate their vision through a story that motivates and inspires people to follow their lead. Telling staff the story of the preventable death of a patient (as in the case presentation) rather than burying the story can motivate change. The fact that every health care worker has experienced such a story (or soon will) is motivational and creates the sense of urgency that is needed to perform the difficult task of eliminating, not just reducing, preventable patient harm. These stories move the work of quality improvement (QI) and safety from the abstract to the tangible.

SYSTEMS AND HUMAN FACTORS

In 1999, the Institute of Medicine (IOM) released its seminal report *To Err is Human*. In that report, the IOM claimed that between 44,000 and 98,000 patients die in American hospitals from preventable medical errors each year. (5) Sadly, 10 years later, the problem had not improved; in fact, today the problem may actually be 4 times worse than predicted. The root causes of these preventable medical errors can be classified by taxonomies of systemic and individual failure modes. (6) To understand these failure modes, clinicians must first grasp the concept of systems thinking and the role of human factors in medical errors.

Systems Thinking

Paul Batalden, MD, Dartmouth School of Medicine, pointed out that “Every system is perfectly designed to achieve the results it gets.” Further, a well-known dictum is that “Insanity is doing the same thing, over and over, and expecting a different result” (attributed to Einstein but actual source is unknown). Thus, to achieve different results, the system must be changed.

A system is a set of interdependent elements that interact to achieve a common aim; a hospital or health care network is an integrated system that has multiple interrelated and interdependent parts. Quality efforts always involve systems with multiple interdependent elements that may work

collaboratively toward a common aim or be at odds over mutually exclusive goals. To establish a successful patient safety program, the interdependency of the program elements must be understood to focus on and accomplish a common goal (eg, to eliminate preventable patient harm). An example of a system composed of interdependent processes is medication management, which involves prescribing, dispensing, administering, and monitoring medications. Addressing the problem of medication errors requires understanding how each of these processes interrelates. If a practitioner writes a poorly legible order for a medication, the pharmacist may dispense a wrong medication or the wrong dose of the right medication. The nurse may fail to perform the 5 rights of medication administration by not confirming that the dispensed medication is the ordered medication for the patient to whom she is about to administer the medication. Consequently, an adverse drug event (ADE) and potential patient harm may result. To prevent these errors, an ADE reduction team must work to create a highly reliable medication management system through understanding and optimizing the performance of all of the interdependent system processes.

Human Factors That Contribute to Error

Health care systems are designed and operationalized by people who are less than perfect. In the case presentation, the new intern did not understand the gravity of the signs of septic shock in his patient and did not follow well-accepted guidelines for the management of septic shock. Although there is a component of individual failure in this case, educating the individual does not guarantee that the same error would not be made by another intern. The tendency is to blame individuals for all their (human) failings, but the system deserves blame for errors when it is not designed to mitigate the fact that humans are a part of every system and cannot be expected to be perfect. A human factor is a physical or cognitive characteristic that influences how people interact with systems. When medical errors occur, human factors such as fatigue, stress, external distractions, and personal issues may be responsible, but poorly designed medical equipment may also be contributory (eg, different doses of medications in poorly distinguishable packaging). The study of human factors is a multidisciplinary science that combines the expertise of psychologists, engineers, industrial designers, statisticians, and others. "The primary goal of human factors science is to promote efficiency, safety and effectiveness by improving the design of technologies, processes and work systems."⁽⁷⁾ Human factors science seeks to understand human capability and apply and integrate this knowledge to system design.

Human factor errors are commonly evident where technology intersects with individuals performing high-risk functions. Critical care units frequently are sites of high-risk activities such as blood transfusion and invasive procedures. When engaged in these activities, the medical and nursing staff must recognize when human factors can impair their performance. Lack of situational awareness and failure of critical thinking are root causes of individual failures that contribute to medical error.

Just as health care workers cannot avoid performing high-risk activities, so they cannot avoid the burden of human factors that contribute to medical error. However, human behavior can be modified to recognize when human factors are at play. Staff can be taught error prevention techniques to aid their performance. One such technique (adapted from the International Organization for Standardization) is Qualify, Validate, and Verify (QVV). Using the QVV technique, when individuals are in doubt about how to proceed, they are expected to ensure that the act complies with a standard, obtain corroboration for their action, and ensure that their understanding of a situation is accurate.

To reach high reliability with regard to safety behaviors and tools, leaders must support and reinforce the staff. Leaders must be trained in the methodology that promotes patient safety and preventable patient harm. *Rounding to Influence*,⁽⁸⁾ *Safety Leader WalkRounds*TM,⁽⁹⁾ and daily huddles to proactively identify safety risks are some of these techniques. Providing effective feedback to frontline staff regarding their use and nonuse of safety behaviors and tools is also important, ideally in a ratio of 5 positive comments to staff about their effective use of safety behaviors and tools for every 1 critical comment regarding their lack or inappropriate use.

SYSTEM AND PROCESS ANALYSIS AND DESIGN

Most systems are dynamic; while the function of the system may remain the same, the relative efforts of the system are under constant flux. Two important concepts in system design related to this dynamic are "stocks" and "flows." Stocks are an accumulation, whether of money, people, or other resources. For example, the number of patients in the ED is a stock. Flows describe the paths through which stocks are affected. For example, admissions and discharges are flows affecting the patient census stock. Most systems have complicated interrelationships between multiple stocks and flows, and the system attempts to maintain equilibrium when affected by outside forces. When the number of patients in the waiting room of the ED increases, the system adapts in an attempt to return the waiting room to the

desired baseline, such as by trying to identify patients who can be treated quickly to achieve quicker turnaround. An important aspect of this concept is that different players in the system may have different ideal stock levels. Patients wish for the stocks of patients in the waiting room and ED to be as low as possible, while nursing management may wish for the presence of a specific number of patients to justify staffing. When considering interventions to “improve” a system, it is important to recognize that the definition of improvement varies among individuals, and their actions to affect the flows seek to bring the stocks to their own ideal.

A number of qualities can be designed into a system to increase the ability to function well over a wide range of conditions, including resilience, self-organization, and hierarchy. Resilience indicates the ability of a system to return to a baseline state after being pushed away from that baseline. Resilience does not suggest that the stocks and flows in a system never change; rather, the design of the system allows them to return after an exerted pressure. One method of building resilience into a system is to design multiple mechanisms of adaptation that work on different scales. For example, if the number of patients presenting to the ED increases, putting pressure on nursing staff, 3 stages of options are to call in extra nurses for a shift (a short adaptation), use a float pool (a medium adaptation), and hire more nurses if the increased census becomes prolonged (a long adaptation). Self-organization refers to the ability of a system to reorganize itself or become more complex as situations change as opposed to operating in only one manner. This is related to having an appropriate hierarchy where subsystems are allowed to self-regulate while the top of the hierarchy maintains responsibility for coordinating the efforts of subsystems without “micromanaging” them. In this case, the hospital administration must ensure that efforts to improve a situation in the ED do not worsen the situation on the floor and vice versa.

Two common QI tools used to analyze a system are the process map and the Ishikawa (fishbone) diagram. Process maps are best created by having the members of a system describe the steps they take and subsequently verifying this by observation because the process is often more complex than system members recognize. Recognizing the complexity of even the simplest processes often allows the QI team to work to reduce steps and delays, a central tenet of the LEAN philosophy (10), which seeks to create improvement by reducing waste. Figure 1 demonstrates an extremely simplified version of a process map for treating the patient with septic shock in the ED. Fishbone diagrams are based on process maps and created when team members brainstorm for every possible cause of system failure and categorize these into a few basic groups. For health care processes, these groups could be Policy, Procedure, Plant, People, Environment, and Measurement. For each potential cause of failure, the team drills down repeatedly, asking “Why would that happen?” until that cause is fully explored (this is known as the “5 Why’s” technique). Figure 2 demonstrates an extremely simplified version of a fishbone diagram for treating the patient with septic shock in the ED.

TEAMWORK IN QUALITY AND SAFETY EFFORTS

The delivery of health care has become a “team sport.” Accordingly, the work of eliminating preventable patient harm can only be accomplished by multidisciplinary teams focused on a specific aim. Improvement teams have proper size and composition. Hierarchical relationships do not exist. Team processes for communication, decision making, and conflict management are clear, and leadership “emphasizes excellence and conveys clear goals and expectations...Effective teams have a culture that fosters openness, collaboration, teamwork, and learning from mistakes.” (11)

Including individuals perceived as leaders or authorities on improvement teams may create hierarchy and impair

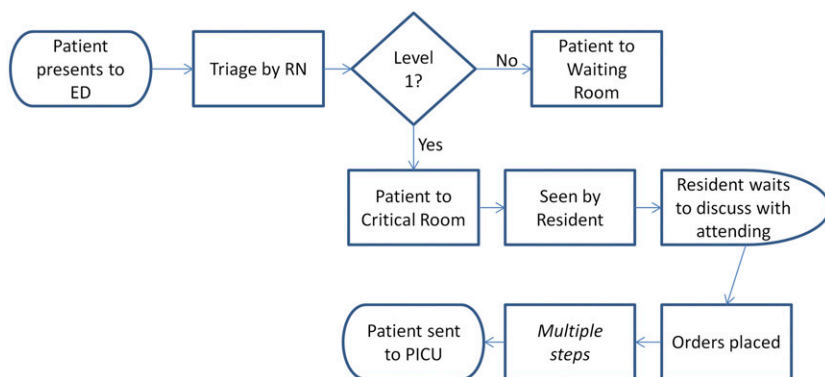
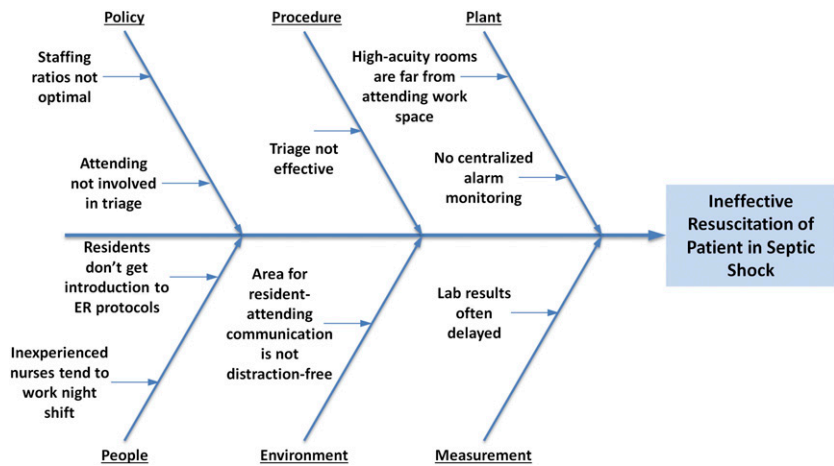


Figure 1. An extremely simplified process map for a patient with septic shock. Each person with any involvement in the process should participate in mapping his or her part of the process to reveal complexity and allow for identification of ways to simplify the process and/or build in reliability to critical steps. ED=emergency department, RN=registered nurse.

Figure 2. Fishbone diagram for a patient with septic shock. In this very simplified version, team members brainstorm to identify possible causes of failure. For each cause found, they should continue to “drill down” by repeatedly asking “Why is that?” until the root causes are identified. ER=emergency room.



successful team functioning, but in our experience, the presence of physicians on teams is advantageous as long as they respect the content knowledge of other team members. For example, a team assembled to improve the resuscitation of patients in shock (case presentation) requires physicians who can understand the work process and identify barriers that need to be addressed. However, the physicians must recognize that the process of treating these patients involves registration clerks, nurses and nurse managers, pharmacists, care assistants, patient transport, respiratory therapists, and more. A physician can demonstrate leadership by motivating the team and providing positive feedback that conveys his or her appreciation and pride for the additional effort of the team members without dominating the discussions of how the process should be fixed.

An executive presence can also augment effective team functioning. Sometimes the leaders of teams lack the conviction that what they are trying to accomplish is worth their effort. They may not believe that the interventions are effective. That disbelief is often unstated but is communicated indirectly to the rest of the team by innuendo, eye-rolling, or lack of attendance at team meetings. Assigning a senior executive who attends team meetings, reviews progress reports, communicates with other senior leaders, and provides needed positive reinforcement and congratulations can substantially promote team effectiveness. The presence of senior leadership sends the message that the team's work is important and the effort is valued. Finally, the leader can be critical to eliminating barriers to improvement.

THE LEARNING ENVIRONMENT

The delivery of evidenced-based care in the United States is not very reliable. Studies reported more than a decade ago

(12) indicated that Americans receive, at best, 50% of recommended care, and there is little evidence of widespread improvement in this metric. QI work involves implementation of evidence-based interventions, but without a QI team focus, such implementation may take years. Evidence of the effectiveness of an intervention from randomized, controlled trials is not enough. The health care community must believe that the intervention is effective. That belief is created by the learning inherent in the iterative process of implementation: the plan/predict-do-study-act (PDSA) cycle.

Creating a Learning Environment

To Err is Human (5) stressed that creating a learning environment is crucial for the development of a safer and more reliable health care system. The IOM recommended 5 elements of a learning environment. First, learning environments should use simulation in training of staff performing safety-critical functions. Simulation does not require highly sophisticated gadgetry; rather, it requires “practice to perfection” and effective coaching. The Toyota Job Instruction method (13) is a good example of such training.

The second element of a learning environment is a culture of reporting errors and hazardous conditions. Voluntary reporting systems in health care have a notorious reputation for unreliability. However, we have found that within a culture of safety, a voluntary reporting system can be profoundly effective. Thirdly, the reporting of errors must be accountable but free of the “shame and blame” culture that has been common to health care. “The most important barrier to improving patient safety is lack of awareness of the extent to which errors occur daily in all health care organizations.” (5) A punitive culture can eliminate any opportunity for an organization to learn from its errors.

Fourthly, in a learning environment, communication flows freely between and among disciplines involved in a patient's care. Nurses can share their "gut feelings" that something is not right with the patient. They know that the other members of the patient care team will listen to their concerns. Together, they will develop a plan to mitigate the risk of patient deterioration, a "code outside the ICU," or the need for an unplanned transfer of the patient to a critical care unit. If a patient does deteriorate despite the mitigation plan, care can be escalated in a controlled process. (14)

The fifth element of a good learning environment is a system for analyzing errors and identifying their root causes. The cause analysis process must be sufficiently robust to generate a "story" of what happened and why. The lessons learned from the analysis must inform the recommendations generated. Those recommendations must be implemented and monitored for effectiveness and any new safety problems that might result.

THE SCIENTIFIC METHOD FOR IMPROVING SYSTEMS

In the well-known scientific method for research, a researcher constructs a hypothesis, designs an experiment to test the hypothesis, collects data from the experiment, and finally analyzes the data to support or reject the hypothesis. This process allows the researcher to claim a sound understanding of the natural system being tested. More important than the results of a specific experiment, the scientific method allows the researcher to state, "I understand how this works." The Langley Model for Improvement (Associates in Processes Improvement, Institute for Healthcare Improvement) has an analogous process termed the PDSA cycle, which can be repeated as necessary to increase a team's confidence that they understand a system.

In the planning/predictive stage (P), the team uses facts and theories about how a system functions to design an intervention, which may lead to improvement. This is identical to hypothesis development and experimental design. The team then implements a change and collects data (D), analogous to running an experiment. As data are collected, the team studies (S) and performs analysis to determine if the hypothesis regarding the effect of the intervention was accurate. Finally, the team acts (A) based on the results of the analysis. If the intervention proves to be effective, the team may adopt the change as permanent in the process and possibly expand use of the change after testing it on a smaller scale. If the intervention needs to be refined or retested, the change may be adapted for another cycle. Finally, if the intervention proves clearly ineffective, the change may be abandoned.

The initial size of a PDSA cycle should be determined by 3 factors: 1) how great is the belief that the change will create improvement, 2) how willing are those affected to attempt the change, and 3) what are the risks of failure from the change? If a team is convinced that a change will be good, the front-line staff is eager to implement the change, and the risks of failure are inconsequential, the change might be immediately implemented. However, such instances are rare. More commonly, a team (or leader) may feel the first criterion is met and issue a dictum or policy change that is not well received because the latter two conditions are not met. Such behavior is likely to create resistance to further efforts to effect change. When confidence that a change will lead to improvement is low, the staff must "buy in" to the merits of a change or some risk of backfire exists. The PDSA may involve a single episode involving 1 nurse or 1 patient for 1 day before completing the "study" and "act" parts of the PDSA cycle.

USING DATA TO UNDERSTAND VARIATION AND IMPROVEMENT IN SYSTEMS

The goals of clinical research and QI are similar: to introduce a change and ascertain if improvement is achieved. Research and QI differ in the approach to dealing with variation. In a typical randomized, controlled trial, variation between the test groups is eliminated as much as possible. In research, variation in the data is accounted for by measures of spread of the data (eg, standard deviation or ranges) and plays a role in the calculation of statistical significance such as the t-test. Randomized, controlled trials must be conducted with an appropriate sample size to ensure that after an extensive trial, with extensive data collection, the null hypothesis can be rejected with the desired statistical significance for an expected magnitude of the effect. In contrast, QI is performed on systems with ongoing variation, usually involves a sequence of interventions, and requires the ability to detect improvement rapidly. Ideally, the goal of the work is to associate with some confidence the timing of the introduction of an intervention with the timing of improvement. Thus, the approach to data collection and analysis must differ from that used with clinical research.

Run Charts and Control Charts to Look for Improvement

The solution to understanding variation in data was developed in the 1920s by Walter Shewhart, and his techniques have been the standard in industry for almost a century. He realized that data must be collected and graphed over time to see the inherent variation present (known as "common cause" variation) and to determine when new data points

indicate that something unusual is occurring (known as “special cause” variation). Mathematically, common cause variation refers to variation that fits within the statistical bounds of an expected distribution, while special cause variation does not fit this expected distribution. Unfortunately, human psychology frequently relies on heuristics such as ignorance of sample size and misperception of randomness to conflate common cause and special cause variation, thus “eyeballing” data or “having a feeling” about whether variation is common or special cause is inappropriate.

The simplest graphs of QI data are “run charts” (Fig 3) that do not require special software or statistics. Each data point is plotted on graph paper and the median line is drawn. As change activity occurs, the run chart is evaluated for signals of improvement: either 6 points in a row all on one side of the median line or a trend of 5 continually increasing or decreasing points. Data that follow either of these patterns are not “random” or common cause variation and signal that the process has been fundamentally changed.

The drawback of run charts is that without any statistical analysis, the ability to detect signals of special cause is limited. Once approximately 20 data points are available, a more powerful chart, the Shewhart (a.k.a. control) chart may be created with appropriate statistical software. In these charts, the type of data being collected (continuous measurements such as time or laboratory values versus counts such as number of events) determines the expected type of data distribution. Continuous data are expected to follow a normal distribution and are plotted on I- (for individual) or X-bar (for averaged data) charts. Count data or normalized count data follow Poisson distributions (the probability of a number of independent events occurring in a fixed time) and are plotted on c- or u-charts (number of defects per sample chart or number of defects per unit chart), respectively. Percentage data follow a binomial distribution and are plotted on p-charts.

Data are still displayed over time on Shewhart/control charts, but the statistics behind the chart allow identification of points that do not fit the previous distribution. These can be either individual points that are well out of range or a

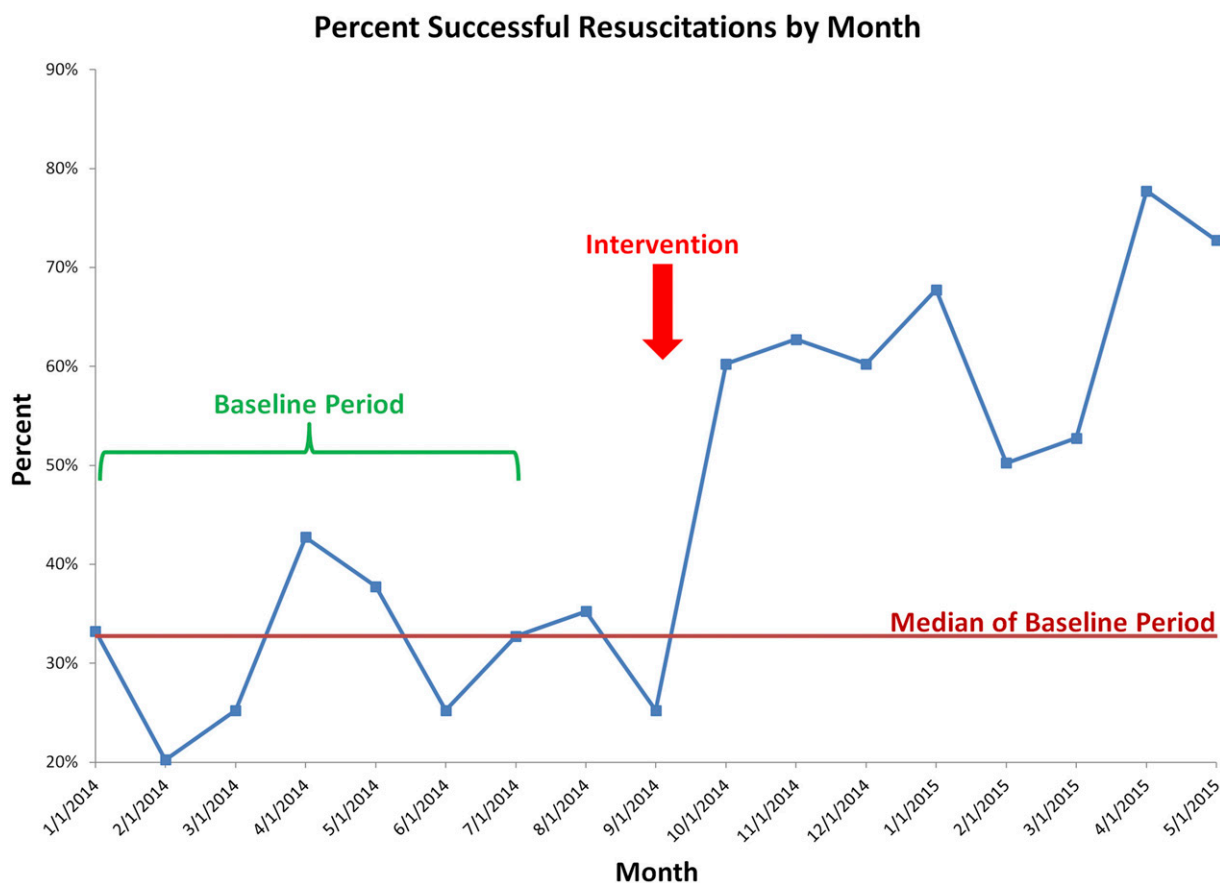


Figure 3. A run chart for successful resuscitation of patients within 1 hour. Each month, 1 point is plotted for the percent successful resuscitations. A median line is drawn to determine if the process has shifted to a new level. In this example, 6 successive points above the median indicate that a new process has been created that is fundamentally improved and stable.

series of points that suggest that the distribution has shifted. The most commonly used special cause rules (known as the Nelson rules) are: 1) any point beyond 3 standard deviations from the mean, 2) 9 points on one side of the mean, 3) a trend of 6 increasing or decreasing points, and 4) 2 points more than 2 standard deviations from the mean. Figure 4 demonstrates a control chart where rule 1 (an outlying point) is identified. This would not have been detected as special cause on a run chart. Once this point is seen, the team can learn about their process by investigating what led to this special cause.

The Perils of “Before” and “After” Data

A strong tendency of those who are accustomed to research techniques is to aggregate all the data from before and after the intervention to perform statistical tests on 2 samples (pre- and postintervention). This must be avoided for reasons shown in Fig 5. Referring to the case presentation, data have been collected each week for 7 weeks to determine

the number of times the septic shock protocol was not followed in the ED. The graphic presentation provides a sense of the inherent (common cause) variation in the process. An intervention is put into place in week 7, and data continue to be collected. Case 1 clearly demonstrates that the system has changed, with none of the postintervention points overlapping with the preintervention points. The reviewer could feel confident claiming that the intervention placed in week 7 led to this result (unless another persistent change to the system that happened concurrently can be identified). Case 2 demonstrates no change from the intervention. Case 3 demonstrates that the system performs better after week 7, but display of data over time suggests that the intervention is not responsible for the improvement because the system is already changing. Case 4 demonstrates improvement that is lost (possibly from another cause), and case 5 demonstrates sustained improvement that began before the intervention was put in place. Finally, case 6 shows an outlier in week 4. Each of these charts tells

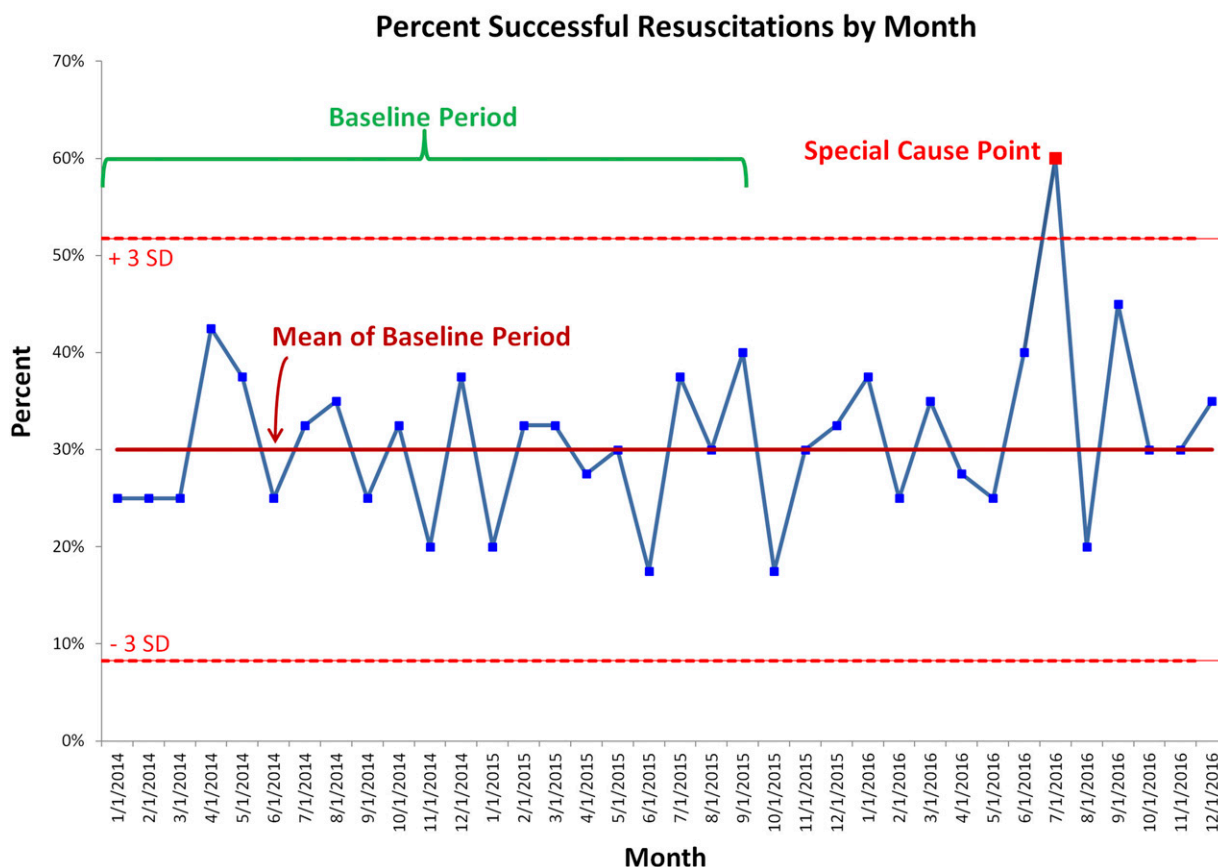


Figure 4. A control (Shewhart) chart for successful resuscitation of patients within 1 hour. Each month, 1 point is plotted, and once 10 to 20 points are available, the control chart software can define expected limits of variation (± 3 standard deviations [SDs] for the distribution type). The point in July 2015 is above the upper control limit and suggests that something unusual occurred that month (in this case, something good), which should be investigated to determine what led to system improvement.

a vivid improvement story. Grouping all the data points from weeks 1 through 7 (“pre”) and weeks 8 through 14 (“post”) would show a t-test significance ($P < .05$) for cases 1, 3, 4, and 5. However, in 3 of those 4 cases, failing to display data over time and relying on a statistical test of the aggregated pre- and postintervention data would have led to an erroneous conclusion about the effectiveness of the intervention in week 7.

Associating Interventions with Improvement

As stated previously, the goal of QI is to make changes that lead to improvement. As we make changes to our systems, we use run or control charts updated in real time to identify if improvement is occurring (by looking for special causes in our data). If the timing of an intervention is temporally correlated with special cause and no other changes to the system occurred at the same time, we have strong reason to believe that our intervention was effective. Note, however, that we cannot simply choose to recalculate system performance before and after the change. We know the system is performing differently when we see the signal, not just because we put an intervention in place.

One question the improvement team needs to consider is the type of data to be used to assess for improvement:

continuous versus count data. Continuous measurements require a measuring device (ruler, thermometer, clock, scale) and can take on any value. Counts are simple counts, including percentages (which are counts of pass and fail) and rates (eg, counts per 1,000 line days). Continuous measurements may be more difficult to collect because of the requirement of a measuring device and ensuring accuracy may also be difficult. For example, the time to complete the septic shock protocol depends on use of a stopwatch or synchronized clocks. However, in some cases, shifts in data may be more easily detected with continuous measurements. Count measurements are simpler to collect. For example, the team may choose to note whether the septic shock protocol is completed within 60 minutes for each patient. However, time to complete the protocol may improve without changing the percentage of patients completed within 60 minutes and, thus, a signal of improvement might be harder to detect. Despite this limitation, in some situations using a pass/fail metric is appropriate when a good measure for success with important ramifications exists. In the case presentation, improving from a mean of 120 minutes to 90 minutes may not be cause for celebration if a low percentage of patients are still experiencing the expected care within 60 minutes.

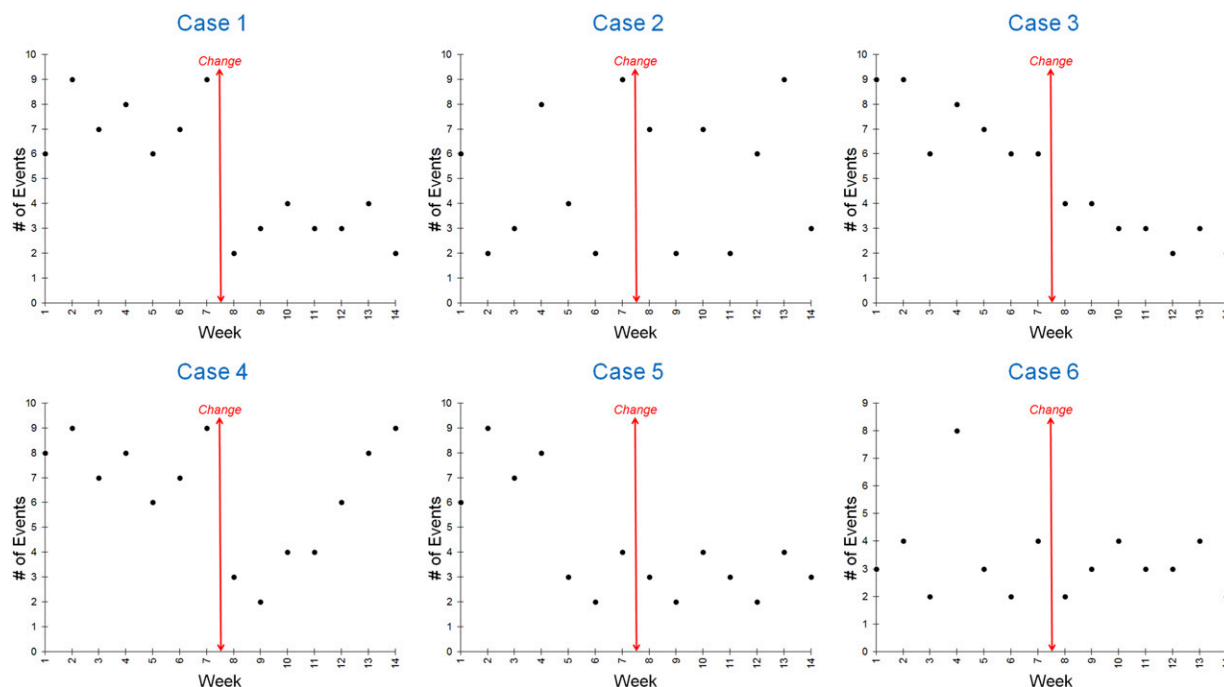


Figure 5. Example of why data must be displayed chronologically. Quality improvement data must be displayed over time to allow for correlation between changes introduced to a system and the results of those changes. Simple pre-/postintervention analysis with t-tests can be misleading if changes in system performance become hidden in aggregated data. Cases 3, 4, and 5 meet criteria for significance pre- and postintervention (in week 7), but graphical display over time allows for a more robust interpretation of how the system is functioning. Adapted from Provost and Murray (15) with permission.

PSYCHOLOGY AND MOTIVATION OF CHANGE

We are all abundantly aware of how difficult it is to motivate and sustain change in ourselves, much less in others around us. Yet in the words of Winston Churchill, “To improve is to change; to be perfect is to change often.” Without change, improvement cannot possibly occur. Motivation to change can occur through extrinsic or intrinsic means. Extrinsic motivation is commonly referred to as “carrots and sticks”: rewards and punishments to drive a desired behavior. Certainly transparency and accountability are fundamental to QI, and accurate reporting of individual or unit performance can be a beneficial motivator. When individuals or teams can see hard data demonstrating their performance relative to others, those at the bottom may find it difficult to justify their behavior. Managers may wish to report blinded data (by using letter codes for individuals, only known to those individuals) for a period of time before switching to transparent reporting of performance.

More effective than extrinsic motivation is intrinsic motivation that is driven from within. Intrinsic motivation occurs when an individual finds an inherent satisfaction in performing a task, even if that task is a change from prior activity. The 3 essential components to intrinsic motivation are autonomy, competency, and relatedness. Autonomy indicates that people undertaking a task are doing so because of their own free will; they have decided for themselves what to do. Competency is the belief that one will be successful in the task. Relatedness describes an understanding of the importance of the task and how it connects to something bigger than oneself. In our example, the ED team should experience intrinsic motivation when they play a role in deciding what changes to implement, they feel supported by leadership and believe the changes will be effective, and they relate their work to the poor outcome of the patient in the case presentation.

Changes are accepted by different individuals at different rates. Everett Rogers, in *Diffusion of Innovations*, described a continuum from innovators to laggards, with early adopters, early majority, and late majority between these two extremes. A particular individual may act as an innovator in one context or in response to one change and a laggard in another, suggesting that both extrinsic and intrinsic factors play a role in acceptance of the change. As an improvement team considers which changes to implement, involving

individuals from the entire spectrum is ideal because eventually all must accept the change. Innovators may be excited about implementing any change but may be dismissed by others in the workplace as “the person who will try any crazy thing.” Laggards may be best able to identify flaws in the proposed change but at some point need to be convinced to give a change a try despite their recalcitrance.

CONCLUSION

Creating improvement requires effectively leading and motivating change based on a firm understanding of system behavior and identifying whether improvement has occurred with the change. Strong skills in leadership, motivation, experimentation, data collection, and data analysis are required to implement QI activities. Support from administration is critical for an institution to develop a culture of QI. As health care seeks to mimic the successes of industry in the past century, the tools and techniques described in this article need to be applied by those with content expertise (physicians, nurses, other health care workers) who are also trained in 1 or more of these essential improvement activities.

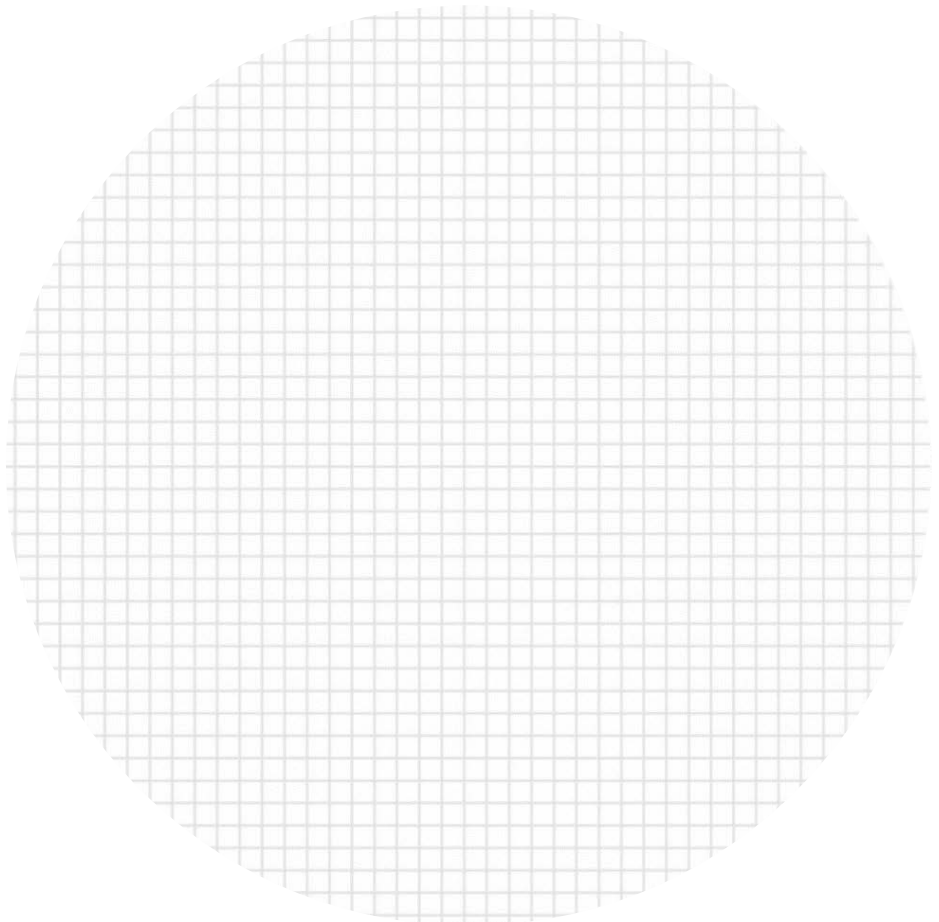
Summary

- On the basis of consensus, leaders and physicians need to inspire their teams to undertake quality and safety efforts.
- On the basis of consensus, multidisciplinary teams are essential to understand how a system currently operates, imagine changes that can lead to improvement, and motivate change in themselves and others.
- On the basis of consensus, quality and safety activities must eliminate blame and instead focus on understanding how systems can be improved as the primary goal. The plan/predict-do-study-act (PDSA) cycle is a necessary step in creating learning about systems.
- On the basis of consensus, data must be collected and displayed over time on either run charts or Shewhart charts to identify correlation between interventions and improvement.

References, Suggested Readings, and CME quiz for this article are at <http://pedsinreview.aappublications.org/content/37/10/407>.



5 Whys: Finding the Root Cause



5 Whys: Finding the Root Cause

The key to solving a problem is to first truly understand it. Often, our focus shifts too quickly from the problem to the solution, and we try to solve a problem before comprehending its root cause. What we think is the cause, however, is sometimes just another symptom.

One way to identify the root cause of a problem is to ask “Why?” five times. When a problem presents itself, ask “Why did this happen?” Then, don’t stop at the answer to this first question. Ask “Why?” again and again until you reach the root cause.

This simple tool can be surprisingly insightful in helping you figure out what is really going on, and can help you avoid quick fixes. It is especially useful for tackling chronic problems that show up over and over again in a complex system.

The technique is attributed to Taiichi Ohno, father of the Toyota Production System, which revolutionized automobile manufacturing with methods now known as Lean. It’s important to note that there may be multiple root causes of a problem, and that different people who see different parts of the system may answer the questions differently. For a more comprehensive tool, please see [Root Cause Analysis](#).

Here is an example of how to ask “Why?” five times:

1. Why did the patient receive the wrong medication?

The nurse did not complete patient identification.

2. Why did the nurse not complete patient identification?

The patient did not have a wristband.

3. Why did the patient not have a wristband?

The wristband had been removed for a procedure and not replaced.

4. Why was the wristband not replaced?

The printer for the wristbands was not working.

5. Why was the printer not working?

The staff needed to support IT had been reduced and was overworked.

The problem identified by the fifth “why” is very different from the original event, and requires a very different solution.

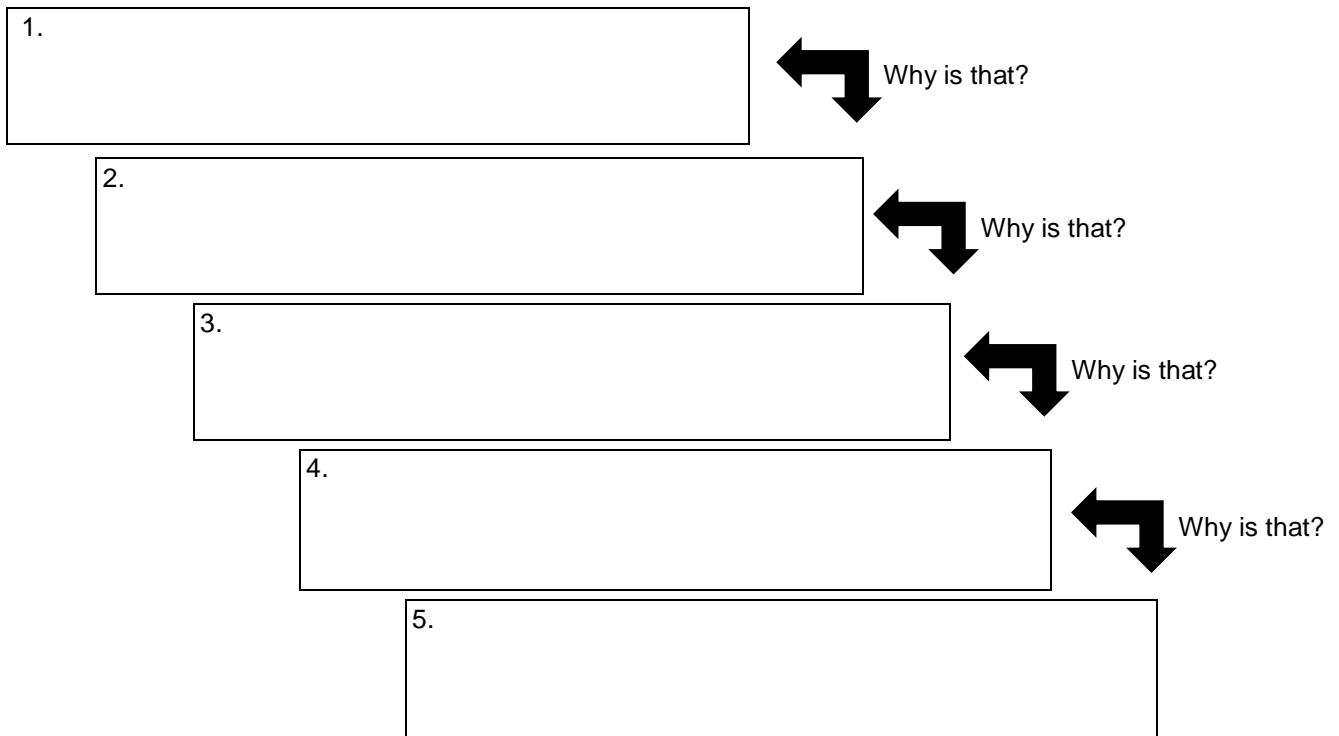
Try it yourself with the worksheet below.

NOTE: Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

EVENT. What happened? Define the problem as an *event*:

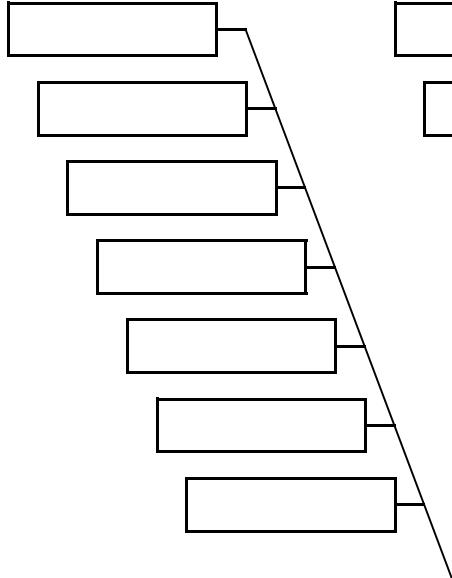
PATTERN. What's been happening? Define the problem as a *pattern* by selecting a poor performance factor:

STRUCTURE. Why is it happening? What are the tangible and intangible structures determining the results we see?

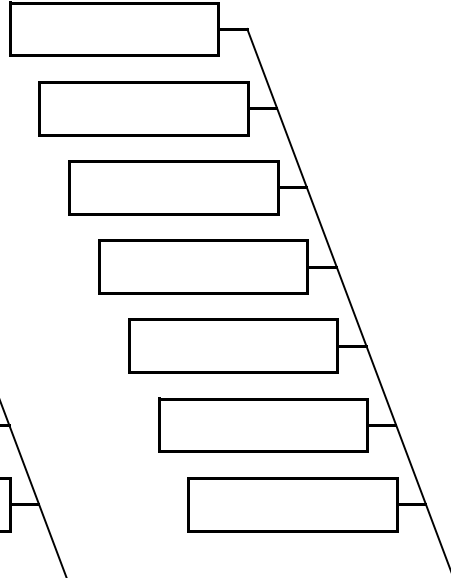


ACTION. What are the implications for action? What can you do to change the results?

Measurement



Policy

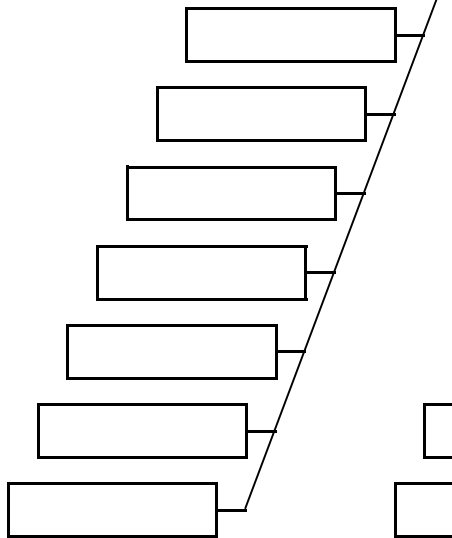


PROBLEM STATEMENT

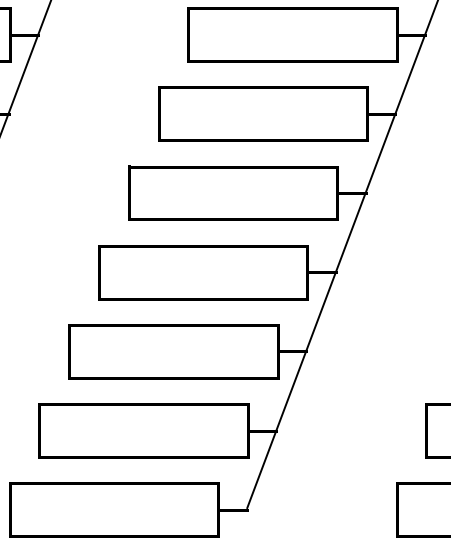
Problem Statement



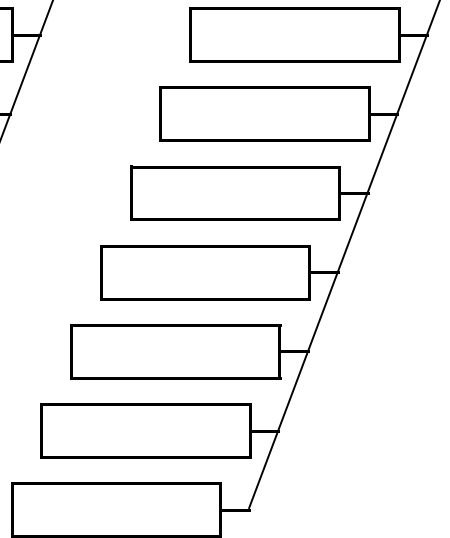
Environment



People



Plant



Quality Improvement/Patient Safety Case

Note: this case is derived from several real PSRs recorded in the Pediatric PCMH in Fall 2017 and Winter 2018.

As the senior on the ward, you attend Dr. Rogers' weekly safety huddle. In the huddle, you hear of a PSR placed by a clinic provider after admitting a 2-week-old severely dehydrated NATO patient who was *still* 12% under his birth weight. On the day of admission, the provider reviewed the AHLTA record, and found the following:

- The patient was seen by a pediatric resident for a newborn follow-up at 4 days of life, and was 14% down from birth weight at that time. The resident's note stated that the patient should return to clinic for a weight check in 2 days.
- The resident immediately referred the patient to lactation, and the patient was evaluated and treated during Drop In Monday. The lactation note recommended follow up in 2 days.
- The chart did not contain health literacy screening (SILS).

What are some possible reasons that the patient did not return for the recommended weight check?

- Basically, the bottom line here is that either (1) there was miscommunication between resident, lactation provider, and patient or (2) the patient had an appointment but no-showed.
- **POOR COMMUNICATION OPTION 1:** Resident did not communicate the instructions clearly (e.g. did not get a translator when one may have been needed, did not write instructions on a treatment plan/discharge sheet, did not ensure that a follow-up appointment had been made at the discharge desk before or after appointment with lactation)
- **POOR COMMUNICATION OPTION 2:** Patient did not understand the instructions to return or the gravity of the situation (e.g. poor English understanding, poor health literacy [especially considering the family had a new baby at home and was probably exhausted....], forgot about the instruction by the time the lactation evaluation was completed, thought it was only a suggestion and not a true recommendation, did not understand how to make an appointment [new to the clinic, never had to make an appointment before])
- **POOR COMMUNICATION OPTION 3:** Nobody told the patient to return (lactation thought that the resident told the patient, and the resident thought that lactation would tell the patient ... So no one told the patient)
- **PATIENT NO-SHOW:** Appointment was made, but patient failed to show for the appointment

In the PSR, the provider expressed concern that the patient never returned for the weight check as instructed. When she saw the patient at 2 week of life, she stated that she spoke with the patient's parents about the prior visit, and obtained the following information:

- The patient's father and mother were both present at the 4-day visit, but the father reports that the mother was experiencing significant pain from her C-section on that date and wasn't really able to participate in the visit.
- The mother speaks only Spanish, and the father is primarily Spanish-speaking though he understands some English.
- The father states that he thinks the clinic nurses made an appointment for the patient, but he thought they were making a 2-week appointment and did not understand that there was an additional necessary appointment.

Why was it important for the provider to speak with the patient about this issue? In general, what information can be gained by including the patient in patient safety investigations and PI projects?

- *Patients often hear and understand us differently than we hear and understand ourselves.*
- *The patient's perspective can shed light on issues that we, as staff, often do not consider, such as the complexity of the well baby appointment schedule, how to make and cancel appointments, how to navigate the hospital (to the pharmacy, lab etc), the importance of a particular follow-up appointment, the risks associated with not returning for that follow-up, etc.*
- *In this case, if we had not asked the parent, we may never have known that the patient did not hear/understand the importance of follow-up as stated by the resident at the 4-day visit – we may have improperly concluded that another reason was the root cause of the failed visit, and may have initiated the improvement process for the wrong thing!*

Meanwhile, the patient safety manager received the PSR and began gathering information. He conducts Step #1 in a root cause analysis (RCA): **Determine what happened.** In reviewing the chart and talking with the resident, clinic manager, and lactation provider, he discovered the following:

- At 4 days of age, the resident made an appointment for the follow-up and verbally gave the patient the date and the time of the appointment.
- The lactation provider thought the resident had discussed the follow-up plan with the patient and thus did not educate the patient to come back in 2 days or ensure an appointment had been made.
- Drop In Monday was very busy on the day of the initial lactation consultation. At the time the patient arrived, there was no additional support staff assisting the lactation provider with the visit.

Suppose a similar issue with newborn follow-up occurred several times, and your

supervisor charges you with developing a team to continue the RCA by conducting Step #2 (Determine what should have happened) and Step #3 (Determine causes and contributions). Who would you include on the team, and why? (Many answers are possible here.)

- Resident: to evaluate if resident experience/supervision could play a role in this problem
- Attending: to evaluate the organizational process for following up on high risk patients, and give preceptor perspective on GME supervision
- Parent: to evaluate the process of making and keeping follow-up appointments; to provide feedback about the communication the hospital/clinic provided in the first days of life
- Nurse: to evaluate the process of making follow-up appointments and communicating time/date to the patient
- Lactation provider: to contribute knowledge about the process of weight check appointments and follow-up appointments for high risk infants
- Discharge desk staff: to contribute knowledge about the process of clinic check-out
- Clinic manager (maybe – could be an ad hoc member): to evaluate the overall process for transferring care between providers, weight check, follow up scheduling etc. and provide information about current clinic SOPs

Once your team is created, what are some leadership traits or processes you might use to encourage teamwork? (Many answers are possible here.)

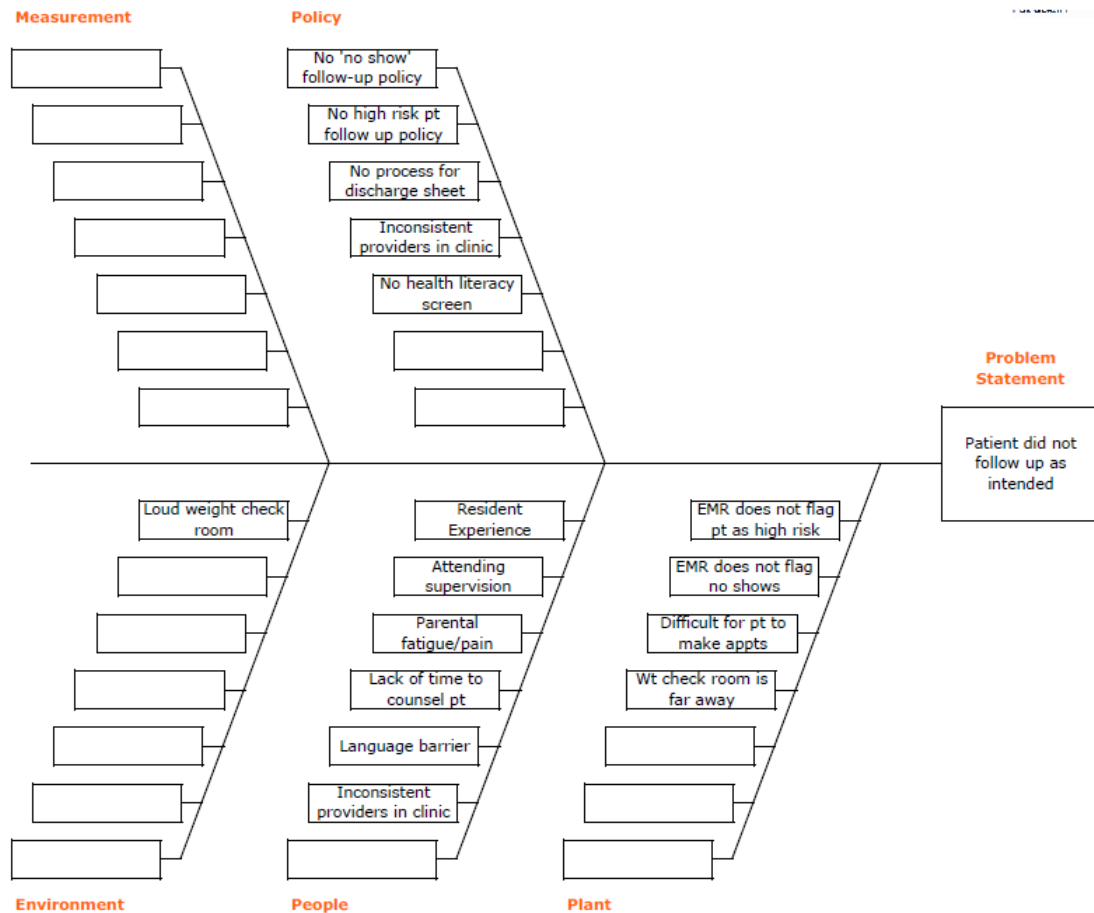
- **Ensure hierarchical relationships do not exist.** Use the High Reliability Organization (HRO) principle of “Deference to Expertise” – those at the front lines of a process know the process best. For example, providers cannot know exactly what it’s like to man the discharge desk; our admin staff are best suited to give this feedback.
- **Do not tolerate “shame and blame”.** Be clear up front that this will not be allowed. A punitive culture eliminates any chance that you will gain the insight you need to get to the bottom of the issue and ultimately make positive change.

Fishbone diagrams (sometimes called cause and effect diagrams) are a graphic method to display contributing factors for a process error; they are one way to visualize **causes and contributors** in Step #3 (Determine causes and contributions) of an RCA. After watching the IHI video and using the following questions as a guide, draw a fishbone diagram to identify contributing factors for this issue. Remember to state your problem and put it in a box on the right of your fishbone.

Faculty note:

- Draw the fishbone diagram on a white board as you talk through these questions.
- There are many ways to make a fishbone diagram. For example:

- Policy, procedure, plant, people, environment, measurement (PIR uses these and these are used below)
- Machines/equipment, methods, materials, and people
- Materials, methods, equipment, environment, people



What “policy or procedure” failure(s) contributed?

- No process for following up on no shows
- No process for following up on high-risk patients (e.g. newborns with weight loss, newborns with high bilis, toddlers with pneumonia, etc)
- No process to guide use of treatment plan/discharge sheet containing written information about the visit and follow-up plan
- No screening for health literacy
- Visiting providers or residents may not be present in clinic on the day of follow-up, and may not regularly check this duty out to a colleague (may not know that they need to give their colleague a heads up, may be too busy and forget to check out to a colleague, etc)

What “plant” failure(s) contributed?

- EMR does not allow clinic staff to “flag” a patient as high-risk
- EMR does not provide an alert when a patient no shows for a visit
- Appointing system can be difficult for new patients to negotiate

What “people” failure(s) contributed?

- Bottom line: any of these people could be fatigued, inexperienced, rushed, or have lack knowledge which may lead to errors
- Resident (who saw the patient at 4 days of life): placed a higher importance on the immediate referral to lactation, and less importance on the follow-up; did not check to make sure this patient came back for weight check; did not ensure the parent had health literacy screening during vitals
- Attending/preceptor (who precepted the patient at 4 days of life): did not check to make sure the patient came back for weight check (Is this the attending’s responsibility?); did not ensure the parent had health literacy screening during vitals; did not confirm with the resident that the patient had written discharge instructions
- Lactation provider: did not check with the provider about the follow-up plan; did not discuss the follow-up plan with the patient; did not check to make sure the patient came back for weight check
- Patient: did not understand the need to follow-up

What “environment” failure(s) contributed?

- Busy, loud weight check group visit may not be conducive to detailed discussion of follow-up importance/requirements
- Weight check room in another clinic (in CAPS)

What “measurement” failure(s) contributed?

- None

Though very effective, RCAs take a lot of time and effort. The “5 whys” technique is a much faster (though some would say not as effective) way to assess root causes. Watch the first 2 minutes of a business-related video about 5 whys technique at the Harvard Business Review site [here](#) or read a two page medical review at the Medicare site [here](#).

Using 5 whys, what do you think was the root cause for the patient’s lack of follow-up?

- Patient did not follow-up as directed (why?)
- Parent did not understand that an additional weight check follow-up was needed prior to the 2-week appointment (why?)
- Parent misunderstood the provider’s verbal instructions (why?)

- Parent had poor health literacy in English (why?)
- Parent was primarily Spanish-speaking (Faculty note: this isn't something we can change. So instead of changing the "root cause", below we address the steps in the 5 whys root cause analysis.)

What change(s) would *you* make to ensure this type of error does not happen again?

Faculty note: Many answers are valid, but only a few are quick, low-risk, fiscally responsible, and easy to implement.

One way to help the residents develop ideas for interventions is to look at the 5 whys, above, and intervene at each possible step to prevent the "Swiss cheese" model from occurring. This is particularly important when the final root cause (in this case, "Patient was primarily Spanish-speaking") is not something we can change or improve.

- Patient did not follow-up as directed (why?)
- Parent was not aware that an additional weight check follow-up was needed prior to the 2-week appointment (why?)
 - *Intervention:* communicate between providers to ensure the patient is aware of the need for follow-up (don't assume that another provider has informed the patient)
- Parent misunderstood the provider's verbal instructions (why?)
 - *Intervention:* give the patient written *and* verbal instructions on a clinic discharge sheet; ensure understanding (use the read-back method, take additional time with the patient, refer to disease management, call a translator etc)
- Parent had poor health literacy in English (why?)
 - *Intervention:* screen patients for health literacy and intervene appropriately for failed screening
- Parent was primarily Spanish-speaking

Some other ideas for interventions include (some of these sound crazy but may come up in discussion!):

- Write a new SOP that requires inpatient consultation for all newborns presenting with (say) >10% weight loss
- Require clinic education at the newborn follow-up visit as we do at the 2 week visit
- Increase all newborn appointments to twice the normal length
- Do not allow residents to see newborn follow-up appointments without hands-on attending supervision
- Write a new SOP requiring the use of translators for all NATO patients
- Cancel Drop In Mondays and Weight Check Wednesdays (they are too loud/busy)

Discuss with your group the 3 ways the clinic intervened to ensure this wouldn't happen again. What are the benefits and drawbacks of each intervention? Do you think the 3 interventions together will prevent the "Swiss cheese" model of error?

Attendings, please discuss these 3 interventions, including their benefits and drawbacks:

- (1) We wrote and trained a new SOP that makes it standard practice to call patients <30 days old on the same day when they no show for a scheduled appointment.
 - a. Benefit: contacts newborns (a high risk population) who may not know/understand that their child is sick; patients feel that their medical home cares for them personally
 - b. Drawback: increased clinic time/effort, doesn't address babies >30 days of age (who may also be sick)
 - (2) We retrained all clinic providers and staff to use the treatment plan/discharge sheet for all patients, no matter how simple the plan may be or how much we think the patient knows about our medical system.
 - a. Benefit: communicates follow up plan in 2 ways (written and verbal); patients can take the treatment and follow up plan home with them as a reminder; patients then have the clinic number and IRMAC number at their fingertips
 - b. Drawback: patients may still misunderstand (if they have low health literacy or don't speak English well); patients may throw away or lose the paper
 - (3) Finally, we initiated screening for health literacy at all visits to identify patients who need additional time and education from our clinic staff. We also screen for language preference, but do not necessarily call a translator for patients that prefer another language IF they pass the English version of health literacy screening. *Consider discussing the risks and benefits of requiring a translator for all patients that prefer another language.*
 - a. Benefit: may identify patients who need additional teaching/time; meets a Joint Commission requirement
 - b. Drawback: takes time for patient (to answer questions), screener (to enter answers) and provider (to review answers and/or refer patient to Disease Management)
- *Note regarding health literacy screening:* Health Literacy screening now occurs at all visits. Patients/parents that fail the SILS 2-question health literacy screen must answer the REALM-SF 7-question health literacy screen, and those that fail the REALM-SF must have additional education provided by the pediatric disease manager, Rhoda Kroeker, or by a clinic nurse.

An important way to track patient safety in hospitals is the PSR (patient safety report). Do you know how to enter a PSR? Residents and attendings, do you identify yourself as a part of a GME program when you enter the PSR?

Faculty note: both residents and attendings should be identifying themselves as part of a GME program when entering a PSR!

If you were the provider seeing the patient at the 2-week visit, would you have entered a PSR? Why or why not?

Have you ever submitted a PSR? If so, how many? If not, why not?

**Discuss a specific PSR you submitted (do not discuss specific provider or patient names)
OR a patient safety error that, in retrospect, you WISH you had reported for review.**

Quality Improvement/Patient Safety Quiz

1) What is the role of leadership in promoting a culture of safety?

- Leaders must support a learning environment, protecting reporters from the “shame and blame” often associated with patient safety concerns.
- Leaders must create a sense of urgency in improving patient safety.
- Leaders must drive the transformation to high reliability.

2) What are the 5 elements of a learning environment? Which of these elements does WRNMMC Pediatrics do well? Which could we improve on?

- Simulation to train staff in safety-critical functions
- Robust voluntary reporting system
- Non-punitive culture free of “shame and blame”
- Good communication from all members of the team
- System for error analysis and identification of root causes

3) What is the difference between a run chart and a control chart? Check out these [IHI videos](#) if you are unsure!

- Run charts allow one to evaluate data over time and determine trends in the data **without the application of statistics**. For example, 6 points on one side of the median (a “shift”) or 5 increasing/decreasing data points (a “trend”) are a signal of a fundamental change in the process rather than random variation. (NOTE: Run charts are required submissions for all [ABP MOC projects](#).) An example of a run chart is the length of a commute (y) over the course of a month (x).
- Control charts are similar to run charts, but they allow data points to be evaluated for “special cause” variation **using statistical methods**. Special causes are environmental factors that affect the dependent variable, and are not associated with the process in question. An example of a special cause is a severe snowstorm affecting the length of a commute; the day of the snowstorm will cause the commute to be much longer. If the length of the commute is $>3SD$ above the mean, this data point could be attributed to special cause variation.

4) Name 2 free online ways to complete ABP Maintenance of Certification (MOC) Part 4 credit.

- ABP Performance improvement modules (PIM)
- AAP EQIPP

5) Flashback to Medical Home Module 1: what are the 5 principles of the AAP's Patient Centered Medical Home?

- Care Coordination
- Enhanced Access to Care
- Team-based Care
- Family-centered Care
- Quality Improvement** -- from the AAP module: *“Focus on quality improvement is essential for a PFCMH to be effective. It requires that clinicians adhere to evidence-based treatment and management protocols and use clinical decision support tools to inform their day-to-day decision making. Concern for quality care also translates into a sense of accountability and a willingness to voluntarily engage in ongoing performance measurement and improvement.”*

Board Review Questions

1. You are caring for a neonate with congenital syphilis in a busy intensive care unit and prescribe penicillin 50,000 U/kg per day divided every 8 hours.

Of the following, the MOST likely medication error to occur in this scenario is:

- A. a "look-alike" drug is administered to the patient
- B. a «sound-alike" drug is administered to the patient
- C. penicillin is administered to the patient at the wrong dose**
- D. penicillin is administered to the patient at the wrong time
- E. penicillin is administered to the wrong patient

2. You are seeing the last patient in your clinic and realize that you are 15 minutes late for an important meeting. You need to give the patient 2 prescriptions and referral information for a subspecialty clinic visit.

Of the following, the intervention MOST likely to prevent a medical error in the scenario described in the vignette is:

- A. increasing the nurse-to-patient ratio
- B. increasing the time allotted for each patient encounter
- C. providing a patient handout about subspecialty referrals
- D. reducing physician fatigue
- E. using computerized physician order entry**

3. You are on a committee charged with decreasing the infection rate in your hospital system. The committee has identified hospital-acquired methicillin-resistant Staphylo-coccus aureus (MRSA) infection rates in intensive care units as a focus for improvement. A recently published article demonstrated that cleansing each patient with antibacterial soap daily decreased the incidence of MRSA infections in an intensive care unit (ICU). Your hospital system does not currently use this practice. The committee plans to evaluate the use of this practice using the Langley model of quality improvement (ie, Plan-Do-Study-Act [PDSA]).

Of the following, the MOST appropriate first step would be to

- A. develop a procedure for ICU staff to use antibacterial soap to cleanse patients**
- B. implement a policy to cleanse ICU patients with antibacterial soap daily throughout the hospital system
- C. implement a policy to cleanse patients daily with antibacterial soap in a single ICU
- D. review MRSA infection rates in an ICU that already uses antibacterial soap at another hospital in your town
- E. wait for more evidence that using antibacterial soap decreases MRSA infection rates

4. An otherwise healthy 2-year-old child, who has a documented milk allergy, is admitted to the hospital for chronic constipation. The child was given a milk and molasses enema per the orders of the resident team. The child had an anaphylactic reaction that required treatment with epinephrine and diphenhydramine, and transfer to the pediatric intensive care unit for observation. The multidisciplinary team undertakes a root cause analysis to determine if latent or active errors may be uncovered.

Of the following, the MOST likely to represent an active error would be

- A. the electronic medical record did not alert the resident regarding milk allergy when the order was placed
- B. the medical student was too intimidated to point out the history of milk allergy to the attending physician
- C. the overworked nurse had the nurse's aide administer the enema
- D. the pharmacist could not find the documentation regarding the milk allergy
- E. the resident who wrote the order for the milk and molasses enema disregarded the history of milk allergy**

5. A mother comes into your pediatric office to verify her child's antihypertensive medication. Her son was recently discharged from the hospital, and a new prescription for clonidine was called into the local pharmacy. After she got home, after picking up the prescription, she thought the pills looked different than the clonidine pills that he was taking previously. She did not give the new pills to her son. She shows you the bottle that is labeled as Klonopin

- A. adverse drug event
- B. near miss event**
- C. never event
- D. sentinel event
- E. serious reportable event