Society for Maternal•Fetal Medicine

Primer on Patient Safety and Healthcare Quality for Maternal-Fetal Medicine Fellows

Patient Safety & Quality Committee
and
Fellowship Committee

Society for Maternal Fetal Medicine
Washington, D.C.

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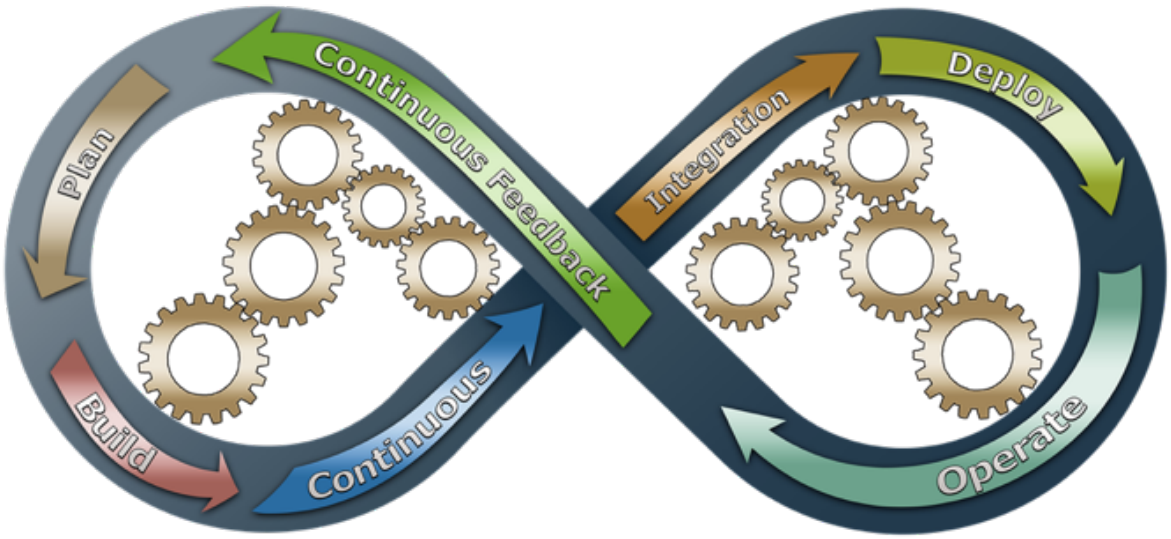
Contents



Overview

"All physicians share responsibility for promoting patient safety and enhancing quality of patient care. Graduate medical education must prepare fellows to provide the highest level of clinical care with continuous focus on the safety, individual needs, and humanity of their patients."

Quoted from: Program Requirements for Graduate Medical Education in Maternal-Fetal Medicine
Accreditation Council on Graduate Medical Education

Education in patient safety and healthcare quality is an essential component of fellowship training in maternal-fetal medicine (MFM). The Accreditation Council on Graduate Medical Education (ACGME) guidebook *Program Requirements for Graduate Medical Education in Maternal-Fetal Medicine* includes 17 pages on safety and quality topics, almost one-third of the total document.

While the ACGME requirements are comprehensive, their sheer breadth and depth is likely to be daunting to fellows and program directors alike. We sought to break the requirements down into smaller, more easily manageable portions. With that goal, we present a suite of three tools intended to provide MFM fellows and fellowship program directors with resources to help them achieve the educational requirements on patient safety and quality topics laid out by ACGME. The three tools are:

- **Curriculum Outline** summarizing the ACGME requirements, some suggested readings and activities for each requirement, and a timeline for completion of each requirement. The outline will be published in the SMFM pages of the American Journal of Obstetrics and Gynecology.
- **Quality Improvement Project Toolkit** to help fellows design, implement, analyze, and report their own quality improvement projects.
- **Primer** (this document) providing a brief synopsis of many essential topics in patient safety and healthcare quality. Each chapter is mentioned in the Curriculum Outline as a suggested reading during the appropriate month during fellowship.

The suggested process is to follow the timetable in the Curriculum Outline, with a few readings and activities each month for the first several months of fellowship. Then the fellow should be well positioned to begin planning, performing, and completing their own quality improvement project.

Our tools are designed as a self-study curriculum under the assumption that not all programs will have dedicated faculty to teach all aspects of safety and quality. If a program has appropriate faculty and resources, then live activities such as didactic lectures or small group seminars can be used to supplement or replace parts of our curriculum. Learners will benefit if materials are made available in a variety of formats including readings, seminars, lectures, and videos.

With these tools, fellows should complete their training with a solid foundation in patient safety and quality relevant to obstetrics.

Patient Safety and Quality Committee
Fellowship Committee
Society for Maternal Fetal Medicine
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Culture of Safety

Safety culture is defined as an organization's shared perceptions, beliefs, values, and attitudes that combine to create a commitment to safety and an effort to minimize harm.

High-reliability organizations consistently minimize adverse events despite carrying out hazardous work on an ongoing basis. Such organizations establish a *culture of safety* by maintaining a strong commitment to safety at all levels, from frontline providers to managers and executives.

A culture of safety reflects the core values and behaviors that arise when there is a collective and continuous commitment to emphasize safety over competing goals. Culture of safety improves health outcomes by preventing or reducing medical errors.

Key elements of culture of safety include professionalism, ethics, and an effective learning environment that encourages disclosure so that errors can be studied with a view toward preventing them from recurring.

A hypothetical example

A hospital was under pressure from payors to lower its cesarean rate, specifically the rate among nulliparous, term, singleton, vertex (NTSV) births. The rate during the recent "baseline" year was 32%. The hospital assembled a team of obstetricians, nurses, MFMs, and managers to study the reasons for the high rate. The most common indication for NTSV cesarean was "fetal intolerance of labor" which accounted for almost half of the cases. The team embarked on an extensive education campaign to teach nurses and obstetricians a standardized algorithm for management of category 2 fetal heart rate (FHR) patterns, emphasizing conservative measures and continued observation for cases with moderate heart rate variability. A series of grand rounds, in-service meetings, and monthly FHR monitor strip teaching conferences was held to introduce and reinforce the algorithm. The team reviewed the FHR for every NTSV cesarean and provided feedback to obstetricians and nurses regarding whether the algorithm was followed.

As shown in the run chart (Figure), the NTSV cesarean rate gradually declined, to 29% in year one, 27% in year two, and 23% in the first half of year three.

This clearly reflected a culture of safety: a cooperative, interdisciplinary effort by nurses and physicians to improve outcomes, with a repeated and continuous focus on improving safety by reducing unnecessary cesarean surgery.

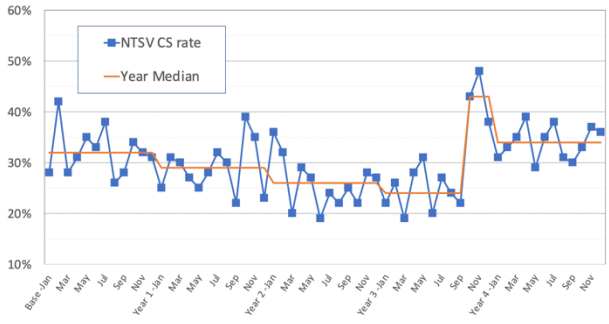

Figure. Run chart of NTSV cesarean rate at hypothetical hospital

In August of year three, there was an adverse event in an NTSV patient. After a protracted first stage of labor, cervical dilation arrested at 6 cm. The FHR initially showed intermittent variable decelerations, then gradual loss of variability and appearance of late decelerations. Over a period spanning 3 nursing shifts and 2 changes of covering obstetricians, there were multiple discussions among the care team as to whether cesarean should be performed, but expectant management was continued until the FHR tracing became agonal. When cesarean was finally performed, the newborn was delivered with Apgar scores of 0 at 1 minute and 1 at 5 and 10 minutes, cord pH 6.74 and base deficit 19 meq/L. The baby was pronounced dead after 45 minutes of attempted resuscitation.

In the ensuing Root Cause Analysis, the nurse who managed the patient for an entire shift was judged responsible for misreading the FHR tracing and was fired immediately, ending her previously spotless 12-year career on labor and delivery.

Immediately thereafter, the hospital's NTSV cesarean rate spiked to over 40% and the hospital was unsuccessful at reducing the rate to under 30% in any subsequent month. The staff were simply no longer willing to manage category 2 patterns with conservative measures.

Culture of blame

This example illustrates the response of hospitals to an adverse event that was typical throughout much of the 20th century. If something went wrong, it was understood that somebody had made a mistake and that the responsible person(s) should be reprimanded or punished. Patient safety, then, was driven largely by fear of reprisal if one's performance was less than perfect. This approach is called a *culture of blame*.

The example shows how a culture of blame can backfire and lead to unintended adverse consequences. In this case, the nurses came to live in fear of losing their job if they attempted to manage a category 2 tracing conservatively and would pressure physicians to proceed with a cesarean delivery for many category 2 tracings that might have been managed without a cesarean.

Another way that culture of blame hinders patient safety is that people become unwilling to report near-miss events if they are afraid that someone will be punished. As discussed in the chapter on Sentinel Events and Event Reporting, we now know that such reports are an essential way for a facility to learn about unsafe systems so it can then begin to correct them.

No-blame culture, where people are never punished or held accountable in any way for errors, is the opposite of culture of blame. However, a system with no accountability permits individuals to "go rogue" by ignoring protocols and acting irresponsibly.

Just culture

Just culture strikes a balance between culture of blame and no-blame culture. It is based on an understanding that health care is delivered by human beings and that human beings are not perfect. Therefore, errors are inevitable. In a system where errors are anticipated, then, the focus of just culture is to build a system that can compensate or correct for errors in such a way that they do not result in harm to patients. When patients are harmed, just culture attempts to understand how the system allowed the error to occur. It assumes that the major fault should be attributed to the system rather than the individual. Firing the person who made an error will not prevent someone else from making the same error in the future. To prevent the next error, the system must be examined for opportunities to improve it.

There are 3 essential components to just culture:

- Raising awareness, e.g., sharing information, education.
- Implementing policies to support just culture. The best way is to eliminate policies that do not allow incorporation of just culture, e.g., eliminating policies that require punishment for errors.
- Building "just culture" principles into daily practice

Just culture is not the same as no-blame culture. Just culture differentiates three kinds of human behaviors and suggests appropriate responses to errors that occur with each type of behavior:

- *Human error:* inadvertent action; inadvertently doing other than what should have been done; slip; lapse; mistake. Response: support the individual, identify systems or processes that can be corrected to reduce the probability of the error being repeated
- *At-risk behavior:* actions that increases risk where the risk is not recognized or is mistakenly believed to be justified. Response: coach the individual to recognize the behavior and stop it.
- *Reckless behavior:* to conscious disregard of substantial and unjustifiable risks. Response: disciplinary action.

In just culture, then, individuals and systems hold each other accountable for errors, using combinations of system change, individual support, coaching, and punishment as appropriate for each type of error.

Additional Reading

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Medical Error and Adverse Events

Learning from error is critical to the success of individuals and organizations.

Definitions of medical error.

- An unintended act (either of omission or commission) or an act that does not achieve its intended outcome.
- Deviations from the process of care, which may or may not cause harm to the patient.

Types of error

Errors of commission or omission

Errors can be *errors of commission* (doing something wrong) or *errors of omission* (failing to do the right thing) leading to an undesirable outcome or the significant potential for such an outcome. Some examples:

- **Error of commission:** ordering penicillin for Group B Strep prophylaxis in a patient with anaphylaxis to penicillin
- **Error of omission:** failure to order venous thromboembolism prophylaxis for a patient admitted to antepartum service for a prolonged stay for monoamniotic twin pregnancy or placenta previa with repeated bleeding episodes.
- Here is an example where potential for error cannot be avoided. A nulliparous patient at 25 weeks of gestation presents with painful contractions every 5 minutes and cervix is closed, 50% effaced. A course of betamethasone is given, and magnesium sulfate is given for neuroprotection. Contractions stop and she is discharged 3 days later. At 27 weeks of gestation, she returns with painful contractions every 5 minutes and cervix is still closed but now 100% effaced. The question is whether to give a "rescue" course of betamethasone. The clinician has two options:
  - Give the betamethasone. It is possible that the contractions will stop and she will not deliver. If she then presents with ruptured membranes at 29 weeks and cervical dilation 4 cm, she will not be eligible to receive more betamethasone and there will not be any fetal or neonatal benefit from the 2 courses she has already received. In this scenario, giving the betamethasone at 27 weeks was an error of commission.
  - Don't give the betamethasone. It is possible that she will deliver in the next day or two without benefit of betamethasone. In this scenario, not giving the betamethasone at 27 weeks was an error of omission.

  Because the clinician cannot reliably predict whether the patient will deliver within the next 7 days, the decision to give or withhold antenatal corticosteroids will always be fraught with the potential for error. Any time you must predict the future, there will sometimes be errors.

Acts of commission are likely easier to recognize than acts of omission but acts of omission are likely a bigger problem. There are probably many unrecognized instances where an additional test, treatment, or preventative measure was not performed, but could have impacted the outcome. For example, it may be easy for us to recognize when a provider ordered an incorrect dose of aspirin for a pregnant patient in the setting of preeclampsia prophylaxis. It is harder to recognize the likely many more cases where patients would have qualified for aspirin for preeclampsia prophylaxis, but it was never ordered.

Errors of execution or planning

An *error of execution*, also called a *slip*, is the failure of a planned action to be completed as intended. An *error of planning*, also called a *mistake*, is the use of a wrong plan to achieve an aim. On the other hand, are when no plan to do the right thing is ever made, it is simply an error of omission. Some examples:

- **Error of execution:** Provider requests methylergonovine during a postpartum hemorrhage to a patient with significant asthma, but carboprost is administered instead
- **Error of planning:** Provider administers carboprost during a postpartum hemorrhage to a patient with significant asthma due to lack of knowledge regarding contraindications to carboprost use

Active versus latent error

Active errors occur at the point of contact at the front lines. Active errors are sometimes referred to as *errors at the sharp end*, figuratively referring to a scalpel. Active errors are often noticed first because they are committed by the person closest to the patient.

Latent errors are less obvious. These are failures of systems or organization that contribute to errors. Latent errors are sometimes referred to as *errors at the blunt end.* They occur at the many layers of a health care system

that contribute to the actions of the person holding the scalpel.

Many safety events have both active and latent components. For example, imagine that an IV antihypertensive was administered to the "wrong" patient in triage, a normotensive patient who has a similar name to a severely hypertensive one next door. The provider administering the medication made an active error. But latent errors, errors in the system, allowed the event to happen as well. Examples of the latent errors in this case include lack of an alert that there are two patients in triage with similar names and lack of a double-check that the medication was being administered to the correct patient.

Adverse event

An *adverse event* is any injury caused by medical care. This means that an unexpected or undesired outcome occurred, not from the underlying disease, but from the process of diagnosis and treatment. **Importantly, an error does not always lead to an adverse event, and an adverse event is not always the result of an error.**

For example, even if a chorionic villus sampling was performed with technical perfection and without error, a spontaneous pregnancy loss within days of the procedure would be considered an adverse event.

Other adverse events are more clearly linked to error. For example, a cesarean wound infection would be attributed to an error if routine preoperative antibiotic prophylaxis was not given.

Adverse events are often categorized as *preventable* or *non-preventable*. A preventable event does not always mean an error was made. For example, imagine a patient admitted for expectant management of preterm preeclampsia with severe features. The patient develops pulmonary edema on hospital day 6. This may have been preventable with earlier delivery, but providers had been following standard of care when following guidelines for expectant management, so the event does not reflect an error. Further, just because an adverse event is classified as non-preventable does not absolve the care team of all responsibility; we should always challenge ourselves to discover new ways to prevent the non-preventable events.

Near miss

When an error does not lead to an adverse event, this is termed a "*near miss*" or "close call". Sometimes the avoidance of an adverse event is due to chance. Sometimes it is due to someone "catching" the error and implementing a timely, active intervention to prevent an adverse outcome.

An example of a near miss: Routine prenatal lab results show a positive RPR result with positive reflex anti-treponemal test. The provider does not notice the abnormal result. A covering colleague sees the patient at her next visit, double-checks the recent lab work, and finds the missed result. The patient is then appropriately treated. This is a near miss. No harm occurred, and there was timely intervention in response to the missed result.

The Venn diagram in Figure 1 summarizes the relationships between errors and adverse events.

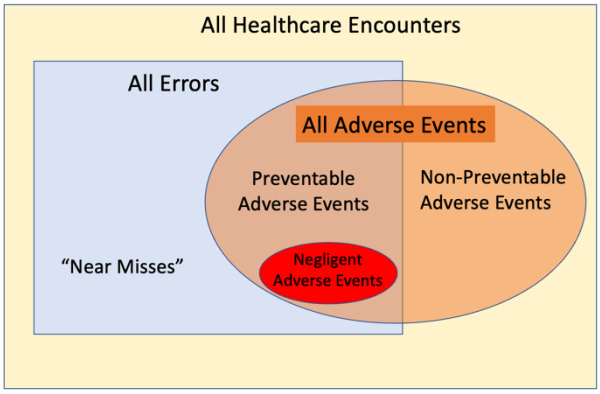

Figure 1. Relationships between errors, adverse events, and near misses. Modified from Wachter and Gupta, Understanding Patient Safety.

Specific types of errors

Medication errors are one of the most common threats to patient safety because there are numerous steps from prescribing to administration, each of which carries a risk of error. In the inpatient setting, errors can be made by the physician generating prescriptions, the clerk transcribing orders, the pharmacist filling the orders, or the nurse administering the medication. In the ambulatory setting, the patient herself may make errors.

Medication errors are of critical importance in obstetrics. Labor and delivery is a high volume location with fast turnover. Kfuri et al performed a review of on medication errors in obstetrics from 2003 to 2005 using MEDMARX, an Internet accessible, anonymous, medication error reporting program. They collected data on ~4500 obstetric medication errors. Notably, errors occurred most often at the administration phase and ranged from errors of omission (did not give an ordered medication) to wrong time, improper dose, and wrong drug. Errors occurred most with antibiotics, oxytocin, ibuprofen, and narcotic pain medications, but also occurred with magnesium and terbutaline

In recent years, technology has promised decreased medication prescribing errors through centralized prescribing systems, computerized decision support tools, and bar coding. However, these technical fixes have not solved all medication related issues.

One of the key medication safety strategies is the "Five Rights", providing a checklist for a provider to utilize before administering any medication:

1. Right patient
2. Right route
3. Right dose
4. Right time
5. Right drug

Another important way to avoid medication errors is to follow principles of *conservative prescribing*. If we limit medications to what is truly indicated, we limit the potential for medication error.

Surgical and procedural errors include issues like wrong site/wrong surgery and retained sponges. One of our most important means of combatting surgical error is The Joint Commission's Universal Protocol, a thorough **pre-procedural timeout** to prevent wrong-site, wrong-side, wrong-person surgery. Many hospitals have implemented a more detailed multi-step surgical safety checklist for cesarean and other surgeries as discussed in another chapter.

For many procedures, there is evidence for a volume-outcome relationship, where centers and providers who do more of a certain procedure have less adverse outcomes. For example, in maternal fetal medicine, volume is important in invasive procedures like amniocentesis. **Simulation** is one means of reducing surgical error by increasing provider procedure volume in a simulated environment.

Ambulatory procedures like amniocentesis and chorionic villus sampling should be treated with as much respect as an OR surgery, with an equally thorough pre-procedural timeout to prevent error. SMFM has presented checklists for use with amniocentesis and CVS.

Retained sponges are a critical cause of surgical error in obstetrics, for both cesarean and vaginal delivery. As described in the Council for Patient Safety in Women's Health safety bundle, sponge counts, and the use of robust detection technologies are recommended after each delivery and can help decrease these risks significantly.

Diagnostic errors. Despite our advances in medicine, including advanced imaging and laboratory work, diagnostic errors remain common. These are some of the most difficult errors to measure and fix. Good diagnosticians use hypothesis testing and reasoning rather than "gut" impression in reaching a diagnosis.

Common errors include cognitive biases like **anchoring** (getting stuck on initial impressions) and **the availability heuristic** (being unduly influenced by prior cases). For example, imagine a woman who presents in the third trimester with shortness of breath and tachycardia. The provider seeing the patient has had 3 patients with similar presentations in the last few months, and the work-up was eventually unrevealing. Therefore, she decides not to order any testing for pulmonary embolism such as D-dimer or CT angiogram which would be indicated for this presentation. In this example, both anchoring and the availability heuristic led to a suboptimal work-up that will miss the diagnosis of pulmonary embolism if it is present.

There are many other types of cognitive bias that can lead to diagnostic error. Methods to improve diagnostic errors include computerized decision support, as well as clinician education and training to improve adherence to standardized diagnostic protocols.

Documentation/computer errors. While electronic health records reduce some kinds of errors described here, such as medication and diagnostic errors, there are errors that come simply from the existence of electronic records. As users of technology, we commit errors when we utilize a template physical exam in our notes, even when we did not examine the patient, or copy and paste findings from one day to the next. This information is then propagated and communicated to numerous subsequent providers, who mistakenly trust the information they are receiving.

Transition and handoff errors can occur whenever a patient is transferred from one location to another or from one covering physician to the next.

In obstetrics, we are often engaged in shiftwork, with a long list of similar young, healthy patients to sign out to the next team in an environment. Unfortunately, handoffs are frequently interrupted when a delivery or other emergency occurs during the sign-out, leaving ample room for error.

Optimizing handoffs requires standardized protocols, should occur at designated times and without distraction, as well as cover likely scenarios with if/then statements. Structured handoffs are covered in more detail in the chapter on Teamwork.

Teamwork and communication errors occur when the healthcare team is not well functioning. Well-functioning teams allow for all levels of provider to express concern, use the "SBAR" technique to communicate, and participate in debriefings. An entire chapter in this Primer is devoted to teamwork.

Healthcare associated infections (HAIs). HAIs are potentially preventable adverse events that can be minimized by adhering to evidence-based strategies.

Cesarean surgical site infection rates can be reduced with use of prophylactic antibiotics, clipping rather than shaving the surgical site, maintaining perioperative normothermia, and attention to reasonable postoperative glucose control.

Catheter associated urinary tract infections (CAUTIs) are another common HAI for which obstetric patients are at risk. Strategies to prevent CAUTIs include rigorous hand hygiene, strict sterile technique for catheter insertion, and removal of urinary catheters at the earliest possible time.

Models and Tools to Understand Adverse Events

Errors and adverse events are usually multifaceted and complex. While near misses are also important to analyze, in patient safety, we often begin with an adverse event. Tools and models help us frame and understand how such events occur, so that we can come up with effective solutions. Many of these tools overlap and intertwine in their process and goals and can be used together.

Swiss cheese model: Before the current thinking around patient safety, providers were often blamed for committing errors. Now, we understand that a single person making a single error "at the sharp end" is usually insufficient to lead to an adverse event. When an adverse event occurs, latent error in various layers of the system (holes in layers of Swiss cheese) most often occur as well.

In principle, we can improve safety both by shrinking the holes in the cheese (that is, by reducing the probability of an error in each layer of a system) and by adding multiple overlapping layers. Doing both will make it less likely for the holes to align and will reduce the chance of patient harm.

An example in maternal-fetal medicine: At 20 weeks of gestation, a scheduled ultrasound for fetal anatomy survey shows reveals a twin pregnancy (previously undiagnosed), monochorionic-diamniotic, with fetal death of both twins attributed to probable twin-twin transfusion syndrome. There is *a diagnostic error* because the multifetal gestation was not diagnosed. There are several "holes" in the Swiss cheese:

- The monochorionic diamniotic twin diagnosis was made on a 9-week emergency room ultrasound. However, the patient had not established care, so this was not reported to any obstetric provider.
- Patient was non-English speaking, no translator used in the emergency department, and she only understood that the pregnancy was normal.

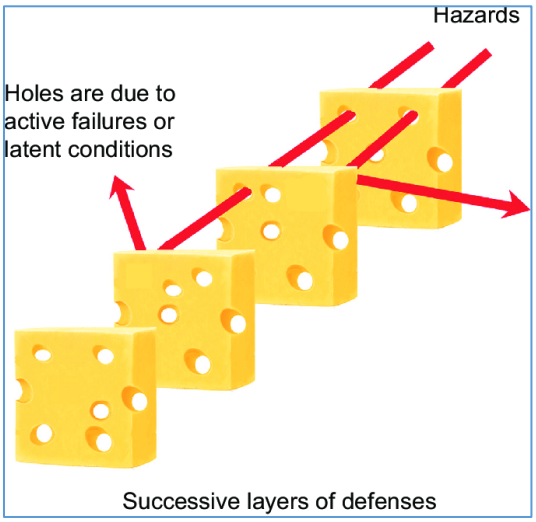

Figure 2: Swiss cheese model

- New prenatal visit at 12 weeks was at a different health system and the obstetric provider missed twin diagnosis during in-office ultrasound
- A different provider did not note size greater than dates at 16-week prenatal visit.

This type of analysis helps us see solutions to create safer systems and prevent recurrence: methods for handoffs of obstetric information from the ED when patients haven't yet established care, ease of translation services, and provider knowledge around ultrasound. Further, in addition to ways to shrink the holes, we can plan to add another layer of cheese to prevent this error from occurring again. This could include an automatic consult to OB when any pregnant patient comes to the ED, or a review of all in office ultrasound images by a second provider.

Root cause analysis (RCA) is a deliberate dissection of an error to get to the underlying source of an issue rather than stopping at superficial explanations. RCAs are usually performed within a committee, require leadership and facilitation, an interdisciplinary approach, include individuals who were involved in the error, and focus on identifying multiple concrete, corrective actions that will "close **the Swiss cheese**" and prevent future harm.

An example in maternal-fetal medicine: A patient undergoing cerclage placement in OR was given phenylephrine by the anesthesia team instead of metoclopramide as intended for nausea; patient experienced severe hypertension and acute ischemic stroke

An RCA could be performed for this event, led by hospital safety leadership with experience performing such analyses. Anesthesiologists, obstetricians, nursing, and OR staff involved in the case should be invited to

attend the meeting. Results of such a meeting might determine multiple concrete action items, such as:

- Routine anesthesia medication drawer audits to ensure that medications are not being drawn up in advance of a case
- Education for anesthesia providers that medications should only be drawn up when needed and to avoid drawing up multiple medications at one time
- Implementation of bar code scanning for medications given in OR

Failure mode and effect analysis (FMEA): Adapted from engineering, an FMEA breaks down all the minute steps of a process, then assigns each step (a) a probability of failure (1 to 10, with 1 being extremely unlikely and 10 being inevitable) and (b) an "*impact score*". The impact score is defined as how problematic it would be if that step failed and is also graded 1 to 10 with 10 being catastrophic. The probability of failure and impact score are multiplied, to produce a "*criticality index*" for each step. In addition, sometimes these are also multiplied by a third factor, a "*detection rating*", which grades how likely we are to detect an issue at that step. Steps in the process are then ranked by criticality index to create a priority list for error-proofing.

An example in maternal-fetal medicine: A patient with is diagnosed with peripartum cardiomyopathy at term and undergoes repeat cesarean delivery. Postpartum, she has close follow-up with cardiology and MFM, but does not have any counseling about contraception. She returns 3 months later with a positive pregnancy test.

A sample FMEA for this situation is presented in Table 1. This analysis tells us that the 2 critical processes to focus on related to contraception for high-risk postpartum women is contraceptive adherence (criticality index=324) and counseling on impact of their high-risk issue on future pregnancy (criticality index=384). Possible solutions include encouraging LARC for these patients, a telephone application designed to help women with contraceptive adherence, and a system for consultation by maternal fetal medicine prior to discharge to discuss the impact of the high-risk issue on future pregnancy.

Table 1: Failure mode and effect analysis for postpartum contraception after peripartum cardiomyopathy

Step in the process	Failure mode (What could go wrong?)	Probability of failure (1-10)	Detection rating (how likely is it we will miss a problem? (1-10)	Impact score if failure occurred (1-10)	Criticality index (probability if failure x detection rating x impact score)
Counseling during prenatal care	Counseling does not occur	6	7	4	168
If desires tubal ligation or immediate post placental IUD, procedure occurs	Unable to perform due to acuity on floor or medical contraindication	5	2	8	80
Counseling prior to delivery discharge if not for immediate contraception	Counseling does not occur	3	7	5	105
Patient making a decision about contraceptive form	Patient is not ready to make a decision; does not communicate decision	2	6	3	36
Placement/prescription for contraception prior to discharge if not for interval IUD	Provider does not give rx/too busy to place nexplanon	1	2	7	14
Scheduling LARC placement after discharge if needed	Never scheduled by administrative team	2	4	6	48
If for prescription contraception, patient picking up prescription	Patient too busy to pick up; insurance issues	6	4	7	168
Adhering to method	Difficulty with adherence	6	9	6	324
Counseling on impact of high risk issue on future pregnancy	Patient unaware of impact on future pregnancy	8	8	6	384

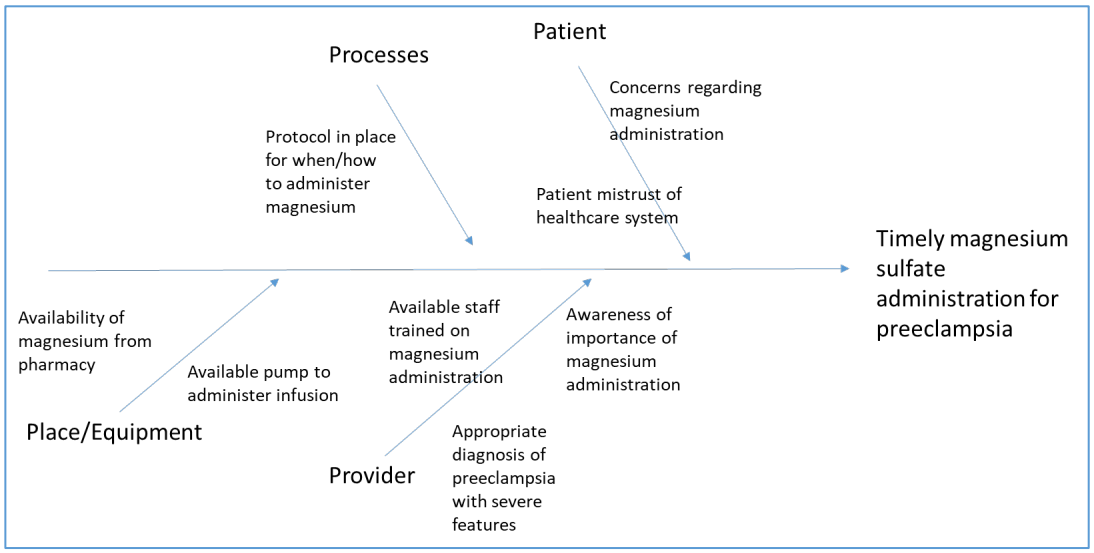

Figure 3. Fishbone diagram, factors contributing to timely magnesium sulfate administration

Fishbone diagram (or Ishikawa diagram) is a cause-and-effect diagrams where the "head" of the fish represents the adverse event or error and the "bones" represent categories of contributing factors. A central line (spine) is next drawn to the left of the box in which the error is recorded. Possible categories when considering medical error include the five "P"'s: patients, providers, policies, processes, and place/equipment, but can change based on the error at hand. Each category bone then has primary contributing factors or causes of the effect that fit in that category as sub-branches, with secondary causes branching off the appropriate primary causes in a repeating pattern until there is agreement that the root cause of each primary cause is identified. This process aids in identifying the many possible contributing factors and causes of an event and is often used in teams for "brainstorming".

An example in maternal-fetal medicine: A patient with preeclampsia with severe features is admitted to labor and delivery but not given magnesium sulfate. She then has a seizure. Figure 3 shows the fishbone diagram for this situation.

Pareto chart. The "Pareto Principle" states that a relatively few contributors account for the majority of the effect. A Pareto chart is a bar graph in which the various factors that contribute to an overall effect are arranged in order according to the frequency of their impact on the outcome. First, a list of contributing factors is identified by a tool such as a Fishbone diagram. Then a check sheet (Table 2) is made listing the contributing factors. Next, data collection is undertaken; this can be performed for example by chart review of cases with the outcome to be analyzed. Every time a certain factor contributes to that adverse outcome, it receives a check. The Pareto chart is then created from the check sheet.

An example using the factors we listed in the fishbone diagram above: First, seven charts were identified where magnesium was not administered for preeclampsia in a timely fashion. A check sheet of contributing factors is displayed in Table 2. The Pareto chart created from these data (Figure 4) indicates that the major issues are timely diagnosis of preeclampsia and staff availability to administer magnesium sulfate. A pie chart from the same data (Figure 5) is an alternative presentation that some find easier to interpret.

Table 2. Check sheet used to create Pareto chart

Defect Types/ Event Occurrence	Cases							TOTAL
	1	2	3	4	5	6	7	
Providers were not aware of importance of magnesium administration	1	1	1					3
Providers did not make timely diagnosis of preeclampsia	1		1	1	1	1	1	6
Nursing staff was not available to administer magnesium		1	1	1	1			4
Patient factors delayed magnesium administration						1		1
A protocol was not in place for magnesium administration								0
There was no available pump to administer magnesium		1						1
Magnesium did not come from pharmacy in a timely fashion			1	1				2
TOTAL	2	3	4	3	2	2	1	17

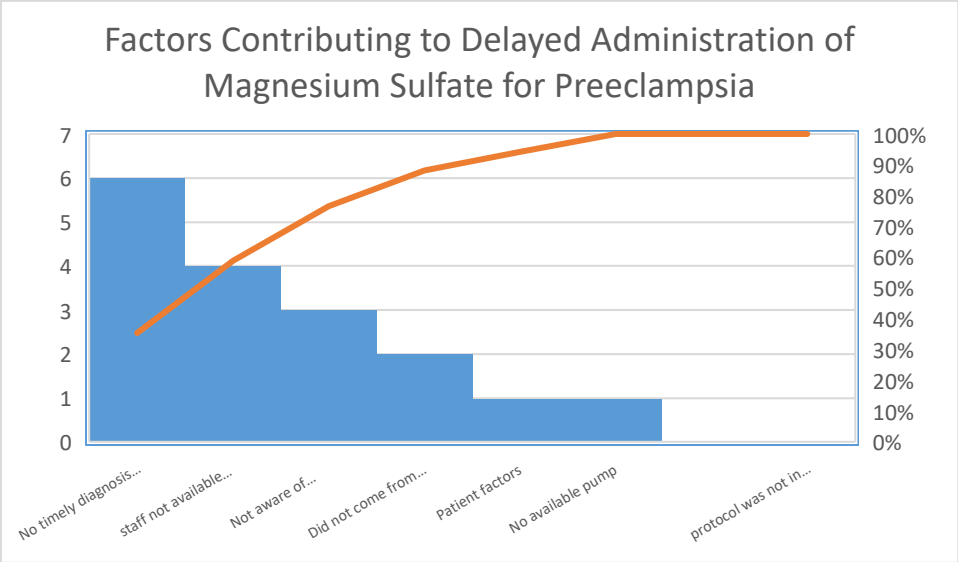

Figure 4. Pareto chart created from the check sheet

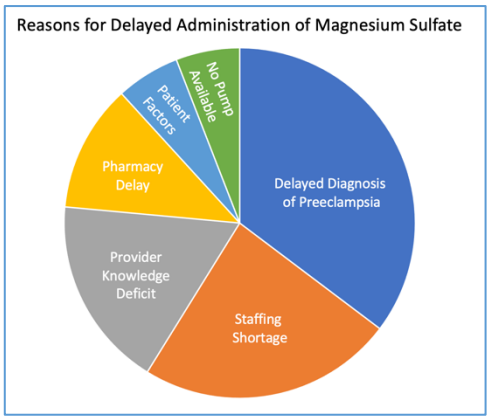

Figure 5. Pie chart from the same data

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Sentinel Events and Event Reporting

Classification of Safety Events

Patient safety is defined by the World Health Organization (WHO as the "*prevention of errors and adverse effects to patients that are associated with health care.*" To prevent harm, events must be reviewed and classified to understand the shared processes that led to the occurrence of the event. Examples of event classification systems include The Joint Commission Sentinel Event Classification and the World Health Organization taxonomy.

The Joint Commission Sentinel Event Classification

In 1996, the Joint Commission on Accreditation of Healthcare Organizations (now called the Joint Commission or TJC) called for adoption of a sentinel event policy. A *sentinel event* or *never event* was defined as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."

The Joint Commission recently updated this definition to clarify the differences between severe and permanent harm. A sentinel event is now defined as "a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm)." All intrapartum maternal deaths and unanticipated term infants' deaths are considered sentinel events under TJC classification.

Hospitals accredited by the Joint Commission are expected to identify and respond accordingly to all sentinel events (Table 1). When a sentinel event is identified, an appropriate team should disclose the event to the patient and/or family and a multidisciplinary event analysis is performed to analyze contributing factors with a focus on systems and processes. Areas for improvement are identified and a corrective action report is implemented to decrease the likelihood of future events. In the United States, any medical-related device adverse events must be reported to the Food and Drug Administration and the device manufacturer within 10 days of the event. If a hospital or healthcare system is not accredited by TJC, there must be a framework to report, analyze and follow up sentinel or never events. Both the UK National Health System and Patient Safety Institute of Canada offer alternative reporting and framework strategies for "never event" review.

Unintended retention of a foreign object is one of the most frequently reported sentinel events.

Example: A fetal scalp electrode is placed in a laboring patient. Cesarean delivery for arrest of descent is performed hours later. The surgical team assumes the electrode has been removed but actually it is dislodged from the scalp during delivery of the head and falls unnoticed into the maternal abdomen. The electrode is not missed until an unidentified object is reported on abdominal X-ray. The patient returns to the operating room for exploration and removal of the fetal scalp electrode. This retention of a foreign object must be disclosed to the patient and reported to the hospital's Patient Safety Committee for further investigation.

The World Health Organization (WHO) taxonomy classification

The Joint Commission's initial reporting system did not capture adverse "near miss" events that could have led to significant harm. To capture these precursor safety events, national and international organizations later developed patient safety event classification systems. In 2009, WHO published the International Classification for Patient Safety, a more conceptual framework used to facilitate reporting and analysis of safety events (Table 2).

Using this framework, WHO collected and validated safety event data over several years. This analysis identified the need to simplify and integrate event-reporting systems with information technology systems. The European Union and WHO responded by collaborating and renaming the conceptual model, Minimal Information Model for Patient Safety Incident Reporting and Learning Systems). A comprehensive review of this model and event reporting is available from WHO and serves as an excellent resource.

Event Reporting

The Institute of Medicine report "To Err is Human" recommended each organization implement an error reporting system with the goal of improving patient safety through learning from all types of events. All organizations are now expected to maintain a confidential system for event reporting. To address this issue, AHRQ's Patient Safety Network's Patient Safety Primer recommends every reporting process to have the following key components:

- Institutions must have a supportive environment for event reporting that protects the privacy of staff who report occurrences.
- Reports should be received from a broad range of personnel.
- Summaries of reported events must be disseminated in a timely fashion.

- A structured mechanism must be in place for reviewing reports and developing action plans.

An organization's safety culture is key to a successful reporting system. A shift from a negative blame culture to a just culture will increase event reporting and learning opportunities to reduce harm. While event reporting systems have traditionally been utilized for serious or sentinel event reporting, reporting of "near miss" events should be encouraged to afford opportunities for feedback, education, and continuous improvement cycles.

Table 1. The Joint Commission List of Reportable Sentinel Events updated July 1, 2021

Any intrapartum maternal death
Unanticipated death of a full-term infant
Discharge of an infant to the wrong family
Unintended retention of a foreign object in a patient after surgery (i.e., after final skin closure) or other procedure
Surgery or other procedure performed at the wrong site, on the wrong patient, or that is wrong (unintended) procedure for a patient
Severe maternal morbidity (not primarily related to the natural course of the patient's illness) when it reaches a patient and results in permanent or severe temporary harm. [Defined as a safety event occurring from intrapartum to 24 hours postpartum requiring transfusion of 4 or more units packed red blood cells and/or admission to the intensive care unit.]
Fall resulting in any fracture, surgery; required consult/management for a neurological or internal injury
Severe neonatal hyperbilirubinemia (bilirubin > 30 mgs/dL)
Administration of blood or blood products having unintended ABO or non-ABO incompatibilities, transfusion reactions or transfusions resulting in severe temporary harm, permanent harm or death
Sexual abuse/assault of any patient while receiving care on site or under the care of the organization
Physical assault (leading to death, permanent harm or severe temporary harm) of any patient, staff member or visitor while on site or providing care at organization
Abduction of any patient or elopement leading to death, permanent harm or severe temporary harm to the patient
Suicide of any patient receiving care, treatment and services in a staffed around-the clock care setting or within 72 of discharge
Fire, flame or unanticipated smoke, heat or flashes occurring during direct patient care caused by equipment operated and used by the hospital
Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to wrong body region or >25% above the planned radiotherapy dose

Adapted from:
https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

Table 2. WHO International Classification for Patient Safety Framework

Incident type	Grouping of adverse events based on shared features e.g. blood/blood products, clinical process
Patient outcomes	Relate to event's outcomes on patient - type of harm, social or economic impact
Patient characteristics	Patient's diagnosis and the reason for seeking care
Incident characteristics	The circumstances surrounding the event
Contributing factors/hazards	Actions and/or circumstances that may have influenced the event
Organizational outcomes	Direct impact on institution
Detection	An action resulting in discovery of an event
Mitigating factors	Actions that prevent the progression of the harmful event. Factors are designed to minimize harm
Ameliorating actions	Actions that compensate for the harm that reached the patient. These actions are used in the rescue phase of the incident recovery.
Actions taken to reduce risks	Steps taken to prevent or reduce the risk of event recurrence.

Source: https://www.who.int/patientsafety/taxonomy/icps_full_report.pdf Accessed October 19, 2021

Additional Reading

The Joint Commission. Sentinel Event Policy https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

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Disclosure of Adverse Events, Patient-Centered Care

Event reporting and disclosure process

Both the American Medical Association (AMA) and American College of Obstetrics and Gynecology (ACOG) acknowledge the rationale for disclosure of adverse events. The AMA Code of Ethics states:

> *"Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred."*

Disclosure of adverse events and medical errors respects patient autonomy, strengthens the patient-provider relationship, and is considered best practice toward promotion of safe and high-quality health care. Barriers to disclosure include fear of retribution, lack of supportive blame-free culture, lack of disclosure process training and fear of litigation. While litigation is a highly cited barrier, there is strong evidence to support immediate disclosure to prevent or reduce litigation.

Example: A patient was undergoing labor induction for preeclampsia with severe features at 34 weeks. Intravenous magnesium sulfate infusion was ordered for seizure prophylaxis. Following a vaginal birth, the patient experienced a postpartum hemorrhage. IV oxytocin and carboprost were given along with a 1-liter IV fluid bolus. The patient noted increasing shortness of breath and O2 saturation dropped to 90%. She became more confused and ultimately suffered cardiac arrest. Attempts to resuscitate patient were unsuccessful. The differential diagnosis included amniotic fluid or pulmonary embolus, maternal cerebrovascular accident, or cardiac event. As the team was cleaning up the room, it was discovered that the bag of magnesium sulfate was empty, suggesting that this bag had improperly been used for the fluid bolus and the patient had inadvertently been given a lethal dose of IV magnesium. Should the family be told about this error?

In 2008, Weiss and Miranda proposed a framework for disclosure which is illustrated in ACOG Committee Opinion No 681 - remember the who, what, when, where, and how.

- **Who**: A faculty attending should lead the disclosure. (patient/family members?)
- **What:** Only facts should be reported. Disclose info as it becomes available.
- **When:** Disclosure should occur as soon as reasonably possible, while emphasizing to the patient/family that it is an ongoing process of communication.
- **Where:** Disclosure should occur in a quiet and confidential setting; one which will be most comfortable to the patient.
- **How:** Patient dignity must always be respected. A disclosure conversation should include empathy for what patients and their families have experienced.

In the case example, experts agree that the facts of the case should be disclosed to the family along with an explanation as to the steps being taken to prevent such an occurrence in the future (e.g., magnesium sulfate will only be dispensed in bags limited to 4 grams and only administered via an infusion pump.

Communication and Resolution Programs (CRP),

The basic principles of any CRP include a timely investigation and engagement of patient and family in open dialogue. The results of the investigation are shared with the patient/family and if appropriate, an apology and/or fair compensation is offered.

Following an adverse event, patients and families often seek accountability and responsibility rather than direct compensation. One of the most publicized and impactful event disclosures was "Josie's Story" described by Sorrel King. Josie was an 18-month-old child who died as a result of a preventable medical error in 2001. Disclosure was swift and Josie's family was offered a settlement. Josie's family initially declined the settlement and later elected to take the settlement to start a foundation devoted to reducing medical errors.

Every adverse event investigation should include a quality improvement process with peer coaching and support from risk management.

CANDOR: (Communication and Optimal Resolution)

The US Agency for Healthcare Research and Quality (AHRQ) developed the CANDOR toolkit for organizations as a guide for communication and resolution of adverse events. The components of the CANDOR process are summarized in the Figure and in Table 1. It is recommended that each institution have a Communication and Resolution team or leaders who can help guide providers and patients through the process.

The Second Victim

A health care professional involved in an unanticipated adverse patient event or medical error can feel victimized or traumatized by the event. The

prevalence of a second victim following an adverse event is estimated between 10-40%. The natural history of recovery for the second victim was conceptualized by Scott et al. and adapted by the AHRQ (Table 4). Compassion and support throughout these stages is necessary to help in the recovery process. Residents and fellows are especially vulnerable to trauma and less likely to acknowledge their suffering. Fear of litigation and loss of employment can be incapacitating following an event. Providing an open, non-punitive culture is critical to helping them cope with their self-imposed feelings of blame and inadequacy.

Recognizing the critical need to support second victims, many institutions have developed toolkits and formalized care support teams to prevent potential risk of self-inflection of harm. One example is the RISE program (Resilience in Stressful Events) developed by Wu, who first suggested the term "second victim".

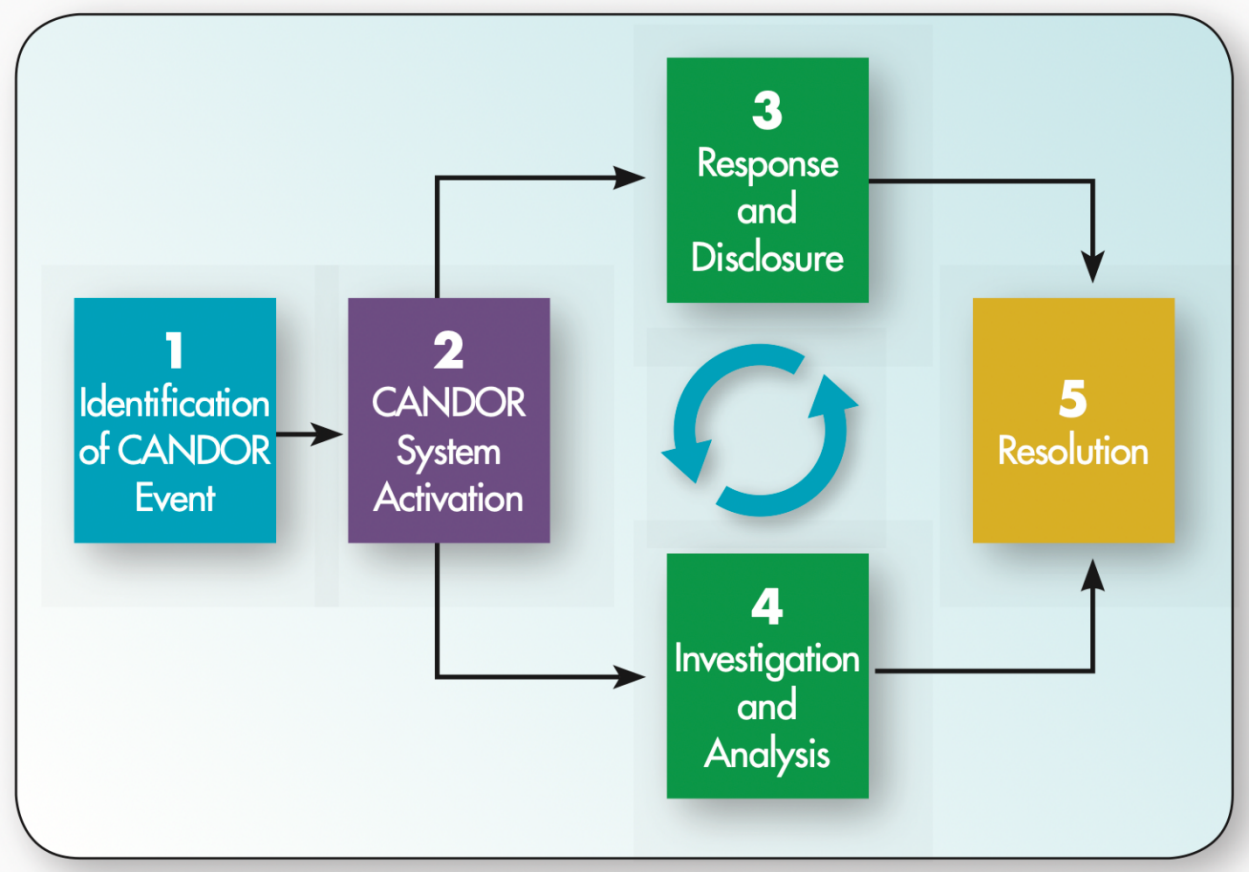

Figure. The CANDOR process.
Source: https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-safety-resources/resources/candor/candor-impguide.pdf

Table 1. CANDOR Process

EVENT REPORT (within hours)	
Receipt of report	Enter event report via an event reporting system
Assess and inform	Ensure patient is stable Provide emotional support to patient/family Activate care for the caregiver program if available Activate trained CANDOR response team if available
Sequester evidence	Secure the event location Gather time sensitive information
EVENT REVIEW (hours to days)	
Initial key communications	Identify a patient/family liaison Prepare communication strategy for communication between patient/family and health system Contact peer-support program, risk management or appropriate health system leadership, graduate medical education directors, unit director Initiate process to hold billing
Event review (within 72 hours)	Schedule interviews with key staff Collect documents to establish timeline
EVENT INVESTIGATION AND ANALYSIS (weeks to months)	
Steps for investigation and analysis	Identify any issues for peer review Use the following as guidance: Joint Commission's National Patient Safety Goals; NQF's Serious Reportable Events; or CMS's "never" events Identify organizational policies and procedures to assess for deviations Flowchart the process Update leadership Monitor and maintain contact with patient/family
Conclude investigation	Conduct consensus meeting with leadership and appropriate providers to review findings and determine next steps. Meet with risk management Implement changes to process and policy as appropriate Meet with patient/family to review findings and include resulting actions to prevent future recurrences of similar events Offer to discuss compensation, if appropriate

Adapted from: Agency for Healthcare Research and Quality, CANDOR Event Checklist
https://www.ahrq.gov/patient-safety/capacity/candor/modules/checklist4.html

Table 2. Second Victims Stages of Recovery

Stage of Recovery	Summary
Chaos and accident response	Clinician experiences internal and external turmoil and may be in a state of shock while trying to simultaneously analyze what happened and manage a patient who may be unstable or in crisis. Clinician is distracted and self-reflected, needs others to take over.
Intrusive reflections	Clinician experiences feelings of inadequacy, self-doubt, and loss of confidence. Clinician engages in continuous re-evaluation of the situation through "haunted re-enactments."
Restoring personal integrity	Clinician seeks support from trusted persons but may not know where to turn and may be fearful of how others will react. Unsupportive responses from colleagues can impair recovery, as they may intensify self-doubt and make it difficult for the clinician to move forward.
Enduring the inquisition	Clinician braces for the institutional investigation, wonders about the impact on their job, licensure, and the potential for litigation. Clinician may be reluctant to disclose information for fear of violating privacy regulations.
Obtaining emotional first aid	Clinician feels uncertain about who is safe to confide in due to privacy concerns and not wanting to expose loved ones to pain. In the study, most clinicians felt unsupported or under-supported, partly due to ambiguity around whom to approach and what can be discussed.
Moving on	Clinicians feel internal and external pressure to "move on," and in the study had three forms of doing so: • **Dropping out:** changing their role, moving to a different practice setting, or leaving their profession • **Surviving:** "doing okay" after acknowledging mistake, but having a hard time forgiving self, finds it "impossible to let go" • **Thriving:** making something good come out of the event

From: Agency for Healthcare Research and Quality, Stages of Recovery for Second Victims: https://psnet.ahrq.gov/primer/second-victims-support-clinicians-involved-errors-and-adverse-events

Additional Reading

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Campbell DA, et al. A better approach to medical malpractice claims? The University of Michigan experience. J Health Life Sci Law 2009;2:125-59

Scott SD, Hirschinger LE, Cox KR, et al. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual Saf Health Care 2009;18:325-330

Human Factors Engineering

Human factors engineering is the discipline that seeks to apply information about human physical and psychological characteristics to the design of devices, systems, tasks, jobs, and environments for human use. Well-engineered systems should be safe, comfortable, and effective to use.

Human factors engineering tools and techniques may be used to improve patient safety in several clinical scenarios as listed in the Table on the next page.

Some of the example solutions require design and development by engineers working for device manufacturers and others require software engineers or other design specialists. However, some of them can be implemented by local care teams and do not require engineering specialists.

Additional Reading

Gosbee J. Human factors engineering and patient safety. Qual Saf Health Care 2002; 11:32-4.

Clack L, Sax H. Inpatient Notes: human factors engineering and inpatient care – new ways to solve old problems. Ann Int Med 2017; 166:HO2-3.

Table. Some Human Factors Engineering Tools

	Explanation	Examples
Usability testing	Testing of a new computer program or equipment to ensure safety such as are no confusing displays on the monitors when using automated order entry or withdrawal of medications	• Alerts in electronic medical record systems • Bar-code system to prevent medication errors
Forcing function	Design of a process or device that prevents an unintended or undesirable action from being performed or allows its performance only if another specific function is performed first	• Removal of concentrated potassium chloride solution from hospital pharmacy (prevents accidental lethal injection) • Removal of 4x4 sponges from cesarean tray (prevents accidental retention) • Design of connectors so that oxygen tubing can only be connected to oxygen supply and not to anesthetic gas supply.
Standardization	Equipment and processes should be the same no matter where or when it is used, no matter who uses it.	• Identical defibrillator equipment across all units in a facility • Use of checklists and hand-offs
Resiliency efforts	Addresses the dynamic aspects for risk management, as there is always a possibility of an unexpected event. It allows for attention to early detection of adverse events and mitigation before they worsen	• Alert for delays in obtaining medication from the pharmacy

Standardized Quality Metrics

Metrics are defined as events or factors that can be counted or measured. A metric can be a score, an interpretation of results, or a risk categorization. Metrics are frequently called measures.

Metrics provide baseline data. Monitoring of metrics allows the health care team to:

- Understand current performance (baseline)
- Come up with ideas to improve performance
- Test changes to see if they lead to improvement
- Follow trends and "adapt, adopt, or discard" any changes being tested
- Ensure that improvements are sustained.

Standardized quality metrics are developed by many organizations for their own internal purposes. Some organizations submit their standardized metrics for endorsement by the National Quality Forum, a not-for-profit multistakeholder organization that strives to provide a consistent process for ensuring that health care quality metrics are valid and useful.

Health care quality metrics have a formalized, standard *specification*. At minimum, the specification includes:

- Title and brief description
- Denominator: the population being measured.
- Numerator (or measure focus): the target process, condition, event, or outcome expected for the targeted population.

Additional specifications may include detailed descriptions of inclusion and exclusion criteria, measurement time period, attributable providers (e.g. individuals, groups, facilities, health plans).

Listings of selected standardized quality metrics relevant to obstetrics are given in the two Tables at the end of this chapter.

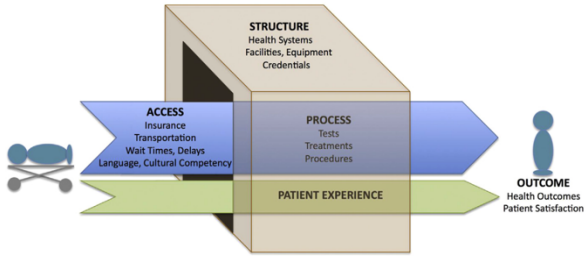

Figure: Types of health care quality metrics
Source: Bailit et al. 2016

Types of Measures

Traditionally, healthcare metrics were subdivided into 3 categories: outcome metrics, process metrics, and structure metrics. This was called the Donabedian model (after the physician who first proposed it). However, modern thinking recognizes that there are many more aspects to healthcare, as shown in the Figure. Every one of these aspects can be measured.

Outcome measures reflect the impact of the health care service or intervention on the health status of patients. The World Health Organization defines an outcome as a "change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions." Typically, outcome measures are the "holy grail" of quality improvement, the ultimate quality and cost targets that healthcare organizations are trying to improve. The 4 main types of outcome measures are:

- *Patient-reported outcomes*, defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else
- *Performance-based measures,* based on completion of specified behaviors or tasks
- *Observer-reported measures,* completed by a parent, caregiver or someone who regularly observes the patient on a daily basis
- *Clinician-reported measures,* completed by a health care professional.

Process metrics reflect how often we "do the right thing" rather than how often we get a good outcome. It is important to measure processes because it is by doing processes that we influence the outcome. For example, in an obstetrical patient with severe hypertension, key safety processes are to repeat the blood pressure measurement within 15 minutes and to administer rapidly acting antihypertensive agent within 30-60 minutes. Doing these processes will reduce the risk of stroke or death. A hospital implementing a severe hypertension bundle will do well to measure these processes, which occur many times per month. The outcomes (stroke or death) will occur so rarely that an individual hospital will not likely be able to demonstrate a meaningful reduction in rate (that is, a decrease from 1 case per year to 0 cases per year is not statistically significant).

Structure metrics reflect aspects of the facility such as the number of ultrasound machines, the percent of sonographers who have an RDMS certification, the percent of MFMs who are board-certified or eligible, whether the practice has an accreditation. Processes such as disinfection of vaginal ultrasound probes or calibration of blood pressure machines can be considered structure measures rather than process measures because they are directed at the structure of the practice rather than individual patients.

Access measures involve aspects of care related to barriers to patient entry into the facility, such as language, insurance, or transportation issues.

Patient experience metrics are patient-reported measures from standardized surveys such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. These metrics reflect details of the patient interaction with the facility or provider, such as "how often did nurses explain things in a way you could understand?" or "how often did doctors treat you with courtesy and respect?" or "how often were your room and bathroom kept clean?" Patient experience is different than patient satisfaction. Satisfaction is obviously correlated with health outcome but can also be influenced by things that have no direct bearing on patient care or outcome (for example, free meals for spouses).

Organizations Involved with Standardized Patient Safety & Quality Metrics

Multiple governmental, and not-for-profit organizations define, prioritize, monitor, and collect outcome measures that are reported to the government, commercial payers, healthcare systems, other organizations and the public at large The metrics are variously used for mandates, care improvement, accreditation requirements, and financial incentives. Several organizations are outlined briefly below. Many others are discussed in an SMFM Special Statement, *Who's Who in Patient Safety and Quality for maternal healthcare in the United State*s.

Centers for Medicare & Medicaid Services (CMS), the federal agency that sets rules for publicly funded healthcare programs, summarizes a variety of metrics in its Star ratings, intended to reflect overall hospital quality. The ratings are publicly available at the CMS website, medicare.gov website. It also has value-based payment programs that incentivize hospitals to improve performance on specified outcome metrics.

The Joint Commission (TJC) evaluates and accredits more than 22,000 health care organizations and programs in the United States. Accredited facilities that provide maternity services are required to report several Perinatal Care (PC) measures annually to the Joint Commission (see Table 1).

National Quality Forum (NQF) has a portfolio of endorsed performance measures that can be used to measure and quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality care

Core Quality Measures Collaborative publishes online core sets of metrics that are anticipated to have high value (large improvement in outcomes per dollar spent).

Leapfrog Group publishes online hospital performance metrics for a variety of self-reported measures of interest to payers and consumers.

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Combs CA, Davidson CM, Einerson BD, et al. SMFM Special Statement: Who's who in patient safety and quality for maternal healthcare in the United States. Am J Obstet Gynecol 2020; 223(1):B2-15

Table 1. Selected perinatal care quality metrics

	Description	Numerator	Denominator
The Joint Commission's Perinatal Care measures			
PC-01 Elective Delivery	Elective vaginal deliveries or elective cesarean births at >= 37 and < 39 weeks of gestation completed	Patients with elective deliveries	Patients delivering newborns with >=37 and < 39 weeks of gestation completed
PC-02 Cesarean Birth	Nulliparous women with a term, singleton baby in a vertex position delivered by cesarean birth	Patients with cesarean births	Nulliparous patients delivered of a live term singleton newborn in vertex presentation
PC-05 Exclusive Breast Milk Feeding	Single term newborns discharged alive from the hospital	Newborns that were fed breast milk only since birth	Single term newborns discharged alive from hospital
PC-06 Unexpected Complications in Term Newborns	The percent of infants with unexpected newborn complications among full term newborns with no preexisting conditions.	Newborns with severe and moderate complications, newborns with severe complications and newborns with moderate complications	Liveborn single term newborns 2500 gm or over in birth weight.
Agency for Healthcare Research and Quality Perinatal Indicators			
Inpatient Quality Indicator 21 (IQI 21) Cesarean Delivery Rate, Uncomplicated	Cesarean deliveries without a hysterotomy procedure per 1,000 deliveries. Excludes deliveries with complications (abnormal presentation, preterm delivery, fetal death, multiple gestation, or breech presentation).	Number of Cesarean deliveries among cases meeting the inclusion and exclusion rules for the denominator	Discharges with an ICD-10-CM diagnosis code for birth delivery outcome
Inpatient Quality Indicator 22 (IQI 22) Vaginal Birth After Cesarean (VBAC) Delivery Rate, Uncomplicated	Vaginal births per 1,000 deliveries by patients with previous Cesarean deliveries. Excludes deliveries with complications (abnormal presentation, preterm delivery, fetal death, multiple gestation, or breech presentation)	Number of vaginal deliveries among cases meeting the inclusion and exclusion rules for the denominator	Discharges with an ICD-10-CM diagnosis code for birth delivery outcome
Inpatient Quality Indicator 33 (IQI 33) Primary Cesarean Delivery Rate, Uncomplicated	First-time Cesarean deliveries without a hysterotomy procedure per 1,000 deliveries. Excludes deliveries with complications (abnormal presentation, preterm delivery, fetal death, multiple gestation, or breech presentation)	Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with any listed ICD-10-PCS procedure code for Cesarean delivery	All deliveries, identified by any listed ICD-10-CM diagnosis code for outcome of delivery
National Quality Forum Quality Perinatal Indicators			
0470 Incidence of Episiotomy	Percentage of vaginal deliveries (excluding those coded with shoulder dystocia) during which an episiotomy is performed	Number of episiotomy procedures (ICD-9 code 72.1, 72.21, 72.31, 72.71, 73.6; ICD-10 performed on women undergoing a vaginal delivery (excluding those with shoulder dystocia ICD-10; O66.0) during the analytic period	All vaginal deliveries during the analytic period-monthly, quarterly, yearly etc. excluding those coded with a shoulder dystocia ICD-1: O66.0
1382 Percentage of low birthweight births	The percentage of births with birthweight <2,500 grams	number of babies born weighing <2,500 grams at birth in the study population	All births in the study population
2902 Contraceptive Care –	Among women ages 15 through	Primary measure: Women ages	Women ages 15 through

Postpartum	44 who had a live birth, the percentage that is provided either: A most effective (i.e., sterilization, implants, intrauterine devices or systems (IUD/IUS)) or moderately (i.e., injectables, oral pills, patch, ring, or diaphragm) effective method of contraception within 3 and 60 days of delivery A long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery	15 through 44 who had a live birth and were provided a most (sterilization, intrauterine device, implant) or moderately (pill, patch, ring, injectable, diaphragm) effective method of contraception within 3 and 60 days of delivery. Sub-measure: Women ages 15 through 44 who had a live birth and were provided a long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery	44 who had a live birth in a 12-month measurement year
0477 – Infants Under 1500g Delivered at Appropriate Site	The number per 1,000 livebirths of <1500g infants delivered at hospitals not appropriate for that size infant.	Liveborn infants (<1500gms but over 24 weeks gestation) born at the given birth hospital	All live births over 24 weeks gestation at the given birth hospital.

Table 2. Other metrics relevant to perinatal care, endorsed by National Quality Forum

Measure	Description
REPRODUCTIVE HEALTH	
0502: Pregnancy test for female abdominal pain patients	Pregnancy test for female abdominal pain patients.
PREGNANCY	
0012: Prenatal Screening for Human Immunodeficiency Virus (HIV)	Percentage of patients who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal care visit.
0014: Prenatal Anti-D Immune Globulin	Percentage of D-negative, unsensitized patients who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation.
0015: Prenatal Blood Groups (ABO), D (Rh) Type	Percentage of patients who gave birth during a 12-month period who had a determination of blood group (ABO) and D (Rh) type by the second prenatal care visit
0016: Prenatal Blood Group Antibody Testing	Percentage of patients who gave birth during a 12-month period who were screened for blood group antibodies during the first or second prenatal care visit.
0582: Diabetes and Pregnancy: Avoidance of Oral Hypoglycemic Agents	This measure identifies pregnant women with diabetes who are not taking an oral hypoglycemic agent.
0607: Pregnant women that had syphilis screening.	This measure identifies pregnant women who had a syphilis test during their pregnancy.
0608: Pregnant women that had HBsAg testing	This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.
CHILDBIRTH AND POST-PARTUM CARE	
0472: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision or at the Time of Delivery – Cesarean section.	Percentage of patients undergoing cesarean section who receive prophylactic antibiotics within one hour prior to surgical incision or at the time of delivery.
0473: Appropriate DVT prophylaxis in women undergoing cesarean delivery	Measure adherence to current ACOG, ACCP recommendations for use of DVT prophylaxis in women undergoing cesarean delivery
0474: Birth Trauma Rate: Injury to Neonates (PSI #17)	Percentage of neonates with specific birth trauma per 1000 births. Exclude infants with injury to skeleton and osteogenesis imperfecta, subdural or cerebral hemorrhage in preterm infant.

Overview of Quality Improvement

Definitions of quality improvement

In health care, quality improvement (QI) is the framework used to systematically improve the ways that care is delivered to patients. Processes have characteristics that can be measured, analyzed, improved, and controlled. QI entails continuous efforts to achieve stable and predictable process results, i.e., to reduce process variation and improve the outcomes of these processes for patients and the health care organization. Achieving sustained QI requires commitment from the entire organization, particularly from top-level management. (AHRQ)

Brief History of Quality Improvement

In the United States, there has been an evolution from quality assurance, where the emphasis was on inspection and punishment for medical errors (the "bad apple" theory) to QI, where we ask, "How did the system fail to support the worker involved in an error?" The Table contrasts the two frameworks.

Model for improvement (MFI)

The Model for Improvement (MFI) is the most commonly used QI approach in health care. The MFI was developed by the Institute for Healthcare Improvement (IHI) in 1996 and published in *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* (1996).

The MFI asks three simple questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in improvement?

The Plan-Do-Study-Act (PDSA) cycle is a method for incrementally introducing a small change, evaluating whether the change resulted in an improvement and then introducing another small change. The QI team develops a Plan to implement each change (Plan), carries out a test (Do), observing and learning from the consequences (Study), and determining what other improvements should be made (Act). Quality improvement teams use successive PDSA cycles until they reach the desired results. This process is depicted in the Figure.

As an example, a QI team is tasked with lowering the hospital's episiotomy rate from its current rate of 38% to under 5%, the benchmark suggested by the Leapfrog Group. In the first PDSA cycle, the physician lead from the team gives a Grand Rounds reviewing the benefits and harms of episiotomy (Plan-Do steps). The following month, the episiotomy rate is 29%, which is an improvement but still far from the target. The team next evaluates individual provider rates and discovers that 3 providers with rates over 60% are driving up the whole department rate (Study step). They ask the department chair to speak with those providers individually (Act). The next month (second PDSA cycle), 2 of the 3 providers have decreased their rate to <10%, but the third still has a 65% rate. The overall department rate is down to 12% (Study). The outlier provider is invited to the next team meeting and is asked to explain their justification for routine use of episiotomy. The provider believes that episiotomy protects the perineum. The provider did not attend the Grand Rounds because of a delivery that was occurring at that time. The provider perceived the conversation with the department chair the previous month as threatening and punitive. The team explains that their intent is simply to encourage evidence-based practice and shares published studies with the provider showing that episiotomy actually increases the risk of anal sphincter injuries. The provider expresses appreciation upon seeing the data and agrees to be more restrictive with the use of episiotomy (Act). The following month (third PDSA cycle), the provider has an episiotomy rate of 16% and the department-wide rate is 6%. The team continues to meet monthly to review the data and seek additional ways to lower the rate.

Additional Reading

Agency for Healthcare Research and Quality. Practice Facilitation Handbook, module 4, approaches to quality improvement. https://www.ahrq.gov/ncepcr/tools/pf-handbook/mod4.html#tab4.

Institute for Healthcare Improvement. Science of improvement: how to improve. http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx

Table. Quality Assurance vs. Quality Improvement approach to analyzing an adverse event

Quality Assurance	Quality Improvement
Individual focused. Detailed chart review to determine exact timeline and who was involved at each step of an adverse outcome. Attempts to ascribe adverse event to an error by one or more health care workers.	Systems focused. Seeks to determine how systems or processes contributed to adverse event, with goal to find ways to modify the system to prevent future errors.
Perfection myth. Assumes that every provider is expected to perform perfectly at all times.	Fallibility recognized. Know that "to err is human." Every person will make a mistake from time to time. The goal is to design a system whereby mistakes can be caught and corrected before they lead to patient harm.
Solo practitioners. Again, focus is on individual performance and individual errors.	Teamwork. Focus on how teams can help each other catch errors before they penetrate to the patient.
Peer review is ignored by practitioners. Worse, it generates denial and defensiveness, neither of which contribute to desirable change in behavior.	Peer review valued because it has a focus on how things can be done better in the future rather than an obsession with how they have been done previously.
Errors punished, including loss of privileges, requirement for proctoring, or ultimately, dismissal from position.	Errors seen as opportunities for learning.

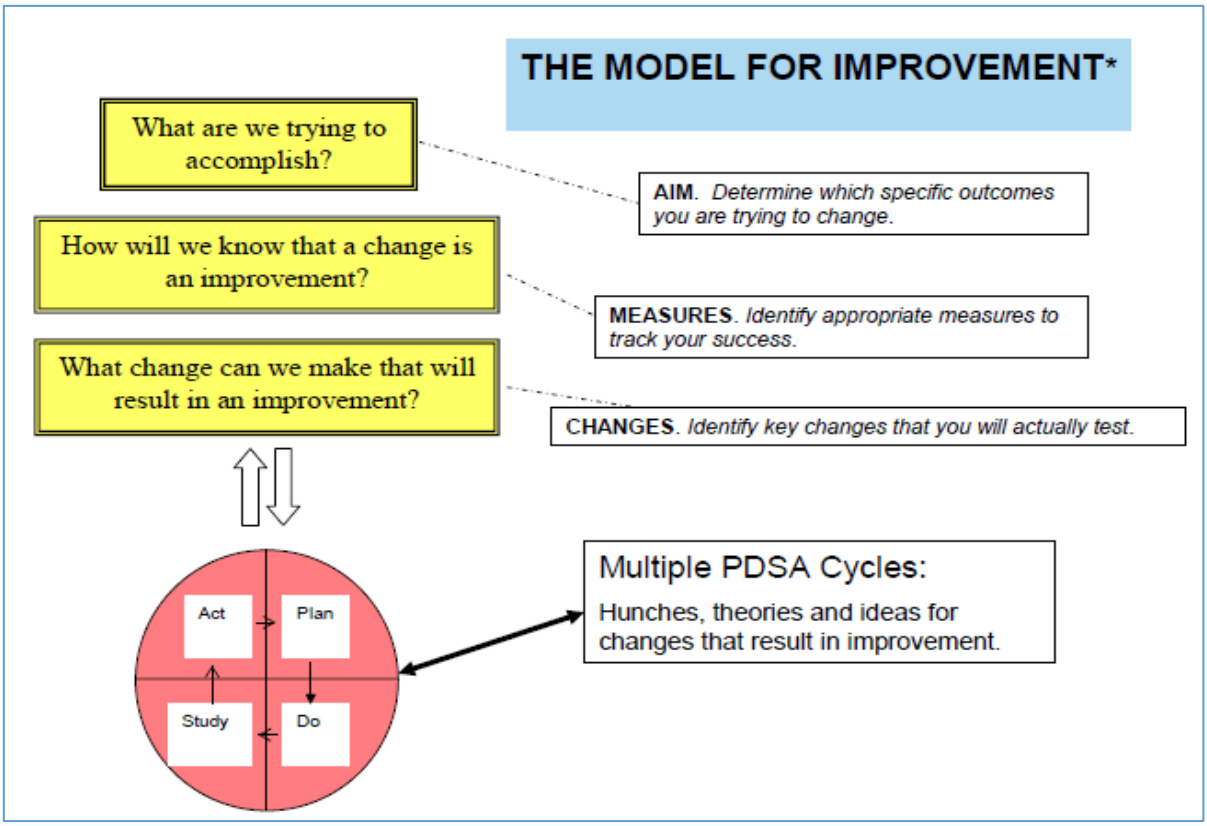


Figure. The model for improvement (MFI).
Source: https://www.ahrq.gov/ncepcr/tools/pf-handbook/mod4.html#

Your Quality Improvement Project: Using and Interpreting Metrics

The ACGME Program Requirements specify that MFM fellows must have "Engagement in quality improvement activities: Fellows must have the opportunity to participate in interprofessional quality improvement activities. This should include activities aimed at reducing health care disparities.

Metrics are the center of all quality improvement (QI) projects. Whether your involvement in QI is designing and completing your own project or being a member of the QI team for a departmental or hospital-wide project, you must know something about using, tracking, reporting metrics.

The ultimate goal of health care is to improve outcomes, so outcome measures are "holy grail" of QI. However, the methods to improve outcomes often involve simply improving processes. Therefore, QI projects that improve processes are important steps toward improving outcomes. In the Model for Improvement, QI is an iterative process: progress toward improved outcome involves successive small steps, improving one process at a time.

In this chapter, we will look at basic tools for tracking and interpreting some of the metrics used in QI. The Table shows an overview of a sample QI project to get us started.

Table. Improvement projects overview

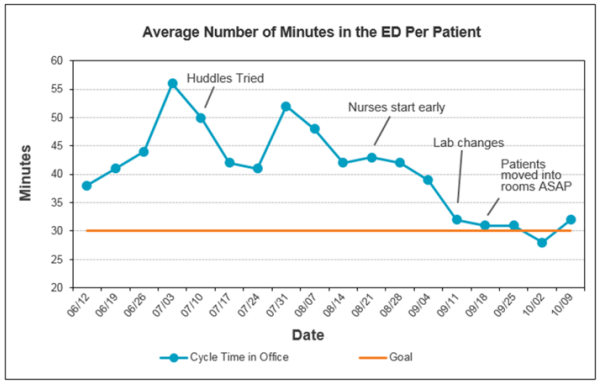
Measures	Personal Improvement Project	Clinical Quality Improvement Project
Aim:	To lose 10 lbs. body weight in 6 months	To decrease primary cesarean rate by 15% in 6 months
Outcome measures: What is our ultimate target?	Total body weight Abdominal circumference < 34 inches BMI <25	Total primary singleton vertex cesarean rate Nulliparous term singleton vertex (NTSV) cesarean rate
Process measure: Are we doing the right things to reach our target?	Days per week that I exercise for at least 30 minutes Days per week that I eat a healthy meal only with no fast food or desserts Days per week that I drink 8 cups of water Days per week that I do not eat after 7 pm Days per week that I do no eat before 11 am	Admission in active labor Management of category 2 Fetal heart rate patterns Adherence duration of labor diagnostic guidelines Active management of labor Patients managed in a holistic natural labor system Macrosomia diagnosis for cesarean section Operative vaginal delivery
Balancing measures: Are the changes introducing any problems?	Level of perceived anxiety or stress daily (1-10 scale) Days with irritability or anger outbursts Sport, muscular or joint injuries	Postpartum hemorrhage rate Chorioamnionitis rate Perinatal mortality rate. Severe perineal lacerations PC-06 – unexpected complications in term newborn

Run Charts

A run chart is a line graph of data plotted over time. Run charts allow you to look at your data over time to assess performance and see whether there are any patterns. Run charts are a valuable tool at the project development phase, as they reveal important information about the existing process. A run chart allows you to:

- Monitor data and performance of processes over time to detect trends, shifts or cycles.
- Compare a performance measure before and after implementation of a solution to measure its impact.
- Focus attention on truly vital changes in the process.
- Assess and show whether changes are resulting in improvement.
- Assess whether improved performance is being sustained.

Here is an example run chart:



Run charts are a simple and effective way to determine whether the changes you made are leading to improvement. Basic characteristics of a run chart:

- X axis: time in chronological order
- Y axis: metric that is being measured
- Goal: the result you're working toward
- Annotations are optional, but they are helpful to show when the team made specific process changes or if any noteworthy events occurred.

You can easily generate and update a run chart using any standard software that has graphing capability (e.g. Excel, Powerpoint, or dedicated scientific graphing software).

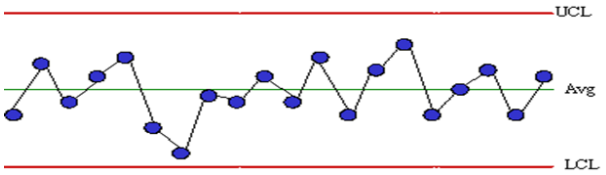
Control Charts (Shewhart charts)

A control chart is a more advanced version of a run chart. In addition to the basic run chart elements, a control chart also has:

- Center line (median or mean)
- Upper and lower *control limits,* typically based on standard deviations from the center line or other statistical measure of variance.
- Optional features may include warning limits and various zones defined by the control limits or warning limits.

A process is said to be *in control* when all the data points fall between the upper and lower confidence limits and *out of control* when data points fall outside these limits.

Here is an example control chart:



Unlike a run chart, control charts require dedicated software to generate and update. There are actually several types of control charts with different inputs for data that are based on counts, totals, or rates (percentages). As new data points are added, the center line and control limits must be revised. The definitions of the control limits must be carefully considered (e.g. 2 standard deviations or 3 standard deviations) depending on the project goal. A statistician or QI expert should be consulted if you think a control chart will be useful for your project.

Types of Variation

Variation is the difference over time in condition, amount or level of a product, performance, workflow or a process. In QI parlance, there are two major types of variation:

- *Common-cause variation* is the inherent variation in a process due to the way it was designed and is managed. Common cause variation is present in stable health care processes. Common cause variation is similar to statistical noise or random variation. It is the natural result of numerous variations in the inputs to a process.
- *Special-cause variation* is from a cause that is not an intrinsic part of the process. It is like a "signal" that can be discerned from the noise.

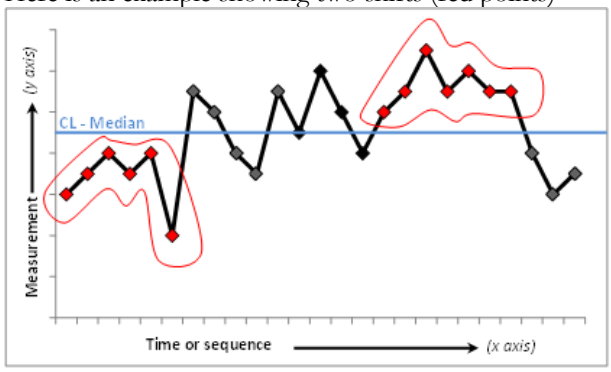
QI projects often start by identifying sources of special cause variation and attempting to minimize them. Thus, it is critical to distinguish special cause from common cause variation. This is not always straightforward. For example, look at the single data point at 56 minutes in the sample run chart on this page. Was this extreme point due to something going on in the ED that week (e.g. director on vacation, nursing walk-out, extraordinarily high patient volume) or was it just a

bad week? In the next section, we will discuss several recognized "rules of thumb" that can help you identify special cause variation.

"Rules of Thumb" for Interpreting Run Charts

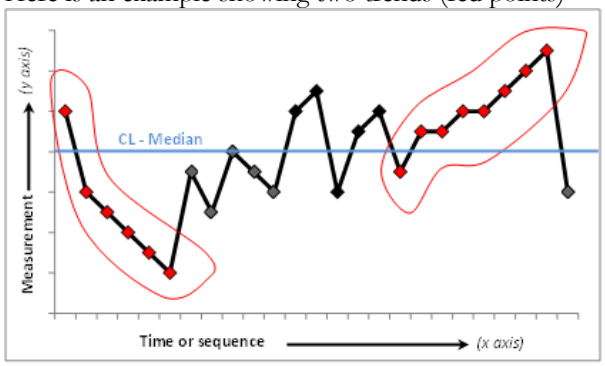
***Shift*:** Six or more consecutive points either all above or all below the center line (CL). Values that fall on the CL do not add to nor break a shift. Skip values that fall on the median and continue counting. Why does this rule work? It's because in a random process, each observation has a 50% probability of being above the median and 50% below the median. If random, the probability of 6 consecutive values above or below is $(0.5)^6$ (0.5 to the sixth power), which is 0.015, or $P<0.02$).

Here is an example showing two shifts (red points)



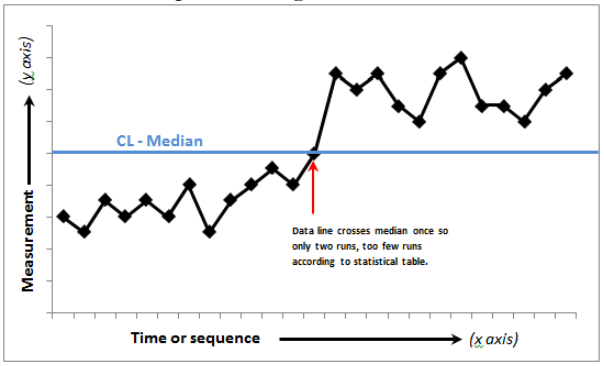
***Trend*:** Five or more consecutive points all going up or all going down. If the value of two or more successive points is the same (repeats), ignore the like points when counting. Why does this rule work? It's because in a random process, each observation has a 50% probability of being above the previous observation and 50% below the previous. If random, the probability of 5 consecutive values above or below is $(0.5)^5$ (0.5 to the fifth power), which is 0.031, or $P<0.05$).

Here is an example showing two trends (red points)



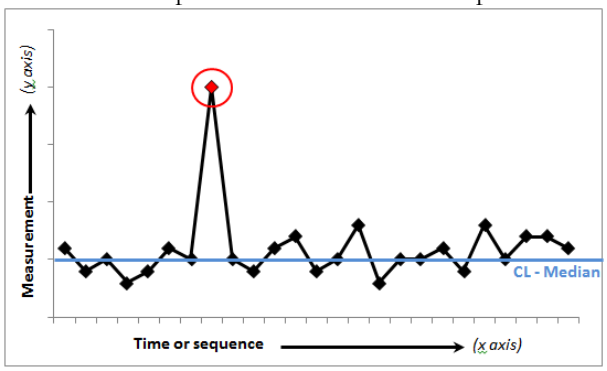
***Too many or too few runs*:** A run is a group of consecutive points that fall on one side of the center line. A non-random pattern is signaled by too few or too many runs, or crossings of the median line. This rule requires a statistical table showing the number of runs expected for a given number of observations (see NHS East London in references for a table). If the number of runs you have outside the range outlined in the table, then you have a non-random pattern or signal of change, possibly due to special cause variation.

Here is an example showing too few runs:



An astronomical data point, a data point that is clearly different from all others. This is a judgement call. Different people looking at the same graph would be expected to recognize the same data point as astronomical.

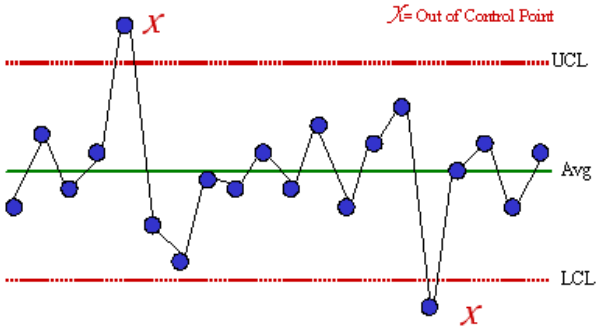
Here is an example of an astronomical data point:



Returning to the example question posed in the previous section (the week with a very long average time-in-ED), the only one of these "rules of thumb" present in that run chart is a "trend" that starts with the point labeled "Nurses start early" and continues for the next 6 weeks). Thus, the "bad week" with a 56 minute time is likely just common cause variation and not necessarily indicative of a process problem or underlying issue. It was the worst data point on that chart, but not astronomical.

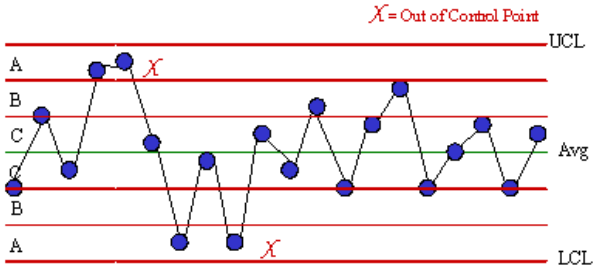
"Rules of Thumb" for Interpreting Control Charts

Point outside control limits: A single out-of-control point may indicate special cause variation. Here is an example:

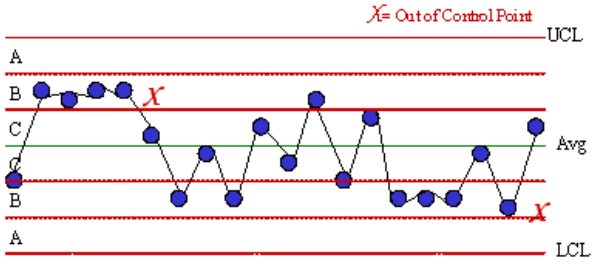


The next several control charts are divided into zones zones labeled A, B and C. The C zones are within 1 standard deviation of the center line, the B zones are between 1 and 2 standard deviations, the A zones between 2 and 3 standard deviations, and the control limits at 3 standard deviation. Special cause variation may be signaled by the following rules:

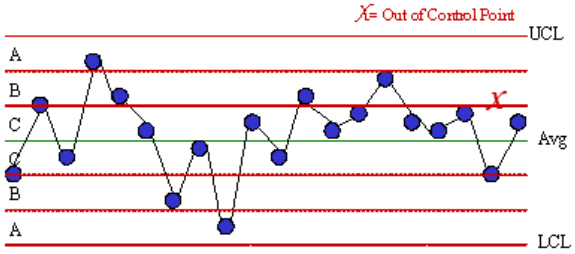
Two out of three consecutive points fall in zone A or beyond, as shown here:



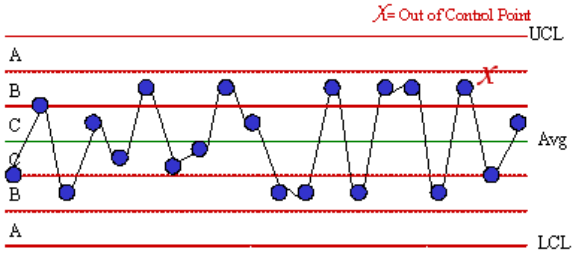
Four out five consecutive points fall in zone B or beyond, as shown here:



Seven consecutive points fall in zone C or beyond, as shown here:



Eight or more consecutive points lie on both sides of the center line with none of the points in zone C. This type of occurrence is a *mixture* and may indicate special cause variation. Here is an example:



In addition to these rules, control charts can also be evaluated using the rules-of-thumb for run charts, that is:

- Shift
- Trend
- Too many or too few runs

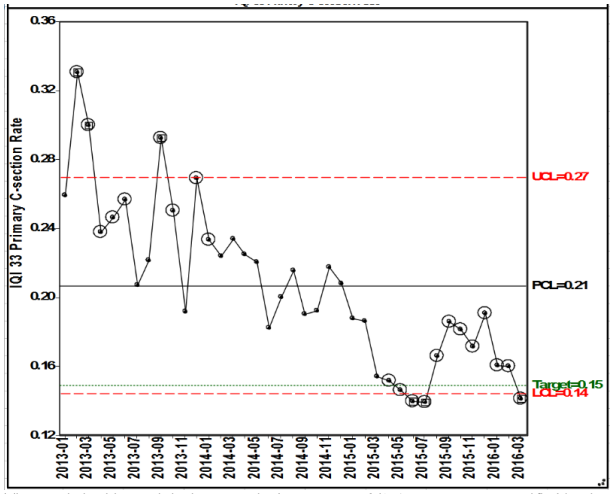
A Sample Clinical Quality Improvement Project

In this section we will examine some control charts generated in a quality improvement project to reduce the rate of primary cesarean delivery. The data are plotted from Ogunyemi (2017). In this study, the period from January 2013 through February 2014 can be considered the baseline. Then from March 2014 until March 2016, a *bundle of interventions* intended to reduce the cesarean rate were introduced over time. These included a detailed review of risk factors, provider and patient education, multidisciplinary reviews based on published guidelines with feedback, provider report cards, commitment to labor duration guidelines, and a focus on natural labor.

Outcome measures

The 2 primary outcome measures for this project were the term, singleton, vertex (TSV) cesarean rate and the nulliparous, term, singleton, vertex (NTSV) cesarean rate. All maternity hospitals accredited by The Joint Commission are required to report their NTSV rate annually, so it is among the most widely studied methods for documenting cesarean rates.

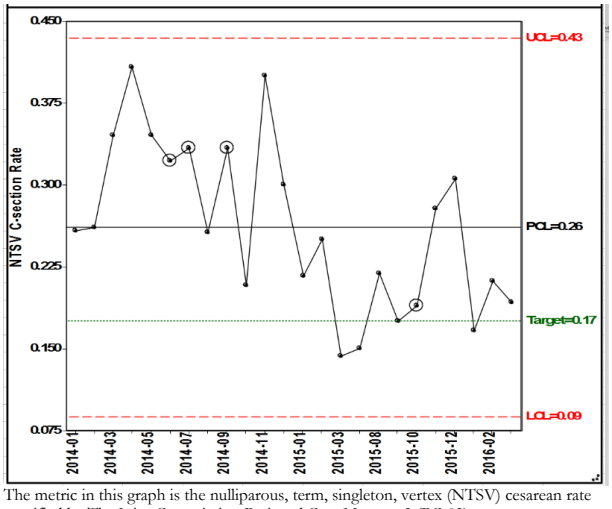
Here is the control chart showing the TSV cesarean rate:



The metric in this graph is the term, singleton, vertex (TSV) cesarean rate specified by the Agency for Healthcare Research and Quality (AHRQ) Inpatient Quality Indicator No. 33

This control chart clearly shows a *shift*: the last 16 data points all fall below the centerline. While this is highly suggestive that the bundle of interventions was likely effective at reducing cesarean rate, it is not really evidence of causation because there is no control group. There may have been other changes that happened during this time period that reduced the cesarean rate regardless of the interventions applied. Nonetheless, in QI, this type of observation is regarded as an improvement. Because many interventions were included in the bundle, it is not possible to state how much any individual intervention contributed to the improvement, if at all.

Here is the control chart showing the NTSV cesarean rate:



The metric in this graph is the nulliparous, term, singleton, vertex (NTSV) cesarean rate specified by The Joint Commission Perinatal Care Measure 2 (PC-02)

This control chart also shows a *shift*: the 7 data points starting January 2015 all fall below the centerline. Even though this shift is not sustained (2 points above the centerline in last 2015), the rate is clearly lower overall after the bundle was introduced.

Process Measures

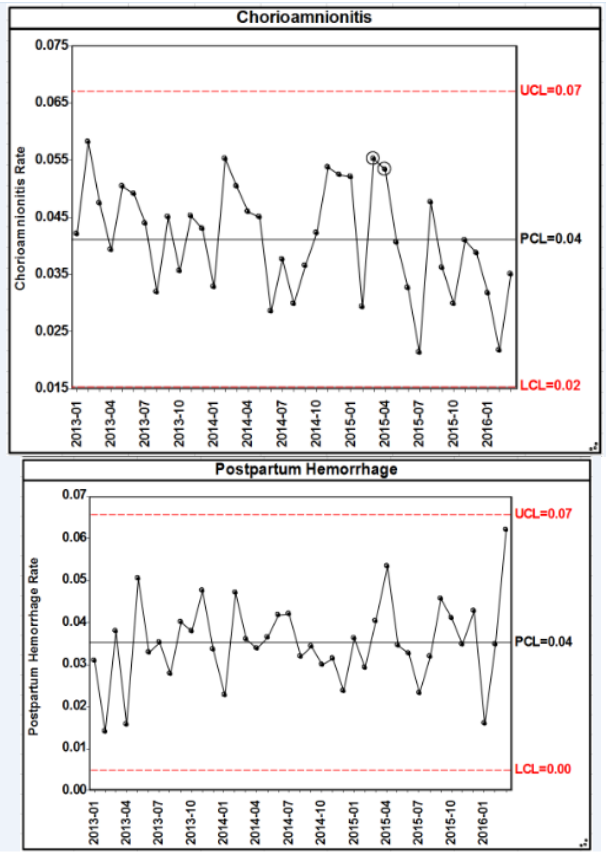
Although the ultimate goal of QI is to improve clinical outcomes, the methodology of QI involves changing processes. In this project, one of the processes that were targeted was to avoid admitting patients to labor and delivery in latent phase of labor. Another was to adopt a management algorithm for category 2 fetal heart rate tracings. Each of these processes can be tracked with a run chart of its own to see how often providers are following recommended practices. If deviations from practice are observed, these can be addressed with individual providers.

Balancing Measures

A major concern with efforts to aggressively lower the primary cesarean rate is that there may be *unintended adverse effects*. For example, requiring additional time in active labor before allowing a diagnosis of arrested labor may increase the risk of chorioamnionitis or postpartum hemorrhage. Or requiring additional observation time before allowing a cesarean for abnormal fetal heart rate tracing may increase the risk of newborn metabolic acidosis or asphyxia.

Balancing measures are examined to evaluate whether improvement in one area is not negatively impacting another area. In this project, the rates of chorioamnionitis and postpartum hemorrhage were

monitored as balancing measures, as shown in the next two control charts.



It is reassuring that neither of these shows a shift or trend suggestive of unintended adverse effects from reducing the cesarean rate.

In 2021, long after completion of this sample project, The Joint Commission introduced Perinatal Care Measure 6 (PC-06): Unexpected complications in term newborns. This is intended as a balancing metric to assess whether lowering the NSTV cesarean rate might risk harm to newborns. All maternity hospitals accredited by The Joint Commission are required to report PC-06 annually, along with their NTSV rate.

Additional Reading

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Including Health Equity Considerations in Quality Improvement Projects

"There can be no Quality without Equity" is a catchphrase among quality improvement (QI) experts. In other words, QI efforts are not adequate if they fail to improve care for all individuals.

An example: Breastmilk feeding rates

Figure 1 shows a run chart from a hospital conducting a QI project to improve its performance on exclusive breastmilk feeding of newborns (Joint Commission metric PC-05). The baseline rate was 12% in 2010. The first intervention was to increase mother-baby contact time by closing the newborn nursery, compelling babies to room-in with their mothers. Over the next few years, the rate improved to 29%. Then the hospital took steps to obtain a Baby-Friendly Hospital (BFH) designation, which involves education of staff and patients about benefits of exclusive breastmilk feeding and requires various interventions to improve the rate. The rate improved further over the ensuing years. When the 5-year BFH renewal came due, it was clear that the rate was being maintained at over 40%, but no further improvement was being made and the rate was perhaps declining.

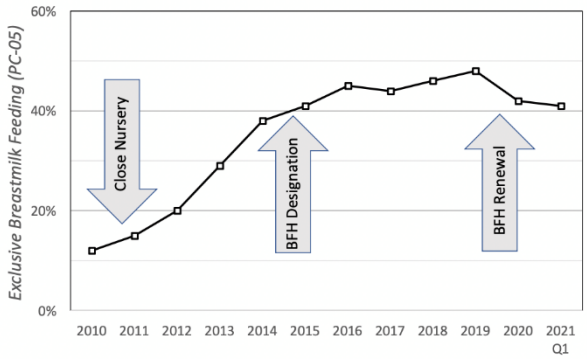

Figure 1. Run chart showing exclusive breastmilk feeding rates and QI project interventions

Figure 1 exemplifies a "color-blind" approach to QI that was typical until very recently. There was a widespread belief that one way to avoid racism was to downplay or ignore differences in race and ethnicity between people. However, this was like "burying our heads in the sand" and failing to see major differences in health care processes and outcomes experienced by people from disadvantaged groups. By ignoring race and ethnicity in our quality improvement efforts, we were missing critical opportunities to identify such disparities, to understand why they existed, and to begin to address them.

The breastmilk project team got a key insight toward understanding why progress was stalled when they decided to stratify the breastmilk feeding rates by maternal race and ethnicity in their monthly data reports. The stratified run chart for their most recent fiscal year (Figure 2) revealed that White mothers had breastmilk feeding rates that were about double the rates of any other group. Once this was revealed, the team took steps to understand why there was a disparity. Interviews with the mothers showed a variety of reasons for lower rates among non-White mothers, including a lack of knowledge about the health benefits of breastmilk, cultural beliefs, language barriers, and other issues. Once the underlying issues were identified, the team began working on addressing each issue to try to reduce the disparity for each race/ethnicity group.

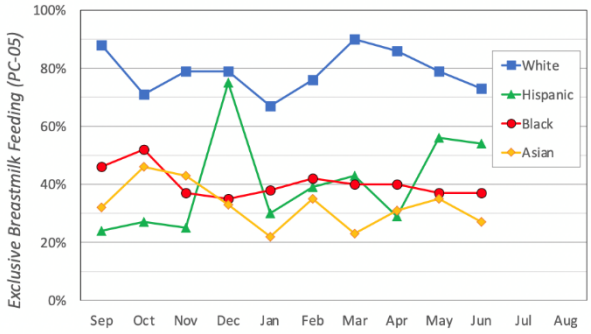

Figure 2. Run chart stratified by race/ethnicity

In contrast to the "color-blind" approach, Figure 2 shows what can be learned in a "race-aware" approach to QI, that is, making a conscious effort to evaluate differences between racial/ethnic groups in health behaviors and outcomes. Progress in any QI project may be stalled until the project team evaluates and attempts to solve race- and ethnic-specific barriers.

Another example: Maternal mortality rates

Figure 3 shows that Black women in the USA have almost 3-fold higher rate of pregnancy-related death than White women.

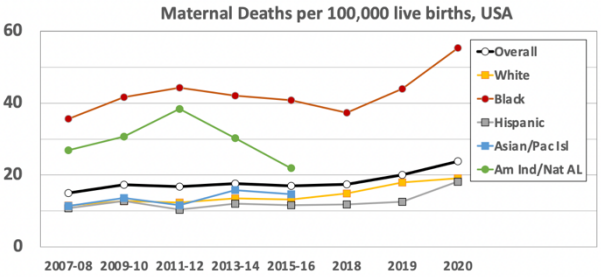

Figure 3. Maternal mortality rates in USA.
Plotted from National Vital Statistics data.

This disparity in maternal mortality is not explained

by any putative biological differences between Black and White mothers or differences in the rates of comorbidities. Rather the root cause is largely systemic racism that produces imbalances in wealth and power and results in inequities in access to care. There is now a widespread effort by public health and professional organizations to identify and mitigate these inequities and reduce the disparities. SMFM Consult Series #62 outlines several best practices in equitable care delivery.

Definitions

Table 1 lists several relevant terms as defined by SMFM. Note that there are subtle but important distinctions between race-vs-ethnicity, disparity-vs-inequity, and racism-vs-prejudice-vs-discrimination. When planning and conducting a QI project, the team should be careful to use the terms correctly.

Categories of Race and Ethnicity

Table 2 shows the categories of race and ethnicity recorded by the US Census Bureau. Five distinct self-reported races are recognized plus one more "some other race" group, for a total of 6 race groups. Ethnicity is distinct from race and is categorized as either Hispanic (or Latino) or non-Hispanic. An Asian person, for example, can be either non-Hispanic Asian or Hispanic Asian. Although there are countless ethnic groups within the USA, the only one captured by Census data is Hispanic (or Latino, Latinx, or Latina). Thus, there are a total of 12 possible race/ethnicity categories.

In practice, however, reports from the Census Bureau and many health researchers combine all Hispanic people into a single bloc regardless of race, as shown in Table 3.

Consider Race and Ethnicity in QI Project Plans

All QI projects should plan from the outset to collect race and ethnicity data and track progress stratified by race and ethnicity. As stated by the American Medical Association Manual of Style Committee,

> "Neglecting to report race and ethnicity in health and medical research disregards the reality of social stratification, injustices, and inequities and implications for population health, and removing race and ethnicity from research may conceal health disparities. Thus, inclusion of race and ethnicity in reports of research to address and further elucidate health disparities and inequities remains important at this time."

Substitute the words "quality improvement" for "research" and this quote remains equally germane.

The categories in Table 3 will be sufficient for most QI projects, but further stratification may be considered depending on the local population. For example, a project in Texas may find it useful to divide Hispanic people into Mexican-vs-other groups, to subdivide the Mexican group into US-born-vs-immigrant subgroups, and to combine Asian, Hawaiian, and Pacific Islanders into a single group. Similarly, a project in Hawaii may want to sub-stratify Asian and Pacific Islander people based on country of origin (such as Japanese, Chinese, Filipino, or other).

The Alliance for Innovation on Maternal Health has a bundle of processes that can be used to assure best practices for:

- collecting valid race and ethnicity data
- educating providers on disparities and their root cause
- monitoring process and outcome metrics stratified by race and ethnicity
- using QI processes to target and eliminate disparities in access, treatment, and outcomes.

Another tool to identify root causes and eliminate disparities in QI efforts is a Racial Equity Impact Assessment (REIA). This is a systematic examination of how different racial and ethnic groups will likely be affected by a proposed action or decision. REIAs are used to identify, reduce, eliminate, and prevent discrimination and inequities in access and care and are best conducted during the decision-making process, prior to enacting new initiatives. A sample REIA checklist can be found at the Seattle Children's Hospital/Foundation link in the Additional Reading section.

Consider Other Social Determinants of Health

Beyond race and ethnicity, many other social determinants of health may be relevant to track and address in a QI project. These include barriers that reduce a person's access to health services or that adversely impact their ability to adhere to recommended treatment. Barriers may include poor health literacy, language difficulty, financial challenges, housing instability, and food insecurity. The QI team should carefully consider the extent to which these may impact QI efforts and should attempt to mitigate any problems identified.

Community-informed models are an approach to addressing social determinants from a patient-centered and community perspective rather than a provider-centered perspective. A community representative on the QI project team may share insights that will lead to more just and equitable outcomes.

Additional Reading

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Society for Maternal-Fetal Medicine, Wheeler SM, Bryant AS, Bonney EA, Howell EA. SMFM Special Statement: Race in maternal-fetal medicine research – dispelling myths and taking an accurate, antiracist approach. Am J Obstet Gynecol 2022; 226(4):B13-22.

Table 1 – Definitions of social determinants of health, race, ethnicity and related terms

Term	SMFM Definition
Social determinants of health	Conditions in the places where people live, learn, work and play that can affect health outcomes, including, but not limited to access to: safe, stable housing; clean water; food and other supplies; translation services; education; transportation; employment
Race	Culturally-defined category based on an individual's physical characteristics such as hair texture, facial features, skin color
Ethnicity	Category based on shared cultural practices that may include language, religion, or other customs
Ancestry	Line of genetic descent and shared traits
Health disparity	Measurable difference in healthcare outcomes that is due to differential treatment based on membership within a marginalized group
Health inequity	Unjust healthcare experiences or outcomes that are due to differential treatment based on membership with a marginalized group
Racism	Negative lived experiences at the interpersonal, institutional, or societal level the stem from biases based solely on physical characteristics
Prejudice	Biased beliefs held by an individual or propagated throughout a group or society about anyt person or groups founded on stereotypes
Discrimination	Biased behavior exhibited by an individual, group, or society to a person or specific group of persons based on stereotypes
Intersectionality	Interplay between multiple aspects of an individual's identity (eg, race, sex, gender, ability)
Antiracism	Actively combating racism and racist ideas at the individual, interpersonal, policy, and societal levels

Table 2 – Categories of Race and Ethnicity as Collected by US Census Bureau

Race	Hispanic or Latino Ethnicity	Non-Hispanic Ethnicity
White	Hispanic White	Non-Hispanic White
Black or African American	Hispanic Black	Non-Hispanic Black
Asian	Hispanic Asian	Non-Hispanic Asian
American Indian or Alaska Native	Hispanic American Indian or Alaska Native	Non-Hispanic American Indian or Alaska Native
Native Hawaiian or Other Pacific Islander	Hispanic Native Hawaiian or Other Pacific Islander	Non-Hispanic Native Hawaiian or Other Pacific Islander
Some other race	Other Hispanic	Other Non-Hispanic

Table 3 – Race and Ethnicity as Reported by US Census Bureau

Race/Ethnicity	Percent of US Population (2020 Census)
Non-Hispanic White	60.1%
Hispanic (Latino)	18.5%
Non-Hispanic Black	13.4%
Non-Hispanic Asian	5.9%
Non-Hispanic Native American or Alaska Native	1.3%
Non-Hispanic Native Hawaiian or Other Pacific Islander	0.2%
Multiracial	2.8%

Team Building

Types of Teams

There are 2 distinct types of teams relevant to patient safety and quality: health care delivery teams and project-specific teams. This chapter is largely focused on care delivery teams, the constantly shifting group of individuals who render care on a hospital unit or outpatient office. The last section offers ideas for building a project-specific team. Many of the team-building principles also apply to such teams.

What is Team Building?

Team building is an iterative process. *Teams do not become teams just because they are called teams or are sent to team building workshops.* Not only does it require finding the right people but also demands the work of building relationships, engendering trust, and setting an agenda that is built on mission, vision, core values, and a strategic plan. Team building is an important method of improving the psychological climate in which teams operate as well as overall team functioning. Not only within the context of sports but also within healthcare, team building interventions have consistently been found to result in improvements in team effectiveness. Just like in sports, teams are a pervasive feature of healthcare. In many instances, health care personnel participate in highly interdependent teams and spend considerable time with each other as Fellows in training and as Attendings. These interactions have a direct bearing on successful individual and team goal pursuits and health outcomes.

Whenever teams are created to maximize their potential there are 2 broad starting considerations:

- Selection of the right personnel and placing them in the right position to perform relevant roles and responsibilities
- Fostering a sense of unity whereby the whole is greater than the simple sum of its parts

Team building has been described as a method of helping the group to

- increase effectiveness
- satisfy the needs of its members and stakeholders
- improve work conditions.

Team building interventions have largely focused on developing a sense of group cohesion which involves the extent to which a group is united in pursuit of its task related and/or social activities.

One model, called the STAR team model, suggests that effective teamwork in the workplace happens when four aspects are considered – **S**trengths, **T**eamwork, **A**lignment and **R**esults: Individuals flourish as they use and develop their **S**trengths. They work together to build relationships which result in effective **T**eamwork. Effective communications between the team members helps **A**lign the strengths of the different individuals so that all unite towards accomplishing meaningful **R**esults.

A basic tenet of deriving team building cohesion is that team members should foster a sense of unity or togetherness. This exerts a catalyzing effect in bolstering individual members' efforts (increased motivation), directing them towards common goals and improving team performance outcomes.

Effectiveness of Team Building Interventions

A metanalysis of team building interventions in sports settings (Martin 2008) showed a measurably improved effect in improving performance and cognition. When taken together, this suggests that team building interventions may, in fact, be more influential via other psychological (individual and group), processes than via the process of simply bringing people closer together and helping them to feel more united. The most effective interventions are those that focus on the setting of common goals, by developing group cohesion.

Team building interventions are effective regardless of whether they are delivered directly to the team by an interventionist or indirectly where the interventionist communicates the information that has been given by a coach or manager to be shared with the team. Further, the interventions are increasingly more effective as the duration of the interventions increase. Those that last less than 2 weeks result in nonsignificant effects, those that last between 2 and 20 weeks result in a medium sized effect and those that lasted longer than 20 weeks, have the largest measurable and reproducible effects.

In the health care setting, 24/7 patient care requires high fluidity and turnover of team members, resulting in short team lifespans and decreased stability of workflow. However, the role required by each team member is stable. In a meta-analysis Hughes et al (2016) evaluated the effectiveness of team training and the conditions which help create successes. Team training was viewed positively by trainees; they found that training enhanced their ability to learn and retain. Trainees were able to successfully implement that knowledge into their patient care roles, resulting in improved patient outcomes. Use of diverse training tools (e.g., videos, lectures, simulation, etc.) helped cement the successes of the training because team members remained interested and open to learning via the different modalities. The best successes occurred when the trainees had common and easily understood goals and had homogeneous backgrounds and workplaces. This helped reduce

differences in clinical competencies and in hierarchy in the clinical settings when caring for patients.

Teamwork is an integral part of successful team building. This is more than simply building group cohesion. Teamwork is a dynamic process involving a collaborative effort by team members to effectively carry out the independent and interdependent behaviors required to maximize a team's likelihood of achieving its purposes. Teamwork is composed of multiple and measurable behaviors. Group cohesion is considered an emergent state that derives from teamwork. When group dynamic interventions focus on developing improved teamwork, teams experience higher levels of group cohesion. Across healthcare settings, interventions designed to enhance teamwork behaviors result in improvements in team effectiveness.

Rousseau et al (2006) identified 2 main components that make teamwork successful:

- management of team maintenance
- conflict management

Management of team maintenance requires behaviors designed to keep a team together. The focus is on the interpersonal dynamics of a team, including providing psychological support (i.e., social support), to team members and conflict management strategies. When highly effective teams pursue their goals, they go through a series of *phases* that include:

- **Preparation:** behaviors conducted prior to team task performance including *mission analysis, goal specification*, and *planning*
- **Execution:** behaviors that occur during task performance including *coordination, cooperation,* and *communication*
- **Evaluation:** reflective behaviors that occur after task performance including *performance monitoring,* and *systems monitoring*
- **Adjustment:** behaviors that occur in response to the evaluation phase including *problem solving*, *backing up* other team members, intra-team *coaching*, and *innovation*.

Conflict management: A growing body of research has sought to examine the effects of different types of conflict management strategies that affect a team's performance. These are:

- Avoiding
- Collaborating
- Competing
- Accommodating
- Compromising

However, the relative efficiency of these different conflict management approaches has not been studied in the health care domain.

Rules for Building a Successful Team:

To succeed, one must focus on having a collaborative approach. Rather than having individuals function and perform individually, they need to be coached towards working together to achieve a common goal. Building a successful team will involve assembling a group of individuals who are skilled in their respective areas of expertise.

Some suggested rules for creating a successfully functioning team are:

- ***Everybody should be focused on the same goals:*** No one person is greater than the team. If one person has and is following their own agenda, that will have a negative impact on performance of the entire team. A skillful leader should recognize and correct this immediately. The leader should set goals and establish benchmarks for each team member to meet and accomplish.
- ***Make success the priority:*** It does not matter which position everyone occupies on the team, the only thing that should matter to everyone is the stated goal and success. When this is the constantly held attitude of the leader and the entire team, succeeding becomes easier. The best way to accomplish this is to set achievable goals for each team member to accomplish on an individual basis, but also ensuring that their individual performance aligns with those of every other team member.
- ***Instill a committed work ethic:*** Even very talented individuals may amount to nothing if they do not consistently work hard and are passionate about the stated goals. Lack of effort will lead to failure and negative results.
- ***Establish the importance of communication:*** The teams that succeed are those that know how to collaborate well and have great communication. Constant communication between members should become a requirement. Every person must understand their role and how they can help other team members accomplish their individual and the collective goals.
- ***Find the best talent:*** Creating a disciplined culture will help define roles and responsibilities as well as identify the right skills and people that fit the culture. Always clearly articulate and communicate the vision and the execution plan

- ***Sell the vision to inspire passion:*** The team leader establishes the vision, sets the goals, and motivates the team to rally around the mission. Everyone should have the same desire to win not only for self but for the entire team. Each team member should understand how their role contributes to the overall performance of the entire team and understand that they are also responsible for the success of the other team members.
- ***Apply a coach's mindset to the leadership approach:*** Teams consist of individuals with unique talents and specialized skills. Each member should feel empowered to function autonomously within their individual responsibility. And everyone must understand what is required of them and must work to produce the expected results. The team leader must help each team member function in the right position. The team leader helps manage their performance so that they can perform to the best of their capabilities.

Because of turnover of team members (by choice or necessity), and because of fluctuations in abilities of team members over time, team building is an *iterative process*. Team members may need further development of their leadership or interpersonal skills. At any given time, the members may function less than optimally and will need mentoring and motivation.

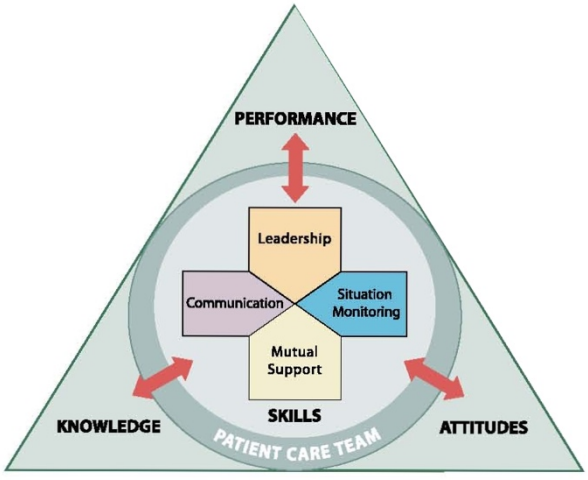

Figure. TeamSTEPPS components.
Source: https://www.ahrq.gov/teamstepps/about-teamstepps/leadershipbriefing.html

TeamSTEPPS

Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) has been designed by the Agency for Healthcare Research and Quality. It is an evidence-based teamwork system derived from more than 20 years of Crew Resource Management by the Department of Defense. The program involves four competency areas: leadership, situation monitoring, mutual support, and communication. It is designed to:

- Expand the team's ability to adapt to changing situations
- Create a shared understanding of team plans
- Develop positive attitudes about being part of the team
- Establish a safe and reliable environment in which to practice.

The components of TeamSTEPPS have proven effective in improving communication and teamwork in many work settings including the health care sector. Parker et al (2019) describe the effectiveness of this tool to reduce clinical errors, improve communication and increase patient satisfaction. They explain that implementation of TeamSTEPPS in a healthcare setting requires a large and ongoing commitment on the parts of all stakeholders including administration, support personnel and the clinicians.

A TeamSTEPPS Implementation Guide is available from the US Agency for Healthcare Research and Quality. The implementation follows a "train-the-trainer" model. Important requirements for success include a strong commitment from institutional leadership, from clinical "champions" and from individual trainers. Trainees are made aware of expectations and to learn by an iterative process of repetition until success is obtained.

A relevant example cited by Parker et al (2019) is of a small OB/Gyn private practice wherein one of the doctors was not receptive to and did not engage in the TeamSTEPPS teaching sessions. This had a detrimental impact on the rest of the team and resulted in adverse outcomes and inability for the program to succeed. Thus, poor participation by any one member of the team can result in overall failure. After corrections were made towards getting improved engagement and buy in from the one person who was initially uninvolved and uncooperative, a marked improvement was noted. This was because all the team members were able to then work cohesively, resulting in improved work efficiency, morale, and clinical outcomes.

Leading the Team you Inherit:

If a leader is put in charge of an already existing team, a 3-step approach is suggested (9).

- **Assess:** size up the personnel, systematically gather data from one-on-one chats and team meetings.

- **Reflect** on the challenges faced, the desired people appropriate for the role, and the degree to which they need to collaborate.
- **Reshape:** adjust the makeup of the team by moving team members to new positions, shifting responsibilities, or replacing them.

Ensure that everyone is aligned on goals and how to achieve them. Changing the goal or direction of the team may become necessary. How the team operates can also be adjusted (eg frequency of meetings, creating subteams). Finally, establish clearly stated ground rules and processes to sustain desired behaviors.

Building a Project-Specific Team

Virtually every quality improvement (QI) project requires a team of people to gather baseline data, evaluate existing quality gaps, plan and implement a strategy to close the gaps, and monitor and maintain the improvements made. The success of a project depends critically upon the effectiveness of the project team.

The project team should include at least one representative from every key stakeholder group who will be impacted by the project. Obstetric (OB) QI projects will almost always involve OB physicians and OB nurses. A patient advocate is recommended to give the patient perspective on problems identified and proposed solutions. For hospital-based projects, support from the hospital administration is essential because they will need to approve expenditures for personnel time, supplies, and equipment. The information technology department may be needed if the project will involve changes in electronic health records or order sets. For many OB projects, individuals from other departments may also be needed, including anesthesia, laboratory, blood bank, pharmacy, and emergency department. A community member should be sought to provide a perspective on the community impact and health equity.

The size of team depends on the nature and scope of the project. Large teams allow input from many individuals, which can be useful during "brainstorming" sessions, but they can be unwieldy and difficult to manage. Small teams can be nimbler and quicker to act, but they may not think of all the possible perspectives that a larger team might have.

The team leader should be someone who has knowledge and experience in the subject at hand, who has the respect of all the team members, and who can delegate assignments to individuals and hold them accountable to complete those assignments in a timely manner. The leader can be a physician, a nurse, an administrator, or another staff member. It is more important for the leader to have the requisite leadership skills than to have a title or degree after their name.

Most projects will need a clinical "champion" among the physicians and a "champion" among the nurses. Champions are team members who have passion for the project and who can communicate the rationale for the project and advocate for the project among their peers. Improvement, by definition, involves change. Many health care providers are reluctant or resistant to changing long-established patterns of practice. The clinical champion can often persuade those providers to accept change or even to embrace it.

Additional Reading

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Communication Tools

Communication breakdown is one of the major causes of adverse outcomes in clinical situations. Poor communication is responsible for over 60% of sentinel events reported to The Joint Commission. The underlying reasons for communication errors include:

- many team members are involved with the care of a given patient and they frequently use a variety of communication methods and tools
- members of the healthcare team change frequently due to shift and schedule changes
- team members may be from different specialties or backgrounds
- professional hierarchies within the system can inhibit communication

Using structured communication tools is one way to minimize communication errors. If both the speaker and the listener are familiar with the tools, then they will have a *shared mental model* about the format of the communication. Two commonly used tools are SBAR and CUS mnemonics.

The SBAR Mnemonic

SBAR is an acronym for Situation, Background, Assessment, Recommendation. It is a concrete, easy-to-remember technique that helps to facilitate prompt, clear communication during an emergency. An example of an SBAR communication is given in Table 1.

SBAR was developed by the United States military to improve communications between team members during urgent, complex situations and was later adapted for use in healthcare.

The Joint Commission, the Agency for Healthcare Research and Quality, and the Institute for Healthcare Improvement now recommend use of the SBAR tool in a wide variety of settings. Its use is included in TeamSTEPPS training.

Training of healthcare teams in the use of SBAR can use a variety of techniques, including classroom instruction, role play, videos, and simulations. No single training methods has been shown to be superior to any other. Likely a combination of these methods will enhance learning.

Use of SBAR for communications from nurses to physicians to report abnormal fetal heart rate tracings was studied by Ting et al (2017). They found improved nursing outcomes (teamwork, job satisfaction) and also neonatal outcomes (5-minute Apgar scores). Thus, they recommended SBAR as a feasible tool for nurse-physician communication in the unique, high stakes environment of obstetrics where communications between team members often involve two patients simultaneously (maternal and fetal patient).

The CUS Mnemonic

CUS is an acronym for Concerned, Uncomfortable, Safety issue. Whereas SBAR can be used routinely for most types of patient communication, CUS is more appropriate for situations that require an acceleration of attention, especially ones where recommendations in a prior SBAR are not being followed. An example of a CUS communication is given in Table 2.

CUS is included in TeamSTEPPS training. It may be useful for the speaker to get the listener's attention by starting the CUS with "I have a few CUS words for you." But this should only be done if the speaker is sure that the listener has had training in the meaning of CUS words.

Additional Reading

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Table 1 – SBAR Communication

Situation. Concise statement of the problem	Speaker identifies self and patient	"Doctor, this is Mary on L&D. I'm calling about Mrs W in triage, complaining of severe headache"
Background information, brief and pertinent information only	Describe medical status, pertinent history, prior diagnoses	"She's a 24-year-old nullipara, 37 weeks pregnant. She's on a business trip from out-of-town, and we don't have her prenatal records. Initial BP is 166/105"
Assessment	Analysis of the problem	"So, she has severe hypertension, maybe severe preeclampsia"
Recommendations	Speaker makes clear, specific requests for action and recommendations for subsequent care.	"I want you to come see her right away. Meanwhile, I am going to start an IV and plan to repeat the BP in 10 minutes. If it is still in the severe range, I will be starting the protocol for antihypertensive medications and start magnesium sulfate. Can I get a verbal order for that now?"

Table 2 – CUS Communication

I am **C**oncerned	Brief statement of problem	"Doctor, Mary on L&D, calling again about Mrs W with the severe hypertension. I'm CONCERNED her BP is still in the severe range despite 80 mg of labetalol and you haven't seen her yet"
I am **U**ncomfortable	Explain why the situation could have an adverse outcome	"I'm very UNCOMFORTABLE about this because we had a patient last month who had a stroke from severe hypertension."
This is a **S**afety Issue	Explicit statement that patient safety is threatened	"This is a SAFETY issue. If her BP doesn't come down right away, I'm going to need to go up the chain of command to get some additional help."

Handoffs

Patient handoffs occur routinely in healthcare. Every change of shift involves a handoff from one provider to another. Handoffs also occur when a patient is transferred from one unit to another or transferred to the operating room or a diagnostic facility such as radiology. Every handoff presents the potential for patient harm due to inaccurate or insufficient information being communicated between providers or care teams.

To ensure patient safety at each transfer of care, the right information must be communicated and accepted by the right people, at the right time, every time. Use of a structured tool for handoff is the best method to ensure a safe handoff. One of the most widely tools is the I-PASS mnemonic.

I-PASS

I-PASS is an evidence-based tool for standardizing the handoff process. The mnemonic I-PASS represents the essential components of a successful, high-quality handoff. (Table). It was initially developed more than a decade ago by Starmer et al (2012). After its implementation in a pediatric residency program, medical error rates decreased by 23% and preventable adverse events by 30%. (Starmer 2013).

In this model, irrelevant, repetitive and wordy information is eliminated. Its usefulness is most evident when it is accompanied by a structured electronic handoff tool. At the very least, the handoff should be done verbally and accompanied by a written list.

Blazin et al (2020) described results after implementation of I-PASS for inpatients across multiple platforms. These were nursing handoffs at the patient's bedside, handoffs amongst doctors, and imaging/procedures handoff. There was overall improvement in the accuracy of and adherence to all 5 of the I-PASS elements. This not only resulted in fewer patient harm events but also in improved nursing and doctor job satisfaction.

Factors that are essential to and closely linked with successful I-PASS implementation are institutional support including both top down and end user commitment, hand-written or electronic tools that incorporate the format and direct observations with formative feedback.

I-PASS differs from SBAR in that it provides a specific summary of patient status with pertinent data and encourages the receiver to ask clarifying questions during the handoff.

Regardless of whether you use I-PASS or some other structured communication tool, remember several key points:

- Transfers of care/handoffs improve with standardized, concise, accurate, and clear communications
- Handoffs are optimized when the communication is uninterrupted, in a dedicated space and at a dedicated time
- Properly executed handoffs are interactive and include opportunity for questions and answers.
- A successful handoff/transfer of care should result in a clear understanding by all stakeholders about which individuals are responsible for which aspect of the patient's care.
- Handoff communication skills require training and practice.
- Direct observation with formative feedback greatly enhances the accuracy of handoffs, thus decreasing patient harms.
- An email may constitute an appropriate form of handoff if it is acknowledged. A voicemail or text is not considered an appropriate acceptable handoff unless it is acknowledged, so that the *loop is closed*.
- Ineffectively organized information by the sender and inattention by the receiver are examples of barriers to effective handoffs.

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Table: Example I-PASS handoff

Item	Explanation	Example
Illness severity	Classify each patient as either • Stable • Unstable • "Watcher":	"Ms AJ is a "watcher" and will need some attention tonight"
Patient summary	Brief pertinent clinical summary	"She's a G2P1 who had cesarean at 9 am today for severe preeclampsia with HELLP syndrome. She developed dyspnea and rales this afternoon, O2 saturation dropped to 88%. We diagnosed pulmonary edema and chest x-ray corroborated. She got 20 mg of furosemide at 4 pm and diuresed 300 cc in the last hour. D-dimers were ordered as a step in evaluating possible pulmonary embolism"
Action items	A short to-do list of action items	"Check on her as soon as we've finished our sign-out and make sure she's improving"
Situational awareness	Things to be aware of, contingencies to plan for	"If O2 saturation hasn't improved, give another 40 mg of furosemide. Be sure to follow potassium. Check on the D-dimers and have a low threshold to order spiral CT to rule out PE. "
Synthesis by receiver	Listener summarizes enough key points to indicate that they understand the situation	"OK, as soon as we're done with the handoff, I will see her and check on the D-dimers. Sounds like pulmonary edema is the most likely diagnosis, but PE is on the differential, so I'll order a CT if she isn't improving."

Drills and Simulation

Simulation can be used in several ways to improve education, training, and maintenance of competency. These improvements should ultimately improve the quality and safety of the care we provide. Simulation can be used to teach and practice technical skills, to reinforce knowledge for complex patient management, to support team building and team training, and to identify systems issues.

Historical Perspective

The use of manikins to teach the technical skills of childbirth has been documented in the midwifery literature since the 16th century and was promoted for teaching medical students and obstetrical residence since the early 20th century.

An expanded role for simulation in health care took root in the 1980s when leaders in anesthesiology and critical care medicine adapted princi ples of Crew Resource Management (CRM) from US Air Force pilot training programs. CRM has a focus on communication, leadership, and decision-making of flight crews. CRM has been adopted by other high-risk industries such as nuclear power, commercial aviation, and air traffic control, industries that share similarities with health care including complexity, intense stress, time sensitivity, multiple players, and a requirement that teams function consistently at high levels where human error could be devastating.

CRM is an integral component of TeamSTEPPS, a program developed by the US Department of Defense's patient-safety program, in collaboration with the Agency for Healthcare Research and Quality (AHRQ). TeamSTEPPS is discussed in more detail in the chapter on Team Building.

Simulation in health care started with rehearsing "codes" and anesthesia emergencies on manikins and has grown to include all aspects of health care. Just as pilots and their teams train to handle emergencies in the air, health care providers train to handle both common and uncommon situations to improve patient safety. Simulation to prepare for obstetric emergencies has become a part of obstetric safety programs nationwide.

The American College of Obstetricians and Gynecologists (ACOG) has a simulation working group with a mission "to establish simulation as a pillar in education for women's health through collaboration, advocacy, research, and the development and implementation of multidisciplinary simulations-based educational resources and opportunities for obstetrics and gynecology." This group can serve as a resource for individuals and institutions working to develop or augment their existing curricula.

ACOG Committee Opinion 590 on *Preparing for Obstetric Emergencies* (reaffirmed 2018) points out that:

- "By conducting a drill in the actual patient care setting, issues related to the physical environment may become obvious. Simulation training can identify and correct common clinical errors made during the emergencies."
- "Emergency drills allow team members to practice effective communication in a crisis…Many aspects of the medical environment may compromise effective communication, including a hierarchical hospital structure, emotional intensity and stress of a situation, and range of educational backgrounds and clinical understanding of various team members… By practicing together, barriers that hinder communication and teamwork can be overcome." and
- "Effective drills may lead to improved standardization of response, health care provider satisfaction, and patient outcomes."

Required Simulations

The Joint Commision (TJC) has published Standards for Perinatal Safety that require TJC-accredited facilities to conduct drills at least annually to identify systems issues in the management of obstetric hemorrhage and severe hypertension. These drills require representation from every discipline involved in the facility's protocol for management of the designated emergency. For example, a hemorrhage drill requires participation by nursing, obstetrics, anesthesiology, laboratory, and blood bank.

The Accreditation Council on Graduate Medical Education (ACGME) guidebook *Program Requirements for Graduate Medical Education in Maternal-Fetal Medicine* suggests that MFM fellows participate in simulations, but does not specify a precise number or type of simulation:

- "Fellows must participate as team members in real and/or simulated interprofessional clinical patient safety activities, such as root cause analyses or other activities that include analysis, as well as formulation and implementation of actions."

The Program Requirements also suggest a role for simulation in disclosure of adverse events:

- "All fellows must receive training in how to disclose adverse events to patients and families. Fellows should hae the opportunity to participate in the disclosure of patient safety events, real or simulated."

Management of Obstetric Emergencies

Many obstetric emergencies lend themselves to simulation, both for practicing the key management steps in the care protocol and for reinforcing team interaction skills. Table 1 lists several scenarios for which simulation curricula have been developed. In a 2018 review, Satin summarized the evidence that scenario-based simulation actually improves clinical outcomes for a variety of emergencies, including postpartum hemorrhage, shoulder dystocia, forceps delivery, emergency cesarean, and neonatal resuscitation. For other emergencies, evidence for improved clinical outcomes is equivocal, but still, multidisciplinary simulation-based team training has benefits in terms of improved team functioning and provider satisfaction.

Table 1. Common Curricula for Simulation of Obstetrical Emergencies

Severe hypertension
Postpartum hemorrhage
Eclampsia
Maternal cardiac arrest
Amniotic fluid embolism
Placenta accreta spectrum
Operative vaginal delivery
Shoulder dystocia
Neonatal resuscitation
Twin delivery

Curriculum guides and practice scenarios are readily available for some of these emergencies. *Practicing for Patients* is a set of curricula for severe obstetric hypertension and obstetric hemorrhage developed by the Council for Patient Safety in Women's Healthcare and is available open-access online.

There is a tendency to believe that simulation requires an expensive, realistic ("high fidelity") manikin and a dedicated simulation center with special equipment and staff. However, "low fidelity" *in situ* simulation with volunteer actors within labor and delivery of the local facility can be just as effective at uncovering teamwork issues and is likely more effective at finding facility-specific equipment problems, process problems and other systems-based issues.

Teaching Technical Skills

While multidisciplinary simulation-based team training is typically thought of as the primary role for simulation in obstetric patient safety, there are increasingly simulation opportunities for technical skills as well. Enhanced technical skill certainly plays a role in providing safe, high quality obstetric and MFM care. Table 2 lists many examples of technical procedures for which simulators and task trainers have been developed.

Table 2. Procedures and technical skills that can be learned or practiced with use of simulators or task trainers

Basic obstetrical skills
Fundal height
Estimation of fetal weight
Leopold maneuvers
Spontaneous delivery
Surgical skills
Knot-tying
Repair of episiotomy
Repair of obstetric anal sphincter injury
B-Lynch suture
Uterine artery ligation (O'Leary suture)
Hypogastric artery ligation
Ex utero intrapartum treatment (EXIT) procedures
Ultrasound and ultrasound-guided procedures
Basic 2-D obstetric ultrasound
3-D obstetric ultrasound
Amniocentesis
Chorionic villus sampling
Intrauterine transfusion

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High Reliability Organizations

Reliability is the likelihood that processes or individuals within an organization will operate correctly every time. Reliability can be defined as 100% (perfect performance) minus the error rate. High reliability can be measured by outcomes, error rates and near perfect results, creating the highest likelihood of safety.

High Reliability Organizations (HROs) are organizations that operate in complex high hazard domains, for extended periods, without serious accidents or catastrophic failures. Some oft-cited examples are the nuclear power industry, the commercial aviation industry in the USA, and the banking industry.

Health care, as it is currently performed, is usually not an HRO, though it strives to become one. The HRO concept is an ideal goal for health care due to the complexity of operations and the risks of significant and potentially catastrophic consequences when failures occur.

Sometimes, high reliability is thought to mean effective standardization of health care processes. However, the principles of high reliability go far beyond simply creating standardizations.

High reliability reflects a condition of persistent mindfulness within an organization where the work environment is hypercomplex with tight interdependence across units and levels. In addition to the hierarchical differentiation and complex communication networks, there is built in redundancy across all systems. A high degree of accountability with frequent and immediate feedback about decisions exists. HROs cultivate reliance by relentlessly prioritizing safety over all other performance measures.

This concept can be described in the example of a military aircraft carrier. Here, despite significant frequent high-risk activities such as fighter jets taking off and landing on the flight deck every 45-60 seconds under constantly changing conditions and frequent changes in the hierarchal organizational structure, personnel consistently prioritize safety. They have both the authority and the responsibility to make real time operational adjustments to maintain safe operations as the highest priority.

Another example where a high reliability concept is essential is in the aviation industry. In this setting, even a small error can lead to catastrophic consequences such as loss of life, property and reputation. Unexpected events can result in disorganization within the workplace. Thus, a combination of anticipation and resilience, called mindful organizing, is needed to avoid such unexpected disruptions. The goal is to manage and sustain an almost error free performance despite operating in hazardous conditions, where the consequences of errors can be devastating, while also ensuring a positive safety culture.

Characteristics of HROs:

HROs use a model of systems thinking to evaluate and design for safety while acknowledging that safety is an evolving rather than a static entity. New threats to safety continuously arise, and result in unique and different adverse outcomes versus similar or identical ones. Thus, successful HROs create a culture where potential problems are expected and anticipated, and are rapidly addressed when they occur, so that catastrophic outcomes can be avoided.

Table 1 summarizes the 5 characteristics of successful HROs: preoccupation with failure, reluctance to simplify, situational awareness, deference to expertise and commitment to resilience. HROs hardwire these traits into the organization's culture. Strategies to develop and sustain these traits are shown in Table 2. The characteristics of HROs are all applied simultaneously, across all work platforms, to avoid serious catastrophes.

Example: A 32 year old primigravida is receiving prenatal care in a high risk clinic because of a 4 year history of asthma. She is using albuterol inhaler on an as-needed basis. At 32 weeks of gestation, she is found to have a blood pressure of 166/98 mmHg. A repeat blood pressure 15 minutes later is 200/100. She is admitted for mangement of hypertension. The MFM Fellow orders 20 mg IV Labetolol. The nurse calls the Fellow to question the medication in light of the patient's asthma diagnosis. The Fellow appreciates the intervention, cancels the IV Labetolol, and orders Nifedipine 10 mg orally instead..

Under the principles of HRO (deference to expertise), the nurse is empowered to question the management plan, without fear of reprisal. When lives are on the line, expertise is far more important than an organizational chart. In an HRO, the one who knows the most about a given subject is trusted (and expected) to make the right decsions. If layers of intimidation exist, errors are likely to occur because individuals may be afraid to speak up or ask questions. This will create an unsafe environment and patients' lives will be endangered, thus jeopardizing the ability to achieve the goal of zero harm.

Table 1: Five Characteristics of HROs

Characteristic	Description	Specific Actions
Preoccupation with failure	All Team members actively focus on what can go wrong and remain vigilant for any signs of potential problems. The absence of errors or accidents results in a heightened sense of alertness for a potential failure versus having a sense of complacency	• Increase transparency with communication and data sharing so that Team members are well informed, thus making them more attentive. • Make rounds to increase visibility and drive outcomes. This results in open, purposeful communication and helps unveil which processes are working versus those that are burdensome and are harmful to patient care. • Don't make assumptions. Leaders should ask questions to find out which processes work, and which ones are harmful to patients. Team members should not assume that their concerns have already been communicated and noted.
Reluctance to simplify	While HROs strive to standardize work (to reduce variation), they acknowledge that teams, processes and relationships in the daily operations are evolving. They resist explaining away and simplifying their understanding of how and why something succeeds or fails. Rather, they conduct root cause analyses and reject simple diagnoses	• Be willing to challenge long held beliefs. • Review data, benchmarks and performance. • Use metrics to probe into why problems are occurring versus simply accepting commonly held beliefs (eg long wait times in Triage)
Situational awareness	Also called "big picture awareness". It requires that team members be aware of whatever is going on around them and understand the relationships between their work and that of the Unit and Organization. This will help them understand how the current state might support or threaten safety	• Identify what is working correctly. • Destigmatize failure. • Find examples within the organization where a process is working well and use that to correct where it is not.
Deference to Expertise	Team members closest to the work are recognized as being the most knowledgeable about that work. Thus, during an emergency, the one with the greatest knowledge may not necessarily be the one with the highest position or greatest power. De-emphasis on hierarchy and a sense of inquiry to learn as much as possible about potential safety threats is valuable. All Team members are empowered with the necessary tools and language to voice concerns without fear of retribution. Leaders welcome input and all feedback is transparently communicated. They walk around, are visible and interact with Team members, a process called "Gemba Walks"	• Meet Team members at their workplaces • Defer to knowledge of Team members about their own areas. • Seek descriptions about prior experiences. Team members can share information about their work in prior organizations. New Team members can look at situations with a fresh pair of eyes. • Seek ideas to help improve workflows, operations, and processes.
Commitment to resilience	Team members assume and expect that the system is at risk for failure. Therefore, they	• Set specific and measurable goals, using score cards and 90-day action plans.

	practice performing rapid assessments of and responses to challenges to safety. They maintain cross monitoring of situations to promptly identify potential safety threats so that they may be avoided/mitigated. Team members prepare in advance for emergencies and have clear and concise communication.	• Relentlessly stay the course in responding to failures and finding new solutions. • Routinely and consistently promote skills development, using self-assessment score cards and action plans. • Clearly communicate "the why behind the ask." This helps to focus on the purpose by tying the results to the purpose and the sense that the work is worthwhile.

Table 2: Strategies to develop and sustain HRO traits

Sensitivity to operations	*Increase transparency* with communication and data sharing so that team members are well informed, thus making them more attentive. *Make rounds* to increase visibility and drive outcomes. This results in open, purposeful communication and helps unveil which processes are working versus those that are burdensome and are harmful to patient care. *Don't make assumptions*: Leaders should ask questions to find out which processes work, and which ones are harmful to patients. Team members should not assume that their concerns have already been communicated and noted.
Reluctance to Simplify	*Be willing to challenge long held beliefs*: Review data, benchmarks, and performance metrics to probe into why problems are occurring versus simply accepting commonly held beliefs, e.g., long wait times in Triage
Preoccupation with failure	*Identify what is working correctly*: Destigmatize failure. Find examples within the organization where a process is working well and use that to correct where it is not
Deference to expertise	*Meet team members at their workplaces* and defer to their knowledge of their own areas. Seek descriptions about prior experiences: Team members can share information about their work in prior Organizations. New Team members can look at situations with a fresh pair of eyes. Seek ideas to help improve work flows, operations and processes.
Commitment to Resilience	*Set specific and measurable goals*, using score cards and 90-day action plans. Relentlessly stay the course in responding to failures and finding new solutions. *Routinely and consistently promote skills development*, using self-assessment score cards and action plans. *Clearly communicate the why* behind the task. This helps to focus on the purpose by tying the results to the purpose and the sense that the work is worthwhile.

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Actionable Patient Safety Solutions. 2019 Patient Safety Movement

Checklists

If you've ever used a shopping list, you have an intuitive understanding of one of the main goals of patient safety checklists: to make sure that you don't forget anything important. We use shopping lists and checklists because we acknowledge that we are not perfect. When we try to rely on memory alone, we may forget key items. The resultant errors of omission may have adverse consequences for your dinner party (in the case of a shopping list) or for your patient (in the case of a patient safety checklist).

Just like a shopping list, patient safety checklists are especially useful in certain situations:

- When there are a lot of items to remember
- When there are certain critical items that must not be omitted
- When the task has steps that must be completed in a specified order
- When the task has new steps that are unfamiliar to those who must perform them.
- When the task must be performed efficiently amid a busy scenario full of distractions, chaos, panic, fear, or another emotional overlay

Brief History of Checklists in Health Care

One of the earliest widely used checklists in health care was the mandatory 3-item pre-procedure Time-Out introduced by The Joint Commission (TJC) in 2004 as part of its Universal Protocol. Immediately prior to the start of every surgery or invasive procedure, the team was expected to confirm that they had: (1) the correct patient, (2) the correct planned procedure, and (3) the correct surgical site and side. This simple checklist was introduced because of an alarming rate of so-called "never events." These are events that should never occur, including wrong-patient, wrong-procedure, wrong-site, and wrong-side surgeries. "Never events" occurred at US hospitals over 4,000 times per year. In other words, they were every-day events, occurring over 10 times per day on average.

In another early use, a simple checklist was included in an intervention bundle for insertion of central venous catheters. The bundle was shown to reduce the rate of central-line-related bloodstream infections (CLABSI) from 7.7 to 1.4 per 1000 catheter days, an 82% reduction (Pronevost 2006). The checklist had only 4 pre-procedure items: handwashing prior to procedure, skin prep with chlorhexidine, use of full barrier precautions (glove, gown, mask, drapes), and avoidance of femoral site if possible. A 5th item was daily assessment of whether the line could be removed. These items were all well-known before the introduction of the checklist, but providers often skipped one or more items. The checklist merely reminded them to follow all the elements of best practice.

The World Health Organization (WHO) Safe Surgery Checklist was introduced in 2009. It included the 3 elements of TJC's Time Out, plus 19 additional items requiring confirmation by anesthetist, surgeon, and nurse, such as verification of equipment readiness, consideration of antibiotic prophylaxis, and assessment of risks of hemorrhage, airway problems, and aspiration. A prospective study conducted in 4 high-resource countries and 4 low-resource countries found that use of this checklist was associated with a 36% reduction in postoperative complications and a 47% reduction in perioperative mortality (Haynes 2009). A subsequent study at 6 hospitals in the Netherlands reported nearly identical findings, a 39% reduction in postoperative complications and a 47% reduction in mortality (DeVries 2010).

Initial enthusiasm for the WHO Safe Surgery Checklist was dealt a serious blow, however, by a 2014 report from Ontario, Canada, evaluating the effect of a Ministry of Health province-wide mandate for hospitals to report adherence to surgical safety checklists (Urbach 2014). The study evaluated all 101 hospitals performing surgery in Ontario, many of which rapidly introduced a surgical checklist in the months immediately preceding the mandate. After introduction of the checklist, there was no significant change in the rates of complications, mortality, or readmission.

Why Checklists Can Fail

Why did the early studies (Haynes, DeVries) show benefit from the WHO Safe Surgery Checklist but the Ontario study (Urbach) did not? One factor may be that the two early studies had several months of team training prior to implementation at each hospital and the hospitals were all engaged and focused on the project. In contrast, no systematic effort at training was involved in the province-wide, government-mandated use of checklists in the Ontario study (Urbach).

Another factor is that most checklists need to be modified or adapted to fit unique circumstances at individual hospitals. Several factors can affect the particulars of a surgical checklist:

- Does the hospital have trainees (medical students, residents, fellows, nursing students)? What will their role be in performing the checklist?
- Is anesthesia given by nurse anesthetist or anesthesiologist?

- Is the blood bank located on-site or does blood come from a central blood bank?
- What ancillary services are available 24/7 in the hospital (lab, pharmacy, radiology, additional surgical specialties if needed)?

The WHO Safe Surgery Checklist clearly states, "This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged." Nonetheless, fewer than 10% of the hospitals in the Ontario study reported customizing the checklist.

Another factor, noted by the authors of the Ontario study, is that performance is likely to be better at hospitals that voluntarily introduce such protocols than in those that are mandated to comply. In an editorial accompanying the paper, Leape (2014) noted that it is not the checking of the boxes on a checklist that reduces complications but performance of the indicated actions. Reported adherence to the checklist was over 90% in the Ontario study. But as noted by Leape, "Gaming is universal." Making checklist completion mandatory encourages people to check the boxes but does not guarantee that the actions are actually performed.

Implementing Checklists

The Ontario experience teaches us that it is not sufficient to simply give a checklist to a hospital, a surgical unit, an obstetrical unit, or an individual provider and say, "Here, use this." It is not sufficient to hang a checklist on the wall or add it to a protocol binder. It is not even sufficient to make it mandatory to use the checklist and to document compliance. As noted by Leape, "Full implementation takes time: time for the team to get it right and time for all units in an institution to get on board."

Successful implementation requires several steps, as outlined in an SMFM Special Report, *The development and implementation of checklists in obstetrics* (SMFM 2017):

- Identify team members who are thought leaders and clinical champions who will guide the implementation process.
- Pilot the use of the checklist with the people who will actually use it. Run pilot tests using a range of different scenarios and environments to assure that the checklist is applicable to a variety of situations.
- Train all potential users in how to use the checklist. Recognize that use of checklists is not yet engrained into the culture of medicine, so many personnel are not familiar or comfortable with their use.
- Keep the checklist in a place where it will be readily accessible during the relevant process. For example, a large poster-sized surgical safety checklist might ideally be posted on the wall of each operating room. A checklist for management of cardiac arrest might best be kept in a side-pocket of the "crash cart". A checklist for amniocentesis might be kept with the amniocentesis trays in the supply cupboard. A "badge buddy" can be used to keep a checklist for hypertensive emergencies handy.
- Pay attention to user feedback, criticisms, recommendations. Remain open to suggestions. Revise the checklist as needed to address user concerns. Users will be much more engaged and supportive if they know that their input is valued. Several iterative revisions may be needed. It is critical to include a version date on every checklist to ensure clarity about which version is the most recent.
- Pay attention to the time it takes to complete the checklist. If the checklist is too long in proportion to the actual task, users will be dissuaded. Ensure that every item in the checklist is essential and that redundancy is avoided.

Example Checklists

SMFM has presented a variety of patient safety checklists covering inpatient and outpatient procedures and circumstances. These include:

- Morbidly adherent placenta (accreta spectrum), preoperative planning
- Morbidly adherent placenta (accreta spectrum), unexpected
- Amniocentesis and chorionic villus sampling
- Diabetes antepartum management
- Care of persons living with HIV
- Monochorionic twin pregnancy management
- Cesarean delivery
- Operative vaginal delivery
- Preeclampsia risk factor screening to guide low-dose aspirin prophylaxis
- Thromboembolism prophylaxis after cesarean delivery
- Maternal transport
- Postpartum discharge in women with hypertensive disorders

Most of these are accompanied by specific suggestions as to how individual facilities might want to customize them to fit their own local circumstances and suggestions regarding implementation processes.

How to Perform a Checklist

Checklists are best performed aloud, with one person reading the items and other team members giving responses to confirm that each item has been completed. This helps to ensure engagement of various team members in the process and facilitates "closed-loop" communication. Checklist performance should be a

dialog between team members. If the patient is awake, she can be engaged as well.

There are some common pitfalls:

- When the list has only a few items and the team has performed the list dozens or hundreds of times, there is a temptation to skip the reading of the items and to perform them from memory. Such a shortcut is fraught. Remember, the rationale for having a checklist is to ensure that no step is skipped because our memories are fallible.
- There is a temptation to include the completed checklist in the permanent medical record, either as a paper form or an electronic document. The decision to do this should be considered carefully. The requirement to complete a chart form means that one team member will be busy with the paperwork rather than actively participating in the dialog and performance. It is more important that the team actually check that each item is completed than for them to mark a checkbox on a chart form.
- Team members will often forget that a checklist even exists to cover a particular situation. It requires considerable training, practice, and reinforcement to make the routine use of a checklist become second nature. Faced with a postpartum hemorrhage, for example, we no longer want the first step to be "Increase the fluids and give methergine" but rather, "Let's get out the obstetric hemorrhage checklist."

Developing Your Own Checklist

You may be working on a quality or safety improvement project that seems ideal for a checklist. If you cannot find an existing checklist that covers the topic, you can develop your own. Several steps are outlined in the SMFM Special Report (2017):

- The checklist should have clearly defined goals and should help to close an existing gap in patient safety or quality of care.
- Use a team approach, involving people who understand the detailed operational minutiae of the topic (often nurses or technical staff) and people who have an overarching view of the evidence supporting particular interventions (often physicians and managers).
- Build the checklist with discrete, actionable steps that are both essential to the process and are in danger of being overlooked.
- Each step should specify who is responsible to perform it.
- Each step should be able to be read aloud so that all members of the care team can participate.
- Follow a standard template for visual design. Specific suggestions are given in *A Checklist for Checklists* (Figure). To improve readability, the checklist should fit onto one page; color should be minimized; font should be sans-serif and large enough to be easily read; upper- and lower-case lettering should be used; and text should be dark on a light background.

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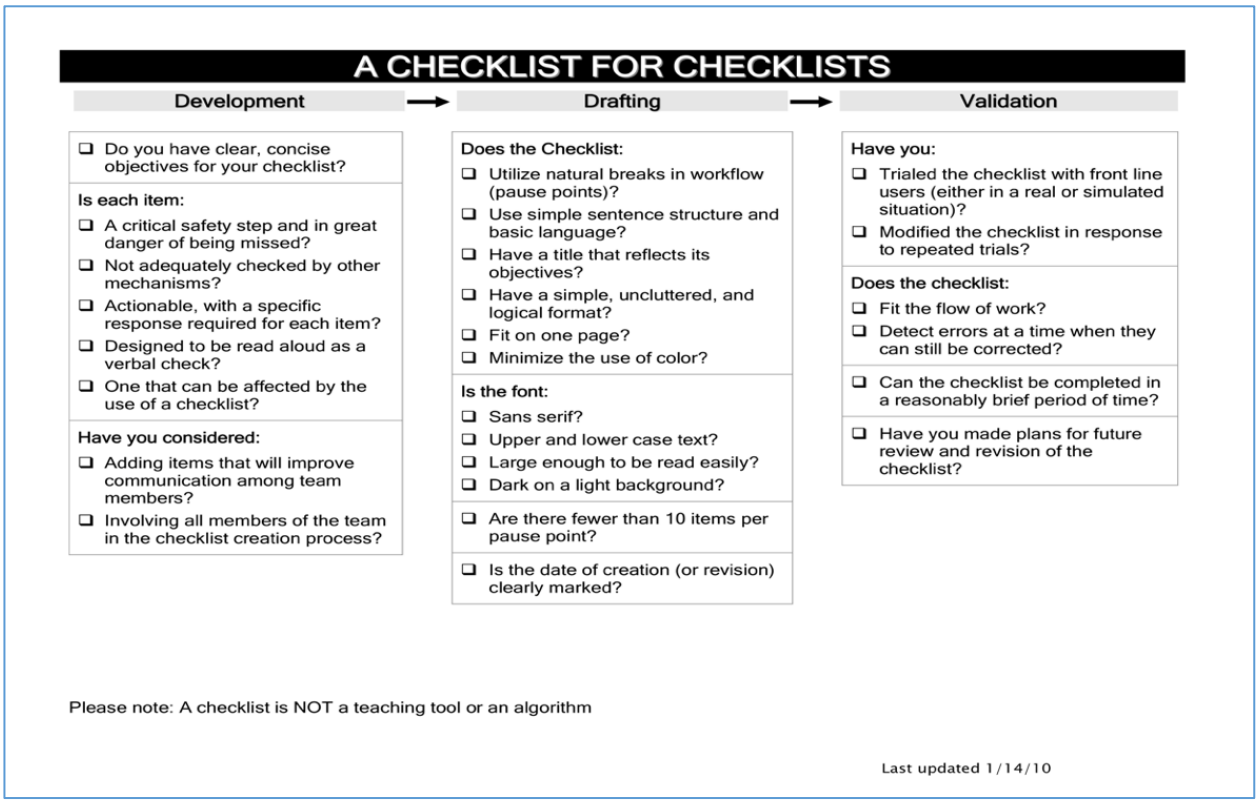

Figure. A Checklist for designing checklists
(Modified from ACOG Committee Opinion 680, 2016)

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