

FLEX CEUs



Medical Errors Prevention



INTRODUCTION

“Johns Hopkins patient safety experts have calculated that more than 250,000 deaths per year are due to medical error in the U.S. [This] surpasses the U.S. Centers for Disease Control and Prevention’s (CDC’s) third leading cause of death — respiratory disease, which kills close to 150,000 people per year” (Johns Hopkins, 2016).

“Medical error is defined as errors or mistakes committed by health professionals which result in harm to the patient. They include errors in diagnosis (diagnostic errors), errors in the administration of drugs and other medications (medication errors), errors in the performance of surgical procedures, in the use of other types of therapy, in the use of equipment, and in the interpretation of laboratory findings. It is also defined as the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). In a broader sense, patients value clear communication and responsiveness and if one lacks those, patients may perceive this as a medical error. Generally, medical errors are considered to be as failed processes which may not essentially result in harm to a patient. Sometimes these medical errors may lead to an adverse event and at other times a near-miss” (Ghaza, 2014).

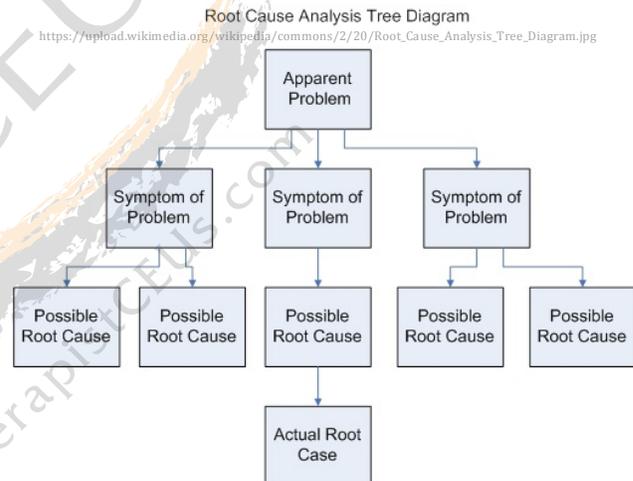
“Researchers caution that most of medical errors aren’t due to inherently bad [health care providers], and that reporting these errors shouldn’t be addressed by punishment or legal action. Rather, they say, most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols, in addition to unwarranted variation in physician practice patterns that lack accountability” (Johns Hopkins, 2016).

“Despite changes in the health care system with new regulatory mandates and reimbursement issues, one constant concern is to ensure exceptional patient safety and care. Patient care must be delivered safely by utilizing safety guidelines based on scientific evidence. Constant revision of processes and guidelines are in order to optimize patient experience and safety. To do so, patient safety systems should focus on building a culture of safety that encourages communication, trust, and honesty. In this process it is pivotal to recognize that humans make errors. Failures occur by choosing the inappropriate method of care or by poor execution of an appropriate method of care. Fortunately, errors can be minimized with proper training, effective communication, and a system of checks and balances. Continual education regarding patient safety not only helps health care professionals by inhibiting errors, but also extends to patient well-being. Concise communication with patients instills trust and strengthens patient-provider relationships. Establishing a medical system of checks and balances ensures that errors are more likely to be caught before they happen and that blame does not rest upon an individual” (Kim, 2015).

“Ensuring appropriate, efficient, effective, and quality care is now a regulated branch of medical practice. Organizations like the National Surgical Quality Improvement Program measure the quality of surgical care and encourage hospitals to implement formal quality improvement projects. Furthermore, Medicare has stopped providing reimbursement for complications deemed as ‘preventable.’ As such, both hospitals and payors have new incentives to reduce surgical complication rates” (Charles, 2016). “Many hospitals and integrated health systems nationally now have an electronic event reporting system (ERS) to identify and analyze [adverse events (AEs)], so that appropriate quality assurance measures can be undertaken” (Zeeshan, 2014).

ROOT CAUSE ANALYSIS

Root cause analysis (RCA) “is a systematic approach aimed at discovering the causes of close calls and adverse events for the purpose of identifying preventative measures. RCA teams look beyond human error to identify system issues that contributed to or resulted in the close call or adverse event. The goal is to answer what happened, why did it happen, and what can be done to prevent it from happening again? The process includes document reviews and interviews with the parties involved in the event. Flow diagramming, cause and effect diagramming, and identifying root causes and contributing factors help to organize the events and determine why an error occurred. Based on the root causes and contributing factors, actions can be developed to prevent the error from recurring. Measuring the outcome of an intervention is also planned in order to determine the success of the RCA. Tools to assist the team include triggering questions, the five rules of causation, and action hierarchy” (Charles, 2016).



“The goal of performing an RCA is to protect patients by identifying and changing factors within the healthcare system that can potentially lead to harm. There are 9 steps, which serve as a guide for performing an effective RCA. Before a RCA can begin, honest and open reporting of errors is required. A Department should strongly encourage residents, midlevel providers, and faculty to report adverse events and close calls (or near misses). A risk based triaging system should be used to evaluate the report to determine if an RCA is required. At [one] institution, there is a patient care committee comprised of faculty and residents who review incident reports and decide if an event would benefit from an RCA. If an RCA is required, it would be assigned to a small team consisting of 4 to 6 individuals who have fundamental knowledge of the specific area involved. Team members should consist of physicians, supervisors, ancillary staff, and quality improvement experts. It is important that members of the RCA team are not involved in the case being reviewed to ensure objectivity. Time to completion of an RCA varies

depending [on] complexity of the case, time required to conduct interviews and synthesize information, and barriers to implementation of corrective actions; however, a typical investigation should range between one to three months” (Charles, 2016).

Process of Root Cause Analysis (RCA; Charles, 2016)

STEP 1: Identify Adverse Event

- **Honest and open reporting of adverse events.**
- **Committee review of clinical documentation to understand basics of what event happened? When? Who was involved? How and why did it happen?**
- **Identify appropriate RCA investigations.**

STEP 2: Organize a Team

- **Team should consist of 4 – 6 members of clinicians, supervisors, quality improvement experts with fundamental knowledge of specific area of interest.**
- **Ensure that despite members having different levels of authority, everyone should be treated as equals.**
- **Members should not be directly involved with the case in question.**
- **Appoint an unbiased team leader / facilitator.**

STEP 3: Develop an Initial Flow Diagram

- **Use a flowchart to describe the processes leading to the event.**
- **Organizing the information to reach a mutual understanding of the problem.**

STEP 4: Develop an Event Story Map

- **Use of Triggering questions to guide further investigation.**
- **Conduct thorough interviews with all parties involved in event.**
- **Thorough review of clinical documentation surrounding the event.**

STEP 5: Develop a Cause and Effect Diagram

- **Identify a single problem statement.**
- **Identify Actions and Conditions that caused the problem statement.**
- **These categories should address communication problems, policies, rules, procedures, and human errors leading to the event.**

STEP 6: Identify Root Cause Contributing Factors (RCCF)

- **Describe how a cause led to an effect and increased the likelihood of adverse event.**
- **Apply 5 rules of causation for crafting RCCF statements.**

STEP 7: Develop Corrective Actions

- **Identify barriers and risk reduction strategies to prevent root cause from recurring.**
- **Multiple actions may be required.**
- **Implement a trial test of corrective action.**

STEP 8: Measure Outcomes

- **Develop outcome measurements to ensure appropriate implementation of actions.**
- **Track quantifiable data to document effectiveness of actions over time.**
- **Evaluate and fine-tune improvement efforts if needed.**

STEP 9: Communicate Results

- **Communicate results of RCA to all staff involved in event and more broadly if applicable.**

“The next step of the RCA process is to create an ‘initial flow diagram’ depicting the known sequence of events leading up to the adverse event being investigated. The purpose of the initial flow diagram is to present the known facts and serve as a springboard to investigate what contributed to each event. Development of a basic flow diagram facilitates a mutual understanding of the event and problem” (Charles, 2016).

“An extensive list of ‘triggering questions’ provides a clinical context and helps postulate what occurred during the time period in which the adverse event took place. Triggering questions serve as cognitive aids to identify areas of inquiry that may not have been previously considered. The questions cover communication, training, engineering, equipment, rules, policies, procedures, and barriers. To answer these questions, any individual who may have contributed to the progression of the adverse event is subsequently interviewed. This includes attending physicians, residents, mid-level providers, nursing, engineering, and ancillary staff. The purpose of these questions and ensuing interviews is to identify exactly what occurred, and fill in details of the initial flow diagram, thus creating an ‘event story map.’ The event story map conveys in significant detail what happened and why it happened utilizing the information collected during the interview process” (Charles, 2016).

“Once the Event Story Map is constructed, it is necessary to develop a ‘cause and effect’ diagram. A cause and effect diagram is composed of a problem statement, an action, and two to three conditions. These categories should address communication problems, policies, rules, procedures, and human errors leading to the event. Each causal event box in the diagram is connected to the preceding box by a ‘caused by’ statement. This process is continued until knowledge of the event is exhausted, it becomes apparent that additional investigation is required, or the causal events identified are too far removed to be of value. The purpose of crafting a cause and effect diagram is to help the teams identify causal links and ascertain ‘root cause contributing factors’ (RCCF) for each event” (Charles, 2016).

“Crafting a RCCF statement begins by describing how something (cause), led to something (effect), that increased the likelihood of an undesirable outcome (event). After the initial RCCF statement or statements are created, the ‘Five Rules of Causation’ are applied to finalize each statement. By correctly crafting the RCCF statement, the teams’ findings are distilled into one or two sentences that describe what happened and why it is important to expend time and/or resources to correct it. This creates a road map leading to the development of corrective actions and their respective process or outcome measures. The implementation of these actions is what ultimately improves patient safety” (Charles, 2016).

Five Rules of Causation for Root Cause Contribution Factor (Charles, 2016)

- 1. Clearly show the cause and effect relationship.**
- 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.**
- 3. Human errors must have a preceding cause.**
- 4. Violations of procedure are not root causes, but must have a preceding cause.**
- 5. Failure to act is only causal when there is a pre-existing duty to act.**

“The RCCFs are placed on the event story map before the primary event where there is a system vulnerability that should be addressed. This placement indicates the location

where an existing barrier needs to be reinforced or where a new barrier needs to be created. Ideally there will be RCCFs identified at multiple points along the event story map, which graphically represents how care processes are designed to be fault-tolerant” (Charles, 2016).

“Finalizing an event story map with appropriately identified RCCF statements would be meaningless to patients if it did not lead to action and change. Using the RCCF statements, specific actions with the goal of sustained system improvement are implemented. While the implementation of the actions is left to department and hospital leadership, the RCA team is responsible for identifying an individual to follow the implementation process and confirm the changes have in fact been made. A properly crafted process or outcome measure should be specific, quantifiable, and provide a timeline on when it is going to [be] assessed. It should clearly tell you if the action that was implemented resulted in the desired system change. Finally, corrective actions identified throughout the RCA should be shared amongst appropriate parties not only involved in the RCA and adverse event or close call but also with other hospital staff and departments as a means to promote quality improvement” (Charles, 2016).

Some causes of errors in health care systems are (Kim, 2015):

- *Lack of continuous training and education*
- *Past tolerance of unsafe practice*
- *Lack of regulations / rules*
- *Gaps in communication among different healthcare providers*
- *Gaps in communication between healthcare providers and patients*
- *Unstable / unreliable systems*
- *Fear of admission of guilt / wrongdoing*
- *Human factors*

INFORMING THE PATIENT

“When an error or mistake occurs, the most common dilemma, faced by [health care professionals], is whether to disclose or not to disclose the error to the patient. Research findings reveal that patients are keen to know about any error that caused them harm. The patient’s bill of rights also demands to have full disclosure of an error. Several studies report that patients do verbalize that such disclosure would enhance their trust in their [health care provider’s] honesty and would reassure them that they are receiving complete information about their overall care” (Ghazal, 2014).

“The principle of beneficence in medical practice refers to avoid and prevent error by doing well. The principle of non-maleficence emphasizes that one should not cause harm to oneself and others. When patients come to a health care system to seek care, they trust the system and health care providers. They expect competency and believe that [their health care provider] will provide the best treatment in accordance with the principle of beneficence. As a moral obligation, the principle of beneficence guides us to remove

condition that will harm others, and prevent harm from occurring to others. Disclosure of error to the patient will enhance the trust in [the health care professional] and prevent lawsuit on to the hospital. Along with this, disclosure to the hospital management will help to improve processes and reduce errors for the future. Therefore, in the light of beneficence and non-maleficence, disclosure of error to patient and management is justified as a better option” (Ghazal, 2014).

“The physician-patient relationship exists between individuals, not between a person and a ‘system,’ and telling injured patients the truth involves honest conversations between patients and the caregivers they know and trust. Health care professional should strive for more truth telling and disclosure of medical errors. Disclosure will enhance patient’s trust on [the health care provider] and the health care system” (Ghazal, 2014).

TYPES OF MEDICAL ERRORS

“Medical errors can be categorized in several ways; these categories include judgmental error, technical errors, expectation errors, and mechanical and system errors. Errors can also be classified as skill-based, rule-based, and knowledge-based. Another mode of classification could be negligent and non-negligent error” (Ghazal, 2014).

Medication-Related

“The most common prescribing errors are incorrect drug, incorrect dose, allergies, and drug-drug interaction. Medication safety can be improved by utilizing the five R’s: right drug, right route, right time, right dose, and right patient. Medication errors are barriers that prevent the right patient from receiving the right drug in the right dose at the right time through the right route of administration at any stage during medication use, with or without the occurrence of adverse drug events. Medication errors represent the largest single cause of errors in the hospital setting in the United States, and are estimated to harm at least 1.5 million patients annually. Health-care professionals must monitor whether prescribed medication is clinically successful, does not cause harm, and is corrected when necessary. Drug interactions can lead to serious adverse events or decrease drug efficacy. Prescribing health-care workers should ask patients of any use of over-the-counter medications or dietary supplements because they are frequently under reported and may cause drug interactions. Prescribing the generic name of drugs simplifies the communication among health-care workers, reducing errors. However, patients need to be educated that their medication may be called by different names (brand and generic name) and they should be encouraged to keep a list of their medications, including both the brand and generic name of each drug” (Kim, 2015).

“The Institute of Medicine estimates that, on average, hospitalized patients are subject to at least one medication error per day. Medication errors are expensive and sometimes harmful to patients. The Institute of Medicine estimates that at least a quarter of all medication-related injuries are preventable, and recommends electronic prescribing (e-prescribing) through a computerized provider order entry (CPOE) system as one way to reduce medication errors and patient harm. Electronic entry of medication orders through

CPOE may reduce errors from poor handwriting or incorrect transcription. CPOE systems often include functionalities such as drug dosage support, alerts about harmful interactions, and clinical decision support, which may further reduce errors” (Radley, 2013).

“Findings suggest that CPOE can substantially reduce medication errors in hospitals. In 2008, ~34% of US acute-care hospitals had adopted CPOE capable of processing prescription orders. At these adoption and implementation levels, [an estimated] 17.4 million medication errors per year [are] avoided due to CPOE — a 12.5% reduction nationally. Given the modest adoption and implementation rates to date, there is still great potential for this technology to reduce medication errors. The projected reduction in medication errors represents an important intermediate indicator of potential gains as health IT systems are expanded and more deeply integrated in care delivery systems nationwide. However, it is unclear whether reduced medication errors would translate into reduced patient harm from medications” (Radley, 2013).

Invasive / Procedural

“More than 200 million surgeries are performed world-wide each year and recent reports reveal that adverse event rates for surgical conditions remain unacceptably high, despite multiple nationwide and global patient safety initiatives over the past decade. Interestingly, adverse events resulting from surgical interventions are actually more frequently related to errors occurring before or after the procedure than by technical surgical mistakes during the operation. These include (i) breakdown in communication within and amongst the surgical team, care providers, patients, and their families; (ii) delay in diagnosis or failure to diagnose; and (iii) delay in treatment or failure to treat” (Kim, 2015).

“Health-care workers should be trained to reduce misinformation or inconsistent information that can lead to errors, such as wrong-site surgery” by utilizing the following guidelines (Kim, 2015):

Scheduling the procedure

Office schedulers must carefully verify patient documentation before scheduling the procedure. All surgery requests must be in writing. No verbal requests by the medical staff should be accepted. An appropriate scheduling form reduces misunderstandings. Illegible hand-writing, unapproved abbreviations, and cross-outs can be pitfalls if not clearly understood by office schedulers. Electronic medical records can improve the safety process, reducing misunderstandings and missing documents.

Verification of every pertinent document such as consent, history, physicals, and surgeon orders at time of scheduling is mandatory. If any inconsistency is found within the documentation during the process, office-schedulers should be instructed not to proceed to the next step without solving conflict or absence of information.

Pre-operative

The preoperative visit is another opportunity to identify and correct any inconsistencies or lack of information in the documentation regarding the surgical procedure. All documents should be checked during the visit and the patient should confirm identity, site of surgery, allergies, and other pertinent information if possible. All discrepancies must be corrected on all forms and documents prior to moving forward.

The informed consent must be received prior to the procedure and the patient must fully understand their procedure including things such as complications, additional procedures, placement of stents, and important alternative treatments that may be used in the present case.

Marking the site of the procedure is critical in order to avoid wrong-site surgery. Preferentially, site marking should be performed with the patient's involvement. The site must be marked by a licensed practitioner who is responsible for the procedure and will be present when the procedure is performed. The marks should be unambiguous and uniform within the institution and should be semi-permanent to be visible after skin preparation and draping.

In case marking the site is not possible due to technical or anatomical impediments (mucosal surfaces, minimal access procedures, endoscopic procedures, natural orifice procedures, etc.), the institution should have a written process to ensure that the correct site is operated on. Alternatively, radiopaque markers can be used in the procedures involving fluoroscopy.

Another important aspect of patient safety is the surgical material used during the procedure. Availability of all instruments and special materials (e.g., guide wires, laser fibers, scopes, stents, loops, prosthesis, etc.) should be verified prior to surgery and checked to ensure that they are the appropriate size for the patient.

Before starting the procedure

Full implementation of safety checklists in surgery has been linked to improved outcomes. The World Health Organization checklist is designed to identify a potential error before it results in harm to a patient. This checklist should be followed in the appropriate manner.

In a study by Russ S. et al., more than 40 % of cases had absent team members, and over 70 % of team members failed to pause and focus on the checks. Performing a time-out and implementing a checklist in the operating room does not mean that the patient is safe. Team members still have to adhere to the protocols and follow them with full attention. Surgical safety performance was better when surgeons led the procedure and all team

members were present and paused. The time-out must be documented at its completion. When multiple procedures are going to be performed on the same patient by different providers, the checklist and time-out should be performed for each procedure.

In the era of digital images, displaying the CT-scan, X-ray, and all other pertinent images during the procedure on an auxiliary monitor can improve patient safety.

The consequences of positioning related injuries are preventable but can be profound and can result in morbidity and litigation. Neurological, vascular, musculoskeletal, and pressure ulcers are the most common position related injuries in surgical patients. Neurological complications can be avoided by placing forearms in neutral position or slightly supinated to minimize pressure in the cubital tunnel. Straps should be properly placed to maintain the correct limb position during the procedure even if the surgical table is moved. The patient's head should be placed in a neutral position and the arm should not exceed abduction of more than 90° to prevent brachial plexus injury. Straps should not be too tight to avoid ischemia and compartmental syndrome. Padding under osseous prominences can help avoid pressure-related complications. Urologists must be careful to avoid possible compartment syndrome (limbs) when positioning patients for open, endoscopic, and laparoscopic surgeries.

Misidentification

“Approximately 1% of general laboratory specimens are misidentified and can lead to serious harm for patients. For patient safety, prevention is the goal and can be accomplished by implementing safety strategies. Health care workers responsible for specific tasks must be educated and motivated to perform those tasks with as few errors as possible. Written policies and protocols detailing responsibilities must be implemented along with a strategic plan to detect errors when these responsibilities are not met. Successful completion of required tasks must be documented in order to move forward, especially in those tasks that are performed as a prerequisite to others. To make the process as simple as possible, reduce the number of steps between collecting the samples and receiving the laboratory report. Redundancy checks must be encouraged in certain steps of the process in order to increase the chance of detecting mistakes before a therapeutic decision is made, especially when the decision is irrevocable and the potential damage caused by error cannot be undone. The use of information technology for data entry, automated systems for patient identification and specimen labeling, as well as two or more identifiers during sample collection are important steps to reduce misidentification. If misidentification is detected, rejection then recollection is the most suitable approach to manage the specimen. DNA analysis to assist with correct identification can be used when recollection is not available” (Kim, 2015).

Falls

“Each year, somewhere between 700,000 and 1,000,000 people in the United States fall in the hospital. A fall may result in fractures, lacerations, or internal bleeding, leading to increased health care utilization. Research shows that close to one-third of falls can be prevented. Fall prevention involves managing a patient's underlying fall risk factors and optimizing the hospital's physical design and environment” (Agency for Healthcare Research and Quality (AHRQ), 2013).

“Staff in acute care hospitals have a complex and potentially conflicting set of goals when treating patients. Hospital personnel need to treat the problem that prompted the patient's admission, keep the patient safe, and help the patient to maintain or recover physical and mental function. Thus, fall prevention must be balanced against other priorities. Fall prevention involves managing a patient's underlying fall risk factors (e.g., problems with walking and transfers, medication side effects, confusion, frequent toileting needs) and optimizing the hospital's physical design and environment. A number of practices have been shown to reduce the occurrence of falls, but these practices are not used systematically in all hospitals” (AHRQ, 2013).

Sentinel Event

“The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of Patient Safety Events (events not primarily related to the natural course of the patient's illness or underlying condition), as well as evaluation of corrective actions, is essential to reduce risk and prevent patient harm. The Sentinel Event Policy explains how The Joint Commission partners with health care organizations that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm” (The Joint Commission, 2016).

A sentinel event is a Patient Safety Event that reaches a patient and results in any of the following (The Joint Commission, 2016):

- *Death*
- *Permanent harm*
- *Severe temporary harm and intervention required to sustain life*

“An event can also be considered sentinel event even if the outcome was not death, permanent harm, severe temporary harm and intervention required to sustain life. Such events are called ‘sentinel’ because they signal the need for immediate investigation and response. Each accredited organization is strongly encouraged, but not required, to report sentinel events to The Joint Commission” (The Joint Commission, 2016).

Organizations benefit from self-reporting in the following ways (The Joint Commission, 2016):

- *The Joint Commission can provide support and expertise during the review of a sentinel event.*

- *The opportunity to collaborate with a patient safety expert in The Joint Commission's Sentinel Event Unit of the Office of Quality and Patient Safety.*
- *Reporting raises the level of transparency in the organization and promotes a culture of safety.*
- *Reporting conveys the health care organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future.*

Never Events and Always Events

“The definition of ‘never events’ as they relate to either (1) conditions listed as ‘serious reportable events’ by the [National Quality Forum (NQF)], in contrast to (2) conditions defined by the *Centers for Medicare and Medicaid Services* (CMS) deemed as ‘non-reimbursable serious hospital-acquired conditions’” (Lembitz, 2009).

“In 2002, the NQF published a first report which defined 27 so-called ‘serious reportable events’ in healthcare. These encompass serious adverse events occurring in hospitals that are largely preventable and of concern to both the public and to healthcare providers. One additional event was added to the updated report in 2006, leading to a total 28 ‘never events’ defined by the NQF. While most on the list of ‘serious reportable events’ include obvious unacceptable errors, such as wrong site surgery or discharge of an infant to the wrong person, not all NQF events are preventable at all times or indicative of obvious negligence. A goal of quality improvement measures should be to institute a reduction of ‘never events’ to zero. Achieving that goal via the cycle of reporting, intervention, and measurement of subsequent outcomes must necessarily begin with a culture of openly reporting these defined events within an institution” (Lembitz, 2009).

“CMS adopted the non-reimbursement policy for certain ‘never events’ - defined as ‘non-reimbursable serious hospital-acquired conditions’ - in order to motivate hospitals to accelerate improvement of patient safety by implementation of standardized protocols. These newly defined ‘never events’ limit the ability of the hospitals to bill Medicare for adverse events and complications. The non-reimbursable conditions apply only to those events deemed ‘reasonably preventable’ through the use of evidence-based guidelines” (Lembitz, 2009).

Serious reportable events (‘never-events’), as defined by the National Quality Forum (NQF consensus report; Lembitz, 2009):

1. *Surgery performed on the wrong body part.*
2. *Surgery performed on the wrong patient.*
3. *Wrong surgical procedure performed on a patient.*
4. *Unintended retention of a foreign object in a patient after surgery or other procedure.*

5. *Intraoperative or immediate postoperative death in an ASA class I patient.*
6. *Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.*
7. *Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.*
8. *Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.*
9. *Infant discharged to the wrong person.*
10. *Patient death or serious disability associated with patient elopement (disappearance).*
11. *Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.*
12. *Patient death or serious disability associated with a medication error.*
13. *Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.*
14. *Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.*
15. *Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.*
16. *Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.*
17. *Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.*
18. *Patient death or serious disability due to spinal manipulative therapy.*
19. *Artificial insemination with wrong donor sperm or wrong egg.*
20. *Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.*
21. *Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated with toxic substances.*
22. *Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.*
23. *Patient death or serious disability associated with a fall while being*

cared for in a healthcare facility.

24. *Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.*

25. *Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.*

26. *Abduction of a patient of any age.*

27. *Sexual assault on a patient within or on the grounds of a healthcare facility.*

28. *Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare facility.*

“‘Never events’ and non-reimbursable adverse events are framed in the negative and likely carry some ‘extra psychological charge,’ as mentioned above. [The] concept of the ‘always events’ represents a positive affirming behavior that can motivate us to improve patient safety and promote better outcomes. Some basic examples of ‘always events’ include” (Lembitz, 2009):

- *Including patient identification by more than one source.*
- *Mandatory ‘readbacks’ of verbal orders for high-alert medications.*
- *Disclosure of adverse outcomes and transparency with patients and families.*
- *Medication error reduction strategies.*
- *Surgical time-out.*
- *Anesthesia monitoring that is appropriate for the level of sedation.*
- *Tracking of critical imaging, lab, and pathology results.*
- *Making critical information available at handoffs or transitions in care.*

STRATEGIES TO REDUCE RISK

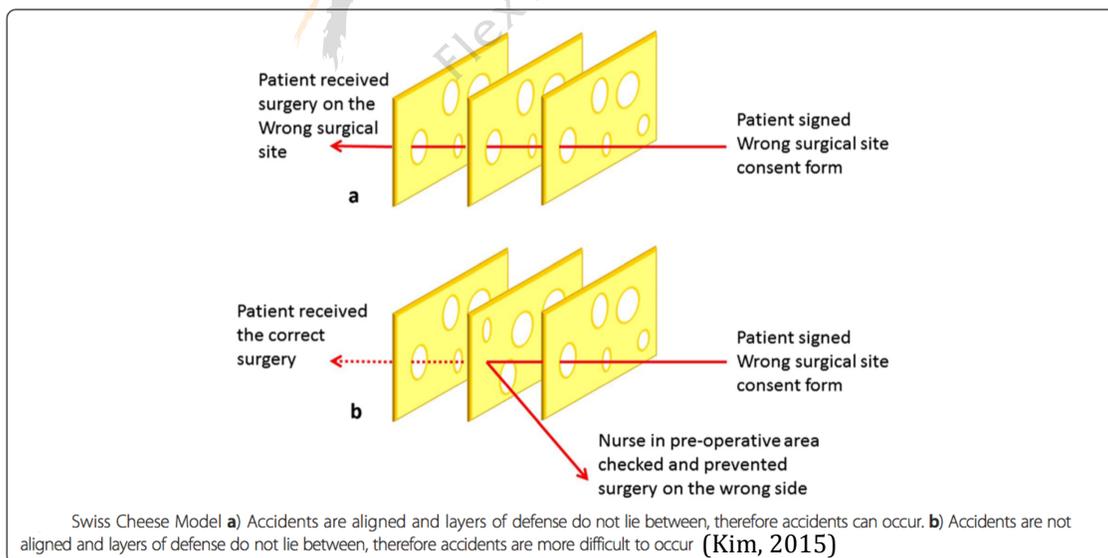
“Strategies to improve the defensibility of care where appropriate, particularly those falling under the non-preventable adverse events list include” (Lembitz, 2009):

- *Pretreatment or pre-hospital documentation of underlying pre-existing conditions, particularly those involving infections, pressure sores, altered mental status, hyper- / hypoglycemia, and patients at high risk for venous thromboembolism.*
- *Hospital outcomes data with identification of care improvements directed at those complications - particularly hospital-acquired infections.*

- *Standardized and universally followed approaches to reduce wrong site / wrong patient surgery.*
- *Culture-changing training around communication, assertiveness, team training, and the use of briefings and debriefings, particularly in high-acuity patient care areas.*
- *The use of surgical checklists.*
- *Understanding and using clear language in policies and publications of the difference between the NQF ‘never events’ and the CMS ‘non-reimbursable serious hospital-acquired conditions’ to avoid claims of negligence.*

The Swiss Cheese Model

“Errors are inevitable, but having a system in place to prevent them from occurring, and remedying them when they do occur, improves overall patient safety in the health care environment. Therefore, the ‘Swiss Cheese Model’ originally formally propounded by Dante Orlandella and James T. Reason of the University of Manchester, what he referred to as system failure model. Every step in a process has the potential for failure, to varying degrees. The ideal system is analogous to a stack of slices of Swiss cheese. Consider the holes to be opportunities for a process to fail, and each of the slices as ‘defensive layers’ in the process. An error may allow a problem to pass through a hole in one layer, but in the next layer the holes are in different places, and the problem should be caught. Each layer would work as a defense against potential error impacting the outcome. The more number of defenses, the fewer and the smaller the holes, the more likely you are to catch and stop errors that may occur. The Swiss cheese model of accident causation illustrates that if hazards and accidents are aligned and layers of defense do not lie between, the flaws in each layer can allow the accident to occur” (Kim, 2015).



The SBAR Model

“Once the issues impeding patient safety have been identified, plans can be established to limit or eliminate them. One treatable factor is the ‘culture of blame’ present in health care systems. Admitting wrongdoing is often avoided for fear of being penalized. Employees should welcome the learning opportunity that mistakes can provide. The system should be modified to encourage teamwork, improve accountability, and reduce individualized blame. There are two facets that should be addressed: a) process and b) culture of patient safety” (Kim, 2015).

a) Process: *Employees benefit from clear rules and transparent processes. The World Health Organization (WHO) has a safety checklist that should be adapted into the current system. It clearly addresses patient safety issues, like allergies, that can be overlooked and lead to severe consequences. The Surgical Safety checklist includes three well-defined steps where the surgical team communicates and identifies possible risks for errors.*

Step 1: Before the induction of anesthesia - a nurse and the anesthesiologist will confirm the patient’s identity, site of surgery, procedure, and check the surgical consent form.

Step 2: Before the skin incision - the nurse, anesthesiologist, and the surgeon will confirm the role and names of the team members, reconfirm the patient’s name, verify the procedure, and check the incision site. The team will also confirm whether antibiotic prophylaxis was given within the last 60 min. Furthermore, the surgeons, anesthesiologist, and nursing team will identify anticipated critical events, i.e.; the length of the case, possible significant blood loss, patient-specific concerns, and equipment issues. Specifically for the urologists, this step will require that the display of essential imaging is verified, i.e.; Computerized Tomography (CT) scan for urolithiasis therapy, nephrectomy, etc....

Step 3: Before the patient leaves the operating room - the nurse, anesthesiologist, and surgeon will verbally confirm the name of the procedure, availability of adequate instrumentation, sponge and needle counts, specimen labeling (if applicable), issues with equipment, and key concerns for recovery and management of this patient.

b) Culture of Patient Safety and Improving Communication among team members: *Success in patient safety depends on [an] optimal line of communication between surgeons, administrators, and other healthcare providers to obtain and apply the necessary resources and improve means of communication and awareness. Ineffective team communication, especially in the operation room (OR), is a major root cause of these errors. Mickan et al. described six characteristics of an effective team involving purpose, goals, leadership, communication, cohesion, and mutual respect. Incorporating these qualities into medical communities can minimize errors and improve patient safety. One effective tool used to help assess*

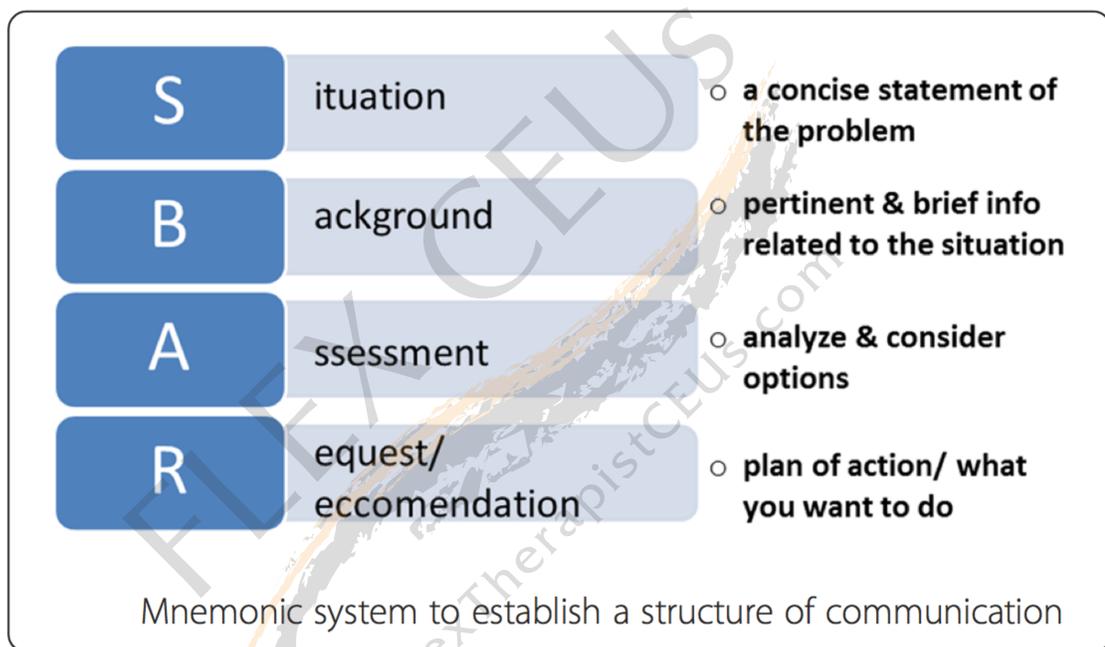
problems and resolve conflicts on communication and other issues is SBAR (Situation, Background, Assessment, and Recommendation). SBAR is an effective and efficient way to communicate important information. SBAR offers a simple way to help standardize, set expectations, and establish structure of communication.

Situation: a concise statement of the problem

Background: pertinent and brief information related to the situation

Assessment: analysis and considerations of options – what you found / think

Recommendation: action requested / recommended – what you want



(Kim, 2015)

“SBAR allows all parties involved in the discussion to be on the same page, proactively giving the listener necessary data and recommendations to solve the problem. A similar commonly used protocol by physicians is the SOAP note (subjective, objective, assessment, and plan). Both tools help to establish a culture of patient safety” (Kim, 2015).

Systems Thinking

“Health care professionals should be trained to encourage team work, ‘systems thinking,’ honesty, and policy adherence. ‘Systems thinking’ helps employees approach problem solving by seeing individual issues as parts of a whole. If there is a checklist before each procedure, the staff needs to know how to accurately complete it and why it is important

to do so. Every employee should be aware of their role in the health care process and alert to possible errors. When health care professionals work together and are properly trained, patient safety can substantially improve. Training may vary among medical care facilities and should be formatted to adhere to policies, regulations, and environments present within the system” (Kim, 2015).

Protocols and Training

“General requirements for emergent and elective care of patients must include screening exams and patient’s consent for care and surgery. In certain emergencies and life-threatening situations the caregivers may not have the ability to obtain proper authorization for care or surgery from the next of kin. In these rare situations, good communication between healthcare providers and others (administrators, social services, and law enforcement), as well as effective use of technology (electronic medical record) is necessary to increase patient safety and decrease possible errors in the system (e.g., unknown co-morbidities, allergies, and past medical history). General guidelines regarding patient safety begin with verification of procedural steps such as patient identification, surgical site, positioning, and preparation” (Kim, 2015).

“Institutional protocols and proper training of personnel should be revised often and current for all steps of patient care including such things as radiation concerns during radiological imaging, environmental safety (sterilization, prevention, and dissemination of infection, etc....), and laboratory services. The National Patient Safety Goals state that the patient should be identified by two or more methods, the test results should be returned promptly to the appropriate staff member, and proper sanitation guidelines outlined by an accredited organization should be followed” (Kim, 2015).

AN ETHICAL DECISION MAKING PROCESS

“To address a medical error, the health care provider should handle the situation and correct the error; secondly, the error should be disclosed. The MORAL is an extensive and clear ethical decision-making model based on five steps of ethical decision making process proposed by Patricia Crisham in 1985. In MORAL, The “M” stands for Massage the Dilemma, “O” stands for outlines options, “R” review criteria and resolve, “A” stands for affirm position and act, and “L” stands for look back” (Ghazal, 2014).

“The first step of MORAL Model involve massage the dilemma; this includes data collection about situation, people, and their value in conflict. This means that a person should analyze the context in which error occurred and should identify the key aspects, facts, underlying ethical principles and values, etc. In the second step one has to identify the possible options for rectification of the error. Then, one should undergo constructive thinking and reflection to analyze the pros and cons of each option. In the third step one has to identify the moral criteria to select the appropriate course of actions, based on moral judgment. On the basis of moral judgment with the help of ethical principles and theories, one has to select the best action in [the] patient’s interest. In the forth step, one should practically integrate the selected option in the patients’ scenario to resolve the dilemma keeping in view the ethical principles. The last and final step in MORAL

emphasis [is] on evaluating the ethical dilemma and its resolution and implementation with [the] final course of appropriate strategies. Evaluation helps us to see the effectiveness of our decision of choosing [the] best option in [the] patient's interest" (Ghazal, 2014).

"As a health care provider, one encounters a number of medical errors every day. The literature strongly suggests that errors should be disclosed to the patients. Yet it appears this practice is uncommon in health care. Health care team feels upset and guilty when medical errors occur. Health care providers involved in an error also report disappointment for their failure to be safe and competent. They also feel anxious about the error's repercussion on their professional growth. In addition, they also report fearful about a possible lawsuit against them or to the hospital in which they are practicing. This contradicts the health care providers professional responsibility to give the high quality of medical care and to act in the patient's best interest. Therefore, the health care providers should be taught about the underpinnings of ethical principles that support truth telling and honesty. Moreover, they should reflect on the patient's expectations concerning disclosure and the factors that hinder disclosure so that the gap between theory and practice can be bridged. Along with that, they should be encouraged to integrate the ethical decision making framework like MORAL. In addition, they should be taught about the specific communication techniques and pertinent apologizing words to be used while disclosing the medical error. Along with that, a non-penalizing error reporting culture should be created so that health care providers do not feel threatened. At the same time, the causes and effects of medical error could be investigated and appropriate actions should be initiated so that one learns from their mistakes and prevent it in future clinical practice" (Ghazal, 2014).

PATIENT DISCHARGE

"Discharge planning has been shown to impact patient safety, patient outcomes, and can prevent readmissions and improve patient satisfaction. Health care workers must be aware that language barriers, socioeconomic status, and age can impact patient comprehension of instructions. Written instruction must also be provided and follow-up visits should be scheduled prior to patient discharge from the facility" (Kim, 2015).

REPORTING

"Several national initiatives, such as the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), have been established to capture standardized information about the type and rate of surgically-related adverse events. Such systems are generally based on collecting data utilizing uniform event reporting protocols. While standardized reporting procedures promotes uniformity and benchmarking, the use of a facility-based or hospital system specific event reporting system has the potential benefit of enabling more detailed and comprehensive information than would be available by the use of national standardized AE reporting systems alone. There may be a significant advantage, for example, to capture surgical event information during the pre-operative and post-operative phases of the hospitalization to provide information on contextual events (e.g., falls) related to the surgical episode" (Zeeshan, 2014).

“The accuracy of reporting adverse events is heavily dependent on the completeness, precision, and motivation of the individuals collecting and recording that information. Barriers to accurate reporting of AEs include the reluctance of some medical providers (particularly physicians) to report AEs, lack of time needed to report events because of workload pressures, availability and complexity of the ERS systems, and fear about the repercussions of reporting errors in practice. There may also be reporting bias with regards to the type of events reported (e.g., ‘near miss’ events). For these reasons, it is likely that not all AEs will be reported, and that estimates of AE rates may therefore represent an underestimate of true event prevalence” (Zeeshan, 2014).

“To address these potential problems, hospital systems [should take] a variety of actions to achieve complete and accurate reporting. The system’s quality assurance department [should provide] extensive training to clinicians and staff in use of the ERS system, actively encourage reporting and the development of a culture of reporting within the hospital system, maintain a well-staffed quality improvement unit that records all events and near misses, investigate reported events, double check ERS system reports against information contained in electronic clinical medical records, and incentivize hospital personnel to file AE reports without fear of reprisal” (Zeeshan, 2014).

“Orthopedic surgeries, especially joint repair and joint tissue incision and excision are numerically the most common surgical categories in which AEs occur. Identifying and documenting those trends helps to focus attention and resources at that area so that effective improvement programs can be developed. For example, a high volume of adverse events occurring in a particular orthopedic surgery unit could spur the development of enhanced communications techniques or acquisition of new information technology” (Zeeshan, 2014).

“Not every health care institution has a similar process for grading the severity of a particular AE. Including a severity scale is beneficial because it potentially enables more precise evaluation and response, along with more efficient use of time and resources. There have been some efforts at the national level to create uniform AE scaling techniques, such as the Common Terminology Criteria for Adverse Events severity scale created by the National Cancer Institute. However, in general, there is still a need to better incorporate uniform severity scales into AE reporting systems” (Zeeshan, 2014).

“To enhance patient safety reporting in the future, hospital systems may need to work cooperatively to develop standardized approaches for event reporting that facilitate benchmarking and trending using common data, while protecting the confidential nature of event data. At the national level a variety of initiatives are underway to aggregate adverse events data to derive more globally applicable information. However, many national adverse event reporting initiatives – such as those undertaken by the National Quality Forum, the Agency for Healthcare Research and Quality, the Joint Commission, and the National Surgical Quality Improvement Program – rely on a relatively small set of common indicators and thus lack the richness, detail, and variety that can often be obtained through use of a customized hospital-based ERS” (Zeeshan, 2014).

“The ideal reporting system would feature uniform AE coding and data collection

processes that would enable benchmarking with other healthcare systems, but that also would be detailed and comprehensive enough to meet the specific quality assurance needs of a particular institution” (Zeeshan, 2014).

FLORIDA LAW

“Hospitals, ambulatory surgical centers (ASCs), health maintenance organizations (HMOs), assisted living facilities (ALFs), and nursing homes (NHs) are required to report adverse incidents” to the Agency for Health Care Administration (Florida Agency for Health Care Administration (AHCA), 2014).

Facility Adverse Incident Report Time Requirements (AHCA, 2014)

Facility Type	Authority	Deadline to Report to the Agency
Hospitals and Ambulatory Surgical Centers	Section 395.0197(7), F.S.	Within 15 calendar days after the incident occurred.
Assisted Living Facilities	Section 429.23(3), F.S. Section 429.23(4), F.S.	Within one business day after the occurrence, the facility must provide a preliminary report. Within 15 days to provide a full report.
Nursing Homes	Section 400.147(7), F.S.	Within 15 calendar days after the incident occurred.
HMO's	Section 641.55(6), F.S.	Within three working days after the incidence occurred. Within ten days after the first report to file a more detailed follow-up report.

CONCLUSION

“In conclusion, health care providers encounter different medical errors in their day to day practices. The disclosure of a medical error is an ethical dilemma that requires deliberative thinking and reflection by the health care providers. It is suggested that disclosure of medical errors be encouraged, keeping in view the principle of beneficence, non-maleficence, [and] patient’s autonomy. This disclosure will lead to better satisfaction from the patients and health care providers. Hence, medical error should be addressed and reported as this can help to improve systems and prevent such errors in [the] future and will contribute [to] more professional growth” (Ghazal, 2014).

In addition, “success in patient safety depends on several factors that include identification, revision of systems, education, and training to address known patient safety issues. Medical educators and mentors must understand and practice the culture of patient safety so the new generation of [health care professionals] will incorporate the same values intuitively by mimicking the leadership” (Kim, 2015).

MORE INFORMATION

- Adverse Incident Reporting:
<http://ahca.myflorida.com/SCHS/RiskMgtPubSafety/RiskManagement.shtml>
- Sentinel Event Hotline: 630-792-3700
- 2017 National Patient Safety Goals:
https://www.jointcommission.org/standards_information/npsgs.aspx
- Toolkit for preventing falls:
https://www.ahrq.gov/sites/default/files/publications/files/fallpxtoolkit_0.pdf

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