Improving Patient Safety by Reducing Medical Errors

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Abstract

Multiple studies benchmarking the incidence of medical errors have led to efforts to improve patient safety, resulting in regulatory agencies and healthcare providers across the nation making the prevention and reduction of medical errors a priority. Providers should understand how regulatory agencies have shaped the patient safety movement, provided a structure for identifying causes of medical errors, and developed effective preventive strategies. Based on state and national reports of patient safety events and malpractice data, regulatory agencies have established patient safety goals for the prevention of medical errors.

Introduction

A medical error has been defined in varied ways by a multitude of patient safety organizations. The Institute of Medicine (IOM) defines a medical error as the failure to complete the intended plan of action or implementing the wrong plan to achieve an aim.¹ This error may or may not lead to patient harm or impact the patient in any tangible way. Errors may be those of omission or commission. An error of commission occurs because of the action of a provider. For example, a provider administers an overdose of medication to a patient. An error of omission results from the failure of a provider to take action. For example, the provider may fail to follow up on significant radiologic study. Errors that never reach the patient also have value in the potential to improve patient safety and prevent future events. A near miss is an event that could have had an adverse patient consequence but did not because a provider or a process served to intervene and prevent that event from reaching the patient or causing harm.

A number of additional definitions have been developed from the underlying cause of the event or the resulting outcome of the error. A latent error is one that results from underlying errors in policies, processes, equipment, or the healthcare organization. Studies have shown that most latent errors are the result of systems issues, rather than one individual provider’s act or failure to act.
Negligence is defined as the failure to meet the reasonably expected standard of care of a qualified healthcare provider under similar circumstances. Florida Statutes define the standard of care as follows: “The prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.” Only healthcare providers and facilities can be liable for medical malpractice. Medical malpractice is negligence committed by a licensed healthcare provider or facility. In order to establish a claim of medical malpractice, the patient must establish four elements: duty, breach, causation, and damages. Prior to actually receiving a medical malpractice claim from a patient, a healthcare provider or facility may identify a medical error that could potentially lead to a medical malpractice claim as a potentially compensable event.

In 2002, the National Quality Forum published Serious Reportable Events in Healthcare: A Consensus Report, listed 27 adverse events that were, “serious, largely preventable and of concern to both the public and health care providers.” These events and subsequent revisions to the list became known as never events. Never events are medical errors that should not ever happen. Examples of never events include: wrong surgery performed on a patient, surgery performed on the wrong body part, or surgery performed on the wrong patient. Centers for Medicare & Medicaid Services (CMS) has determined that when one of these three never events occurs involving a Medicare beneficiary, Medicare will not cover these costs as they are not a reasonable and necessary treatment for the Medicare beneficiary’s medical condition.

The Joint Commission (TJC) is an independent, not-for-profit organization that accredits and certifies nearly 21,000 healthcare organizations across the nation and has become a symbol of patient safety given its commitment to the highest quality performance standards. TJC defines a sentinel event as a patient safety event that reaches a patient and results in death, permanent harm, or severe temporary harm and intervention required to sustain life. These events are called sentinel events because they signal a need to immediately investigate and respond to the event. In 2019, a total of 844 sentinel event reports were received by TJC, with 83% of those self-reported by an accredited facility. The top 10 events reported included:

- Unintended retention of a foreign object events
- Fall-related events
- Suicide events
- Wrong patient, wrong site, wrong procedure events
- Delay in treatment events
- Criminal events (assault, rape, homicide)
- Operation/post-operation complication events
- Perinatal events
- Medication error events
- Fire-related events

Under Florida law, an adverse event is defined as, “an event over which healthcare personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred”, that results in a specified injury, including death, brain damage, additional medical or surgical intervention, or transfer to a higher
level of care. Hospitals, ambulatory surgical centers, nursing homes, and physician offices licensed under Florida law are required to report statutorily defined adverse events to the Florida Agency for Health Care Administration (AHCA) or Department of Health (DOH). Certain licensed facilities are also required to establish and maintain internal risk management programs to track these and other types of events.

Licensed facilities must report specified adverse events, including unplanned foreign objects, wrong site surgical procedures, wrong surgical procedures, or surgical procedures on the wrong patient, within 15 days of the occurrence, hence the name **Code 15** report. Healthcare providers in an office practice setting are also required to report these types of events. The Code 15 Report includes a description of the circumstances surrounding the event, as well as analysis and interventions taken to correct and prevent recurrence. License numbers of practitioners who were directly involved in, or witnessed an adverse event are also required on these reports and are routinely forwarded to the DOH to determine whether to initiate a practitioner investigation. The Florida Board of Medicine has prescribed a range of disciplinary actions for a variety of medical errors, practicing beyond the scope permitted by law or competency, and gross or repeated malpractice.

**Error Reduction and Prevention**

The Institute of Medicine (IOM) is a division of the National Academies of Sciences, Engineering, and Medicine focused on improving health and healthcare in our nation and throughout the world. This team issues recommendations and reports to foster discussion and critical thinking, such as the oft-cited 1999 report *To Err Is Human*. The IOM has estimated as many as 98,000 people die every year as a result of preventable medical errors. A 2016 study published by Johns Hopkins University researchers in the British Medical Journal claims that 251,000 lives are lost every year as a result of medical errors. If correct, this statistic places medical error third among the leading causes of death in the United States, behind heart disease and cancer. Medical error prevention is, therefore, an urgent public health concern requiring close examination of contributing factors and prompt identification of appropriate strategies to reduce risks to patients.

In an effort to control increasing government costs resulting, in part, from pervasive medical error in the United States, Congress passed the Deficit Reduction Act (DRA) in 2006. Among its other provisions affecting domestic entitlement programs, the DRA required CMS to compile a list of conditions that result in high costs that can reasonably be prevented. CMS developed a list of Hospital Acquired Conditions (HACs) and implemented policies denying or limiting payment by CMS for treatment made necessary by HACs. The list of HACs is lengthy, but some notable examples include falls, catheter-associated urinary tract infections, unplanned retained foreign objects after surgery, and significant pressure ulcers. While HACs may not be the result of error or negligent care, CMS reimbursement consequences have raised the stakes significantly in medical error prevention. Since 2010, the Agency for Healthcare Research and Quality (AHRQ) has been collecting information on HACs. In its most recent National Scorecard on Hospital-
Acquired Conditions, updated in January 2019, AHRQ data showed that from 2014 to 2017, HACs fell by 13 percent, saving about 20,700 lives and about $7.7 billion in healthcare costs.9

**Root Cause Analysis (RCA)**

When a sentinel event occurs, TJC requires a Root Cause Analysis (RCA) to be completed within 45 days. While in Florida, AHCA’s definition of an adverse event is not necessarily synonymous with TJC’s sentinel event; most adverse events undergo RCA. The first step involved in RCA is gathering the information and circumstances surrounding the event by using a multidisciplinary team that includes leadership and all those involved in the event. The causal factors identified drive the corrective action plan, and specific individuals and departments are assigned to be the responsible stakeholders for the corrective actions. Once solutions to the patient safety event are determined and implemented, timely follow-up to assess effectiveness is essential.

Not all sentinel events occur because of medical errors, and not all medical errors result in sentinel events. Because reporting is voluntary, reported RCA events represent only a small proportion of actual events. Of the sentinel events reported to TJC through RCA for the past several years, human factors, leadership, and communication are consistently the top three root causes. Since 1998, TJC has published “Sentinel Event Alerts” which address root causes and risk reduction strategies of sentinel events. Many of the strategies and recommendations have since become TJC hospital standards of accreditation.

The proactive counterpart to RCA, Failure Mode and Effect Analysis (FMEA) is a method for evaluating processes before an adverse event occurs by identifying where and how failures might occur. A FMEA team, comprised of individuals involved in the process, reviews the steps in the process to identify and evaluate those parts of the process most in need of change. Prioritizing is important to ensure systems and processes with the highest likelihood of patient or staff harm are addressed first.

In 2015, the National Patient Safety Foundation published “RCA²: Improving Root Cause Analyses and Actions to Prevent Harm.” Recognizing the value of the RCA process, but noting its inconsistent success, RCA² incorporated a second “A” to the RCA acronym: Action. Root Cause Analyses and Action emphasizes the importance of positive action to prevent recurrence of future patient safety events, in addition to techniques to identify causes of past events and remedial measures. “The most important step in the RCA² process is the identification of actions to eliminate or control system hazards or vulnerabilities identified in the causal statements.” Once identified, the focus turns to the development of strong action plans with support of facility leadership. Numerous patient safety organizations, including TJC, have endorsed the use of RCA².

**Patient Safety**
In 2005, Congress passed the Patient Safety and Quality Improvement Act (PSQIA) which established federal privileges and confidentiality for patient safety work product reported to a Patient Safety Organization (PSO).\textsuperscript{1,12} As of November 2020, there are a total of 94 listed PSOs, with 56 serving providers across the nation.\textsuperscript{13} The legal protections of the PSQIA have significantly enhanced provider willingness to share patient safety and performance improvement information to facilitate the development and dissemination of preventive measures and best practices.

In 2002, TJC established the National Patient Safety Goals program to help accredited organizations focus on specific areas of patient safety concern. For 2021, TJC identified the following National Patient Safety Goals for hospitals:

1. Identify patients correctly
2. Improve staff communication
3. Use medicines safely
4. Use alarms safely
5. Prevent infection
6. Identify patient safety risks
7. Prevent mistakes in surgery\textsuperscript{14}

The first goal addresses the issue of reliably identifying the patient for whom service or treatment is intended and matching the service or treatment to that patient using acceptable identifiers, including their name, identification number, or telephone number. Two identifiers must be used when administering medications or blood products. The second goal is to improve the effectiveness of communication among caregivers, focusing on prompt communication of critical test results to the appropriate caregiver so that indicated treatment can be started immediately. The third National Patient Safety Goal promotes reducing or eliminating errors involving medication administration. The fourth goal is the safe use of critical alarms which addresses issues such as overuse. Overuse of alarms may confuse or desensitize staff to critical alerts. The fifth goal is to reduce infections in healthcare facilities, including post-operative infections, central line infections, and urinary tract infections from the use of catheters. Prevention and control strategies must be tailored to the specific needs of each hospital, based on its own risk assessment. The sixth goal is to identify patient safety risks, including patient assessments for suicide risk, which is a frequently reported sentinel event. Identification of individuals at risk for suicide while under the care of, or following discharge from, a healthcare organization is an important step in protecting at-risk individuals. The final National Patient Safety Goal is the prevention of mistakes during surgery. Having a pre-procedure verification process and performing a time-out with the operating room team before anesthesia is administered to ensure the correct procedure, for the correct patient, at the correct site, is a recognized standard of practice. Marking the location of the surgery is also recommended.

Patient safety is also a Florida statutory requirement. Under Florida Statute 395.1012,\textsuperscript{15} each licensed facility is required to adopt a patient safety plan. Hospitals receiving reimbursement from CMS must comply with the CMS Conditions of Participation, and it is sufficient to, “develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.”\textsuperscript{16} Each licensed facility must also appoint a
patient safety officer and a patient safety committee, that includes at least one person who is neither employed by nor practicing in the facility, to promote the health and safety of patients by evaluating patient safety measures of the facility and implementing the patient safety plan.\textsuperscript{15}

**Diagnostic Errors**

Diagnosis is the foundation upon which all healthcare services and treatment rest. It is through correct diagnosis that subsequent healthcare decisions are made. Building upon *To Err is Human*, IOM published *Improving Diagnosis in Healthcare* in 2015, revealing the occurrence of diagnostic errors had been largely underestimated and that most patients would suffer at least one diagnostic error in their lifetime. Noting numerous conflicting definitions of diagnostic error in the healthcare industry, IOM endorses a patient-centered definition: “failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.”\textsuperscript{17} Taking some inspiration from the TJC National Patient Safety Goals, the IOM outlined eight goals to reduce diagnostic error and improve diagnosis:

- Facilitate more effective teamwork in the diagnostic process among healthcare professionals, patients, and their families.
- Enhance healthcare professional education and training in the diagnostic process.
- Ensure that health information technologies support patients and healthcare professionals in the diagnostic process.
- Develop approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance.
- Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses.
- Design a payment and care delivery environment that supports the diagnostic process.
- Provide dedicated funding for research on the diagnostic process and diagnostic errors.\textsuperscript{17}

Diagnostic errors cause harm by preventing or delaying the appropriate treatment or providing unnecessary or harmful treatment. In the outpatient setting, it is estimated that each year, five percent of adults will experience a diagnostic error. In the hospital setting, diagnostic errors are estimated to account for 6-17 percent of adverse incidents each year.\textsuperscript{17} Diagnostic errors are also the leading type of paid medical malpractice claims and twice as likely to have caused the patient’s death, compared to other claims.\textsuperscript{18} In a 2013 study analyzing 25 years of data submitted to the National Practitioner Data Bank, diagnostic errors were the highest claim type at 28.6 percent and accounted for 35.2 percent of total payments, which was also the highest proportion. Diagnostic errors were the leading cause of claims-associated death and disability. After adjusting for inflation, diagnosis-related payments totaled $38.8 billion.\textsuperscript{18}

**Misdiagnosed Conditions**
Recognizing the paramount importance of timely and accurate diagnosis of medical conditions, the Florida Board of Medicine requires continuing education for physician license renewals to include information relating to the five most misdiagnosed conditions during the previous biennium. Effective March 2, 2020, the five most misdiagnosed conditions include:

- cancer related conditions,
- gastroenterology related conditions,
- OB/GYN related conditions,
- cardiology related conditions, and
- neurological conditions.

**Cancer Related Conditions**

In 2020, the American Cancer Society estimated there will be 1.8 million new cancer cases diagnosed, and 606,520 cancer deaths in the United States. Florida had one of the highest state diagnosis rates at 150,500. The top three most diagnosed new cancers in Florida were female breast, lung and bronchus, and prostate cancer.

“Misdiagnosis” of cancer includes missed diagnosis, wrong diagnosis, and delayed diagnosis. In one case presented to the Board of Medicine, the patient’s chest x-ray revealed a focal area of increased density in the lung. The physician documented the findings, as well as the patient’s reluctance to undergo a CT scan, citing lack of insurance. Six years later, new diagnostic studies revealed a small infiltrate of the lung and radiographic follow-up was recommended. The physician documented a plan to follow up, but failed to do so, and failed to order additional studies. Over a year later, the patient presented to another physician, who ordered a CT of the chest, which revealed a malignant appearing mass in the right lung. A biopsy later revealed adenocarcinoma.

The Florida Board of Medicine found that the initial ordering physician failed to practice medicine with the level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by a reasonably prudent similar healthcare provider. The physician was also cited for keeping illegible records, failing to maintain a concise ongoing problem list, and not documenting tests ordered, radiographic follow up, or crucial conversations with the patient.

**Gastroenterology Related Conditions**

In a 2020 study by the Clinical Gastroenterology and Hepatology Journal on medical malpractice, gastrointestinal (GI) claims submitted to one national insurer from 1985 to 2005 were analyzed, and found that GI does not rank high among subspecialties in malpractice claims. Of 12,367 total claims in just one year, 233 or 1.8 percent were classified as a GI claim. Despite the few malpractice claims, the American Gastroenterological Association has created a task force on Quality in Practice and has published recommendations that seek to improve the relationship between quality of care and reimbursements by supporting cost-effective and high quality of care.
In one adverse event reviewed by the Board of Medicine, the patient was consented to undergo a colonoscopy with sedation. Several attempts were made to obtain IV sedation by inserting the needle into the patient’s arms and hands. The IV infiltrated resulting in redness and puffiness in the patient’s arm, but was finally placed. Unfortunately, the provider did not obtain adequate sedation because the patient was experiencing pain during the procedure and asked the provider to stop. The provider continued despite the patient’s loud and repeated cries and requested that the nurses hold the patient down against her will. The medical record failed to document any of these events. The Florida Board of Medicine found that the provider performed a wrong procedure by having performed a colonoscopy without adequate sedation, when the consent was for a colonoscopy with sedation. It was also considered an authorization procedure by virtue of the patient having withdrawn her consent repeatedly by asking the provider to stop. The provider received a reprimand from the Board of Medicine, was fined $15,000, and ordered to perform 100 hours of community service.

**OB/GYN Related Conditions**

Events involving obstetric complications are often related to lapses in decision making that are not identified until reviewed in hindsight. The effects of these lapses can result in injury to both the mother and the child, and therefore, the risks and the resulting toll are amplified and can range from a compromised infant with transitory issues to maternal and fetal death. A benchmarking study of over 800 births found that substandard clinical judgment by healthcare providers contributes to the 77 percent of events. Very often, these events take place during the second, or active, stage of labor and the failure to respond to fetal distress in a timely manner.

In one recent event reviewed by the Florida Board of Medicine, a patient was at 40 weeks and four days gestation with history of a prior cesarean section and the infant had previously been noted to be in breech position. The patient desired a vaginal birth after cesarean (VBAC), but was not advised of the risks of vaginal delivery given her history and breech presentation. The physician ordered Misoprostol, which is contraindicated for VBAC patients due to the increased risk of uterine rupture of dehiscence, and also ordered Pitocin, which is contraindicated for VBAC patients with breech presentation. The physician failed to document the patient’s progress in the medical record, and despite clear signs of fetal distress, the patient was allowed to continue to labor and delivered a stillborn infant two hours later. The physician was required to pay a fine of $20,000, complete 15 hours of continuing medical education, and their license was suspended for four months.

**Cardiology Related Conditions**

There has been much publicity recently regarding the failure to diagnose heart disease, particularly in women, and the historical and cultural reasons for this disparity. According to the Centers for Disease Control and Prevention, heart disease is the leading cause of death for women in the United States. Almost 64 percent of women who die suddenly from heart disease have no previous symptoms, making it more difficult to diagnose.

The Florida Board of Medicine reviewed an incident of a patient who presented to the emergency room with unstable vital signs and complaints of left arm, side, and knee pain subsequent to a
fall. Her history was positive for myocardial infarction, coronary artery bypass grafts, hypertension, and myelofibrosis. The emergency department physician incorrectly interpreted the chest x-ray, despite the radiology report indicating pleural effusion and left lower lobe atelectasis and an abnormal electrocardiogram showing tachycardia. The only treatment rendered was a 500 mL bolus of normal saline. Without further evaluation or timely intervention, the patient continued to deteriorate, coded, and expired.

The Board determined the physician failed to meet the standard of care by failing to properly diagnose and treat the patient, failing to correctly interpret the chest x-ray, failing to address the abnormal electrocardiogram, and failing to recognize a hemothorax in a patient with left sided chest trauma with hypotension and tachycardia. The physician was ordered to pay an administrative fine of $10,000, complete five hours of risk management, present a one-hour lecture to the entire medical staff of the hospital on diagnosis and treatment of hemothorax, and pay investigative costs of $1,073.

Neurological Conditions

A retrospective study of diagnostic errors in neurological emergencies found that these incidents can be classified into three categories: knowledge gaps, cognitive errors, and systems-based errors. Misdiagnosis of cerebellar lesions and erroneous radiology resident interpretations of neuroimaging were the most common mistakes nationwide. Further, neurologic conditions can be challenging to diagnose, because there are a number of diseases that may manifest with neurologic symptoms. These symptoms are even more difficult to diagnose in minors, impaired patients, or those who are differently abled because they may not be able to accurately describe their symptoms. A detailed physical examination and past medical history, as well as imaging, and timely consultation from the neurology service are critical to an accurate diagnosis.

In a related incident before the Florida Board of Medicine, a patient presented with severe headaches, confusion, and dizziness, as well as a history of previous shunt insertion for hydrocephalus. A CT scan revealed hydrocephalus with shunt catheter in place and no signs of acute intracranial hemorrhage. The patient was diagnosed with a malfunctioning shunt and was taken to the operating room where the old shunt was replaced. A left frontal burr hole was also made. The physician documented in the operative report that he had evacuated blood from the patient’s head and informed the patient. Post-operatively, the patient was obtunded and having seizures, requiring ventilator-assistance. The investigation revealed the physician performed an unnecessary procedure by drilling a burr hole that was not indicated and deceptively documented that a hematoma was evacuated.

Conclusion

Medical errors will never be completely eliminated, but by utilizing available patient safety data, adhering to National Patient Safety Goals, and utilizing tools such as RCA to identify those areas of greatest patient safety concern, providers can play an important role in reduction and prevention. As the preceding examples illustrate, commonly encountered challenges with the stages of the diagnostic process can be minimized by consistently performing thorough histories.
and physicals, promptly following up on diagnostic tests, and communicating findings to patients. Medical record documentation is also an extremely important tool for communication between multiple services and healthcare providers involved in a patient’s care. Failure to keep appropriate written records is a frequent cause of Florida Board of Medicine disciplinary action and a hindrance to the provision of appropriate care. The benefits of the electronic health record, including diagnostic decision support, clinical reminders, and system alerts, have the potential to help avert the risk of diagnostic missteps.

References:


8. Makary MA, Daniel M. Medical error—the leading cause of death in the US. BMJ. 2016 May 3;353:i2139.


19. 2020 Florida Administrative Code, Florida Department of State. Department of Health: Board of Medicine- License Renewal and Reactivation; Continuing Education. F.A.C. 64B8-13.005.


1. An event that could have had an adverse patient consequence but did not because a provider or a process served to intervene and prevent that event from reaching the patient or causing harm is known as:
   a. Latent error
   b. Near miss
   c. Negligence
   d. Never event

2. The Institute of Medicine has estimated as many as ______ people die every year as a result of preventable medical errors.
   a. 86,000
   b. 90,000
   c. 94,000
   d. 98,000

3. When one of the three identified never events occurs involving a Medicare beneficiary, Medicare will only cover half of the costs as they are not a reasonable and necessary treatment for the Medicare beneficiary’s medical condition.
   a. True
   b. False

4. When did Congress pass the Patient Safety and Quality Improvement Act (PSQIA)?
   a. 2003
   b. 2004
   c. 2005
   d. 2006

5. Per The Joint Commission, when must a root cause analysis be completed for a Sentinel Event?
   a. Within two weeks
   b. Within one month
   c. Within 45 days
   d. By the end of the following month

6. Which of the following are required to report statutorily defined adverse events to the Florida Agency for Health Care Administration (AHCA) or Department of Health (DOH)?
   a. Hospitals
   b. Ambulatory Surgical Centers
   c. Physician Offices
   d. Nursing Homes
   e. All of the above
   f. A, B, & C above
   g. A & B above
7. The Joint Commission defines a _____ event as a patient safety event that reaches a patient and results in death, permanent harm, or severe temporary harm and intervention required to sustain life.
   a. Latent
   b. Neglectful
   c. Negligent
   d. Sentinel

8. RCA stands for:
   a. Real Cause Audit
   b. Root Cause Analysis
   c. Reason Cause Analysis
   d. Root Cause Audit

9. Diagnostic errors are the leading type of paid medical malpractice claims.
   a. True
   b. False

10. What are the Florida Board of Medicine's most misdiagnosed conditions as of March 2020?
    a. Cardiovascular disease, urologic, cancer, surgical, and OB/GYN related conditions
    b. Meningitis, COVID-19, Tuberculosis, neurological, and surgical related conditions
    c. Cancer, gastroenterology, neurological, OB/GYN, and cardiology related conditions
    d. Brain injury, fractures, surgical complications, appendicitis, stroke

EVALUATION:
1. What will you do differently as a result of this information?
   ______________________________________________________
   ______________________________________________________

2. How will you apply what you learned to your practice?
   ______________________________________________________
   ______________________________________________________
   ______________________________________________________
   ______________________________________________________

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Circle one number using the following scale: 1= Strongly Agree to 5= Strongly Disagree

The article met the stated objectives: 1 2 3 4 5
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