Preventing Medical Errors and Improving Patient Safety

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Abstract
Following a number of studies on the high incidence of medical errors and increasing efforts to improve patient safety, the prevention and reduction of medical errors has become a priority for federal and state regulatory agencies and healthcare providers across the nation. It is important for physicians to understand how federal, state, and independent regulatory agencies have shaped the patient safety movement, provided an organized structure for identifying causes of medical errors, and developed effective preventive strategies. Based on national reports of patient safety events and malpractice data, federal, state, and independent regulatory agencies have established patient safety goals for the prevention of medical errors.

Introduction

The Health and Medicine Division, formerly known as 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*, in which a medical error is defined as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”\(^1\) The IOM 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.\(^2\) If correct, this statistic places medical error third among the leading causes of death in the United States, behind heart disease and cancer.\(^2\) 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.
Error Reduction and Prevention

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 the Centers for Medicare and Medicaid Services (CMS) to compile a list of conditions that result in high costs and 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 current 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. AHRQ has found a downward trend in HACs of 17 percent from 2010 to 2014, and of 8 percent from 2014 to 2016. Based on these reductions, AHRQ estimates there were 350,000 fewer HACs from 2014 to 2016 alone, representing a savings of $2.9 billion in hospital savings and 8,000 inpatient deaths averted. In its most recent National Scorecard on Hospital-Acquired Conditions, updated in June 2018, AHRQ projects that between 2015 and 2019 there will be 1.8 million fewer patients with HACs, resulting in 53,000 fewer deaths and $19.1 billion in hospital savings.

At the state level, the Florida Board of Medicine has prescribed a range of disciplinary actions for a variety of medical errors, such as wrong site surgery, unplanned retained foreign objects, practicing beyond the scope permitted by law or competency, and gross or repeated malpractice. In addition, 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. 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. Licensed facilities must report specified adverse events 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. This 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 personnel who were directly involved in, or witnessed, an adverse event are also required on Code 15 reports. AHCA routinely forwards Code 15 reports to the DOH so that DOH may determine whether to initiate a practitioner investigation. AHCA also maintains an annual report of malpractice claims reported statewide.

Root Cause Analysis (RCA)

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 results in death, permanent harm, or severe temporary harm in which intervention is required to sustain life.\(^8\) 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. They are called "sentinel" because they signal the need for immediate investigation and response.

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. Hospital reporting of sentinel events to TJC is voluntary. Therefore, reported RCA events represent only a small proportion of actual events. Presently, the top ten sentinel events reported to TJC are: unintended retention of a foreign body; falls; wrong patient/site/procedure; suicide; delay in treatment; other unanticipated event; criminal event; medication error; operative or post-operative complications; and self-inflicted injury.\(^9\) 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 (NPSF), an independent, not-for-profit organization, published “RCA\(^2\): Improving Root Cause Analyses and Actions to Prevent Harm.” Recognizing the value of the RCA process, but noting its inconsistent success, RCA\(^2\) 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 RCA\(^2\) 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 RCA\(^2\).
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). As of November 2018, 56 listed PSOs serve providers in Florida. 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 its National Patient Safety Goals program to help accredited organizations focus on specific areas of patient safety concern. For 2019, 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

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. Acceptable patient identifiers include 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. The focus is prompt communication of critical test results to the appropriate caregiver so that indicated treatment can be started immediately. TJC proposes the development and implementation of written procedures for managing the results of critical tests and diagnostic procedures.

The third National Patient Safety Goal promotes reducing or eliminating errors involving medication administration. Since 2005, there have been more than 500 sentinel events related to medication error.

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 Joint Commission requires hospitals to establish alarms as an organizational priority and identify the most important alarms to manage, based on their own internal situations.

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. Between 2005 and 2017, there were more than 1,600 sentinel events reported to TJC involving suicide. 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 seventh National Patient Safety Goal is the prevention of mistakes during surgery. There were more than 1,400 wrong patient, wrong site, or wrong procedure surgeries voluntarily reported to TJC from 2005 through the fourth quarter of 2017. The figure nearly doubled from 2014 to 2015, from 73 reported events to 120. Another 121 wrong patient, wrong site, or wrong procedure events were reported in 2016. This number decreased slightly in 2017 to 95. 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, each licensed facility is required to adopt a patient safety plan. Hospitals receiving reimbursement from CMS must comply with the CMS Conditions of Participation, but may it is sufficient to, “develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.” Each licensed facility must also appoint a patient safety officer and a patient safety committee, which will include 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.

**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.” Taking some inspiration from 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.\(^\text{17}\)

According to that IOM study, 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.\(^\text{17}\)

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.\(^\text{18}\) In a 2013 study analyzing 25 years of data submitted to the National Practitioner Data Bank,\(^\text{18}\) 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.\(^\text{18}\)

**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.\(^\text{19}\) Effective September 10, 2018, the five most misdiagnosed conditions include:

- cancer related conditions,
- surgery complications,
- respiratory related conditions,
- OB/GYN related conditions, and
- cardiology related conditions.\(^\text{19}\)

It is important to look at each condition and actual Board of Medicine case scenarios.

**Cancer Related Conditions**

In 2018, the American Cancer Society estimated 1,735,350 new cancer cases were diagnosed, and 609,640 deaths were attributed to cancer in the United States.\(^\text{20}\) Florida had one of the highest state diagnosis rates at 135,170. The top three most diagnosed new cancers in Florida were female breast, lung and bronchus, and prostate cancer.\(^\text{20}\)

“Misdiagnosis” of cancer includes missed diagnosis, wrong diagnosis, and delayed diagnosis. In one case presented to the Board of Medicine, the patient underwent an x-ray of the chest that revealed a focal area of increased density in her 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 Board of Medicine found that the 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.

Surgery Complications

A surgical complication may encompass a number of usually preventable events throughout the patient’s care, including the actual surgery, the decision to operate, and the management of the patient following surgery. In one comparative benchmarking study of medical malpractice claims, it was found that the vast majority of surgical malpractice cases resulted from errors in clinical judgment, procedural errors (including poor technique), and communication gaps between providers, the patients, and their families. In one recent event before the Board of Medicine, a patient was scheduled to have a right thyroidectomy, due to a suspicious nodule found on his right thyroid. The surgeon mistakenly removed the patient’s left thyroid gland instead. The patient underwent another surgery to remove the right thyroid gland, and the error was disclosed to the patient. The surgeon was found to have performed a wrong site surgery and was fined by the Board. He was also required to pay the costs associated with the investigation, complete several hours of continuing medical education, and provide a lecture on the subject of wrong site procedures.

Respiratory Related Conditions

In one retrospective study of pulmonary embolism, over 30 percent of patients presenting to the emergency department had a delayed diagnosis. Patients were often sent home or admitted to the hospital with an incorrect diagnosis depending on their clinical presentation or other chronic coexisting medical conditions. The Board of Medicine reviewed the treatment of a patient who was sent to the emergency room (ER) from her physician’s office with shortness of breath and chest pain, to rule out a pulmonary embolism. The emergency room physician utilized a shortness of breath template and recorded no new vital signs. After ordering essentially non-diagnostic studies, the ER physician ordered antibiotics and potassium chloride to treat the diagnosis of cough and hypokalemia and discharged the patient. One week later, the patient died from a saddle pulmonary embolism. The physician was found to have practiced below the standard of care by failing to perform a proper history and physical, failing to order appropriate diagnostic studies, and failing to rule out pulmonary embolism. A letter of concern was issued by the Board of Medicine against the
physician’s license. She was also required to pay an administrative fine and the costs associated with the investigation, as well as completing several hours of continuing medical education on the diagnosis of pulmonary embolism. The physician was also required to complete courses on the subjects of risk management and quality medical record keeping.

**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 Board of Medicine, a patient was at 40 weeks and 4 days gestation with history of a prior cesarean section and this fetus 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 contracted 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 an administrative 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 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 of Medicine determined that 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.

**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 Board of Medicine disciplinary action and a hindrance to the provision of appropriate care. As more and more healthcare organizations transition to the electronic health record, the benefits of this technology, such as diagnostic decision support, clinical reminders, and system alerts, have the potential to help avert the risk of diagnostic missteps.

**References:**


4. Agency for Healthcare Administration. AHRQ National Scorecard on Hospital-Acquired Conditions Updated Baseline Rates and Preliminary Results 2014-2016 [Internet]. 2018 June [cited November 2018]. Available from:


19. 2018 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. What is the current number one sentinel event reported to the Joint Commission?
   a. Unintended retention of a foreign body
   b. Equipment defects
   c. Wrong patient surgery, wrong site surgery, wrong procedure surgery
   d. Infection

2. True or false: All sentinel events occur because of medical errors.
   a. True
   b. False

3. Which of the following is not one of the National Patients Safety Goals established by the TJC for 2019?
   a. Improve staff communication
   b. Prevent infection
   c. Discharge patients quickly
   d. Use medicines safely

4. According to the recent IOM study what percent of adults will experience a diagnostic error each year in the outpatient setting?
   a. 2 percent
   b. 3 percent
   c. 4 percent
   d. 5 percent

5. What are the Florida Board of Medicine’s most misdiagnosed conditions this biennium?
   a. Sepsis, cardiovascular disease, urologic disease, cancer, fetal distress
   b. Meningitis, Zika, Tuberculosis, neurological conditions
   c. Cancer, surgery, respiratory, OB/GYN, and cardiology related conditions
   d. Brain injury, fractures, surgical complications, appendicitis, blood dysplasia, Leukemia
6. “Misdiagnosis” of cancer includes which of the following?
   a. Missed diagnosis
   b. Wrong diagnosis
   c. Delayed diagnosis
   d. A and B above
   e. B and C above
   f. All of the above

7. True or false: Diagnostic errors are the leading type of paid medical malpractice claims.
   a. True
   b. False

8. What is the first step involved in Root Cause Analysis?
   a. Suspend the physicians involved with the error
   b. Gather the information and circumstances surrounding the event
   c. Discuss corrective actions with the providers involved
   d. Create a plan for handling future errors

9. A 2016 study published by Johns Hopkins University researchers suggests that _____ lives are lost every year as a result of medical errors.
   a. 231,000
   b. 241,000
   c. 251,000
   d. 261,000

10. 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 what year?
    a. 2003
    b. 2004
    c. 2005
    d. 2006