

# Medical Error Prevention and Root Cause Analysis

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- Read the enclosed course.
- Complete the questions at the end of the course.
- Return your completed Evaluation to NetCE by mail or fax, or complete online at [www.NetCE.com](http://www.NetCE.com). (If you are a physician or Florida nurse, please return the included Answer Sheet/Evaluation.) Your postmark or facsimile date will be used as your completion date.
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### Faculty

**Marjorie Conner Allen, BSN, JD**, received her Bachelor of Science in Nursing degree from the University of Florida, Gainesville, in 1984. She began her nursing career at Shands Teaching Hospital and Clinics at the University of Florida, Gainesville. While practicing nursing at Shands, she gave continuing education seminars regarding the nursing implications for dealing with adolescents with terminal illness. In 1988, Ms. Allen moved to Atlanta, Georgia where she worked at Egleston Children's Hospital at Emory University in the bone marrow transplant unit. In the fall of 1989, she began law school at Florida State University. After graduating from law school in 1992, Ms. Allen took a two-year job as law clerk to the Honorable William Terrell Hodges, United States District Judge for the Middle District of Florida. After completing her clerkship, Ms. Allen began her employment with the law firm of Smith, Hulsey & Busey in Jacksonville, Florida where she has worked in the litigation department defending hospitals and nurses in medical malpractice actions. Ms. Allen resides in Jacksonville and is currently in-house counsel to the Mayo Clinic Jacksonville.

### Faculty Disclosure

Contributing faculty, Marjorie Conner Allen, BSN, JD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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### Division Planners Disclosure

The division planners have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

### Audience

This course is designed for all licensed healthcare professionals.

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### **Special Approvals**

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

This course fulfills the Florida requirement for 2 hours of education on the Prevention of Medical Errors.

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### **Disclosure Statement**

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### **Course Objective**

The purpose of this course is to satisfy the requirement of the Florida law and provide all licensed healthcare professionals with information regarding the root cause process, error reduction and prevention, and patient safety.

### **Learning Objectives**

*Upon completion of this course, you should be able to:*

1. Describe how the Institute of Medicine defines “medical error.”
2. Describe the types of sentinel events the Joint Commission has identified.
3. Discuss what factors must be included in a root cause analysis in order for the Joint Commission to consider it “thorough” and “credible.”
4. Identify what types of adverse incidents must be reported to the Florida Agency for Healthcare Administration.
5. Identify the most common sentinel events reported to the Joint Commission.
6. Evaluate the most common misdiagnoses, as recognized by the Florida Board of Medicine, and outline the safety needs of special populations, including non-English-proficient patients.

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## INTRODUCTION

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The Institute of Medicine's (IOM) 1999 publication *To Err is Human: Building a Safer Health System*, illuminated the unfortunate reality of medical errors in the healthcare industry. The report reviewed the prevalence of medical errors in the United States and highlighted measures that should be taken to prevent them. Specifically, the authors of the report noted that at least 44,000 and perhaps as many as 98,000 Americans were dying in hospitals each year as a result of medical errors and many more were being seriously injured [1]. They further noted that, even when using the lower estimate of 44,000, deaths in hospitals due to medical errors exceeded the annual deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516) [1]. A 2016 report stated that the average number of annual in-hospital deaths attributable to medical error might actually be much higher, at around 400,000 [2]. This report places medical errors as the third leading cause of death in the United States. Certainly, these numbers must be balanced against the millions of admissions to hospitals in the United States, which is in excess of 35 million annually [1; 3].

It does appear that some progress has been made in the past decade. The Agency for Healthcare Research and Quality found a 17% decline in hospital-acquired conditions between 2010 and 2013, or 1.3 million fewer conditions and 50,000 fewer deaths than if the 2010 rate had remained steady [4]. Though the precise mechanism(s) responsible for this decline is not clear, it occurred following a concerted effort by federal agencies, organizations, and individual providers to curtail medical errors. However, the statistics indicate that medical errors continue to be an issue. Healthcare professionals should commit to continuing to pay greater attention to evaluating approaches for reducing errors and to building new systems to reduce the incidence of medical errors.

Spurred by a commitment to reducing medical error incidents, the Florida Legislature mandates that all healthcare professionals in Florida complete a two-hour course on the topic of prevention of medical errors [5]. This continuing education course is designed to satisfy the requirements of the Florida law and provide all licensed healthcare professionals with information regarding the root cause analysis process, error reduction and prevention, and patient safety, as well as information regarding the five most misdiagnosed conditions as determined by the Florida Board of Medicine.

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## DEFINING “MEDICAL ERROR”

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The IOM Committee on Quality of Healthcare in America defines error as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” [1]. It is important to note that medical errors are not defined as intentional acts of wrongdoing and that not all medical errors rise to the level of medical malpractice or negligence. Errors depend on two kinds of failures: either the correct action does not proceed as intended, which is described as an “error of execution,” or the original intended action is not correct, which is described as an “error of planning” [1]. A medical error can occur at any stage in the process of providing patient care, from diagnosis to treatment, and even while providing preventative care. Not all errors will result in harm to the patient. Medical errors that do result in injury are sometimes called preventable adverse events or sentinel events—sentinel because they signal the need for immediate investigation and response [6].

Preventable adverse events or sentinel events are defined as those events that cause an injury to a patient as a result of medical intervention or inaction on the part of the healthcare provider whereby the injury cannot reasonably be said to be related to the patient's underlying medical condition. Thus, for example, if a patient has a surgical procedure and dies postoperatively from pneumonia, the patient has suffered an adverse event. But was that adverse event preventable; was it caused by medical intervention or inaction? The specific facts of this case must be analyzed to determine whether the patient acquired the pneumonia as a result of poor handwashing techniques of the medical staff (i.e., an error of execution), which would indicate a preventable adverse event, or whether the patient acquired the pneumonia because of age and comorbidities, which would indicate a nonpreventable adverse event.

Healthcare professionals can learn much by closely scrutinizing and evaluating adverse events that lead to serious injury or death. The evaluation of such events would also enable healthcare professionals to improve the delivery of health care and reduce future mistakes. In addition, healthcare professionals should have a process in place to evaluate those instances in which a medical error occurred and did not cause harm to the patient. By reviewing these processes, healthcare professionals are afforded the unique opportunity to identify system improvements that have the potential to prevent future adverse events. The Joint Commission, recognizing the importance of analyzing both preventable adverse events and near-misses, has established guidelines for recognizing these events and requires healthcare facilities to conduct a root cause analysis to determine the underlying cause of the event [7].

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## ROOT CAUSE ANALYSIS PROCESS

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The Joint Commission is a national organization with a mission to improve the quality of care provided at healthcare institutions in the United States. It accomplishes this mission by providing accredited status to healthcare facilities. Accreditors play an important role in encouraging and supporting actions within healthcare organizations by holding them accountable for ensuring a safe environment for patients. Healthcare organizations should actively engage in a cooperative relationship with the Joint Commission through this accreditation process and participate in the process to reduce risk and facilitate desired outcomes of care.

The Joint Commission defines a sentinel event as “an unexpected occurrence involving the death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase ‘or the risk thereof’ includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome” [6]. Root cause analysis, as defined by the Joint Commission, is “a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event” [6].

The following subsets of sentinel events are subject to review by the Joint Commission [6]:

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition
- or
- The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):

- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge
- Unanticipated death of a full-term infant
- Abduction of any patient receiving care, treatment, and services
- Discharge of an infant to the wrong family
- Rape, assault (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment, and services
- Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the healthcare organization
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (e.g., ABO, Rh, other blood groups)
- Invasive procedure, including surgery, on the wrong patient or wrong site
- Unintended retention of a foreign object in a patient after surgery or other invasive procedures
- Severe neonatal hyperbilirubinemia (bilirubin >30 mg/dL)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity

Alternatively, the following examples are events that are NOT considered reviewable under the Joint Commission’s sentinel event policy [6]:

- Any close call (“near miss”)
- Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function, whichever is the longer period
- Any sentinel event that has not affected a recipient of care (e.g., patient, individual, resident)
- Medication errors that do not result in death or major permanent loss of function
- Suicide other than in an around-the-clock care setting or following elopement from such a setting
- A death or loss of function following a discharge against medical advice
- Unsuccessful suicide attempts unless resulting in major permanent loss of function
- Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae

(For further definition of terms, please refer to the Joint Commission’s Sentinel Event Policy and Procedures at [https://www.jointcommission.org/sentinel\\_event\\_policy\\_and\\_procedures](https://www.jointcommission.org/sentinel_event_policy_and_procedures).)

As part of the accreditation requirement, the Joint Commission requires that healthcare organizations have a process in place to recognize these sentinel events, conduct thorough and credible root cause analyses that focus on process and system factors, and document a risk-reduction strategy and internal corrective action plan that includes measurement of the effectiveness of process and system improvements to reduce risk [6]. This process must be completed within 45 days of the organization having become aware of the sentinel event.

The Joint Commission will consider a root cause analysis acceptable for accreditation purposes if it focuses primarily on systems and processes, not individual performance [6]. In other words, the healthcare organization should minimize the individual blame or retribution for involvement in a medical error. In addition, the root cause analysis should progress from special causes in clinical processes to common causes in organizational processes, and the analysis should repeatedly dig deeper by asking why, then, when answered, why again, and so on. The analysis should also identify changes that can be made in systems and processes, either through redesign or development of new systems or processes, which would reduce the risk of such events occurring in the future. The Joint Commission requires that the analysis be thorough and credible. To be considered thorough, the root cause analysis must include [6]:

- A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence
- Analysis of the underlying systems and processes through a series of “why” questions to determine where redesign might reduce risk
- Inquiry into all areas appropriate to the specific type of event
- Identification of risk points and their potential contributions to this type of event
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

To be considered credible, the root cause analysis must meet the following standards [6]:

- The organization’s leadership and the individuals most closely involved in the process and systems under review must participate in the analysis.
- The analysis must be internally consistent; that is, it must not contradict itself or leave obvious questions unanswered.
- The analysis must provide an explanation for all findings of “not applicable” or “no problem.”
- The analysis must include consideration of any relevant literature.

Finally, as previously discussed, after conducting this root cause analysis, the organization must prepare an internal corrective action plan. The Joint Commission will accept this action plan if it identifies changes that can be implemented to reduce risk or formulate a rationale for not undertaking such changes, and if, where improvement actions are planned, it identifies who is responsible for implementation, when the action will be implemented, and how the effectiveness of the actions will be evaluated [6].

## **FLORIDA LAW**

Healthcare professionals have an obligation to report adverse events to leadership and ensure that organizations have processes in place to satisfy the Joint Commission requirement. In Florida, certain serious adverse incidents must also be reported to Florida’s Agency for Health Care Administration (AHCA). Florida law requires that licensed facilities, such as hospitals, establish an internal risk management program and, as part of that program, develop and implement an incident reporting system, which imposes an affirmative duty on all healthcare providers and employees of the facility to report adverse incidents to the risk manager or to his or her designee. The risk manager must receive these incident reports within 3 business days of the

incident and, depending on the type of incident, the risk manager may have to report the incident to AHCA within 15 days of receipt of the report.

Florida Statute 395.0197 specifically defines an adverse incident as [8]:

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, and:

- a) Results in one of the following injuries:
  - 1. Death;
  - 2. Brain or spinal damage;
  - 3. Permanent disfigurement;
  - 4. Fracture or dislocation of bones or joints;
  - 5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
  - 6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
  - 7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident
- b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;

- c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through informed-consent process; or
- d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Between July 2015 and July 2016, the Florida AHCA reported that a total of 151 deaths occurred as a result of hospital error, 27.7% of 545 adverse incidents reported for the year. The next most common incidents during this period were surgical procedures unrelated to the patient's diagnosis or medical needs (23.5%), surgical procedure to remove foreign object from a previous surgical procedure (19.3%), surgical repair of injuries or damage resulting from a planned surgical procedure (9%), and surgical procedure performed on the wrong site (7.5%) [9]. The following adverse incidents must be reported to the AHCA within 15 calendar days after their occurrence [8]:

- The death of a patient
- Brain or spinal damage to a patient
- The performance of a surgical procedure on the wrong patient
- The performance of a wrong-site surgical procedure
- The performance of a wrong surgical procedure
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process

- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Each incident will be reviewed by the AHCA, who will then determine the penalty to be imposed upon the responsible party [8]. All Florida health-care professionals who practice in licensed facilities should familiarize themselves with these requirements and ensure that the facility in which they practice has processes in place to ensure compliance.

Unlike Florida's mandatory reporting of serious adverse incidents, the Joint Commission recommends that healthcare organizations voluntarily report sentinel events, and it encourages the facilities to communicate the results of their root cause analyses and their corrective action plans. As a result of the sentinel events that have been reported, the Joint Commission has compiled Sentinel Event Alerts. These alerts are intended to provide healthcare organizations with important information regarding reported trends and, by doing so, highlight areas of potential concern so an organization may review its own internal processes to maximize error reduction and prevention with regard to a particular issue [7].

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## ERROR REDUCTION AND PREVENTION

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Between 2005 and 2015, the Joint Commission reviewed 9,193 sentinel events [11]. Some events, such as fire, impacted multiple patients. Sentinel event reviews during this time period were frequently conducted for unintended retention of a foreign body; wrong-patient, wrong-site, wrong-procedure surgery; delay in treatment; operative and postoperative complications; patient suicide; patient fall; and medication error [11].

## UNINTENDED RETENTION OF A FOREIGN BODY

In 2014–2015, the most frequently reported sentinel event reported to the Joint Commission was unintended retained foreign objects [10]. The prevalence of these events has remained relatively stable since 2009, indicating that preventing these errors remains difficult for practitioners and facilities. The most commonly retained items are sponges, followed by catheter guidewires and other (a broad category encompassing a wide variety of items) [10].

In addition to harming patients and contributing to distrust in the medical system, the unintended retention of foreign objects significantly contributes to patient care costs [13]. The average total cost of care related to unintended retained foreign objects is \$166,000 to \$200,000 [13].

According to the sentinel event data, the most common root causes of unintended retained foreign objects reported to the Joint Commission are [13]:

- The absence of policies and procedures
- Failure to comply with existing policies and procedures
- Problems with hierarchy and intimidation
- Failure in communication with physicians
- Failure of staff to communicate relevant patient information Inadequate or incomplete education of staff

## WRONG-SITE SURGERY

Operating on the wrong part of a patient's body is an obvious sign that there is a problem in the operating room system. Interestingly, wrong-site surgery occurred more commonly in orthopedic procedures than in all other surgical specialties combined. The American Academy of Orthopaedic Surgeons takes this issue seriously, and it has taken special steps to eliminate the problem. For example, it recommends that a surgeon sign their initials at the correct site of surgery with an indelible pen. Unless the initials are visible, the surgeon should not make an incision [12]. Writing "NO" in large black letters on the side not to be operated on was



suggested in the past, but this is discouraged due to possible confusion with the surgeon's initials. In spinal surgery, the Academy recommends that an intraoperative radiograph and radiopaque marker be used to determine the exact vertebral level of spinal surgery [12]. Whatever the mechanism used to prevent and reduce the incidence of this error, it is clear that this is not just the surgeon's problem. All of the operating room personnel, including physicians, nurses, technicians, anesthesiologists, and other preoperative allied health personnel, should monitor procedures to ensure verification procedures are followed, especially for high-risk procedures.

Due to the prevalence of wrong-site, wrong-procedure, and wrong-person surgeries, the Joint Commission, along with more than 50 professional healthcare organizations, convened two summits to help reduce the occurrence of these errors. The first summit, convened in 2003, developed a Universal Protocol that consisted of the following: a preprocedure verification process; marking the operative/procedure site with an indelible marker; taking a "time-out" with all team members immediately before starting the procedure; and adaptation of the requirements to all procedure settings, including bedside procedures. However, the incidence of wrong-site surgeries continued to increase, and in 2007 and 2010, additional summits were organized to pinpoint barriers in compliance and discover new strategies to eliminate these errors [14]. As of 2016, the Universal Protocol has been incorporated into the National Patient Safety Goal chapter of the Joint Commission accreditation manual [15].

### **DELAYS IN TREATMENT**

According to the Joint Commission, more than half of all reported delays in treatment sentinel events in 2010–2014 resulted in patient death [16]. It is important to keep in mind that delays in treatment can occur in any healthcare setting. The most common reason for a delay in treatment is misdiagnosis; however, delays can also result from delayed test results, physician availability, delayed administration of ordered care, incomplete treatment, and even inability to get an initial appoint-

ment or follow-up appointment in a timely manner [16]. The main root causes contributing to delays in treatment are inadequate assessments, poor planning, communication failures, and human factors. Recommendations from the Joint Commission include avoiding cognitive shortcuts, improving health information technology, incorporating diagnostic checklists into the electronic record, promoting provider-to-provider communication, engaging leadership in developing solutions, focusing organization attention on the scheduling process and on ordering tests and reporting test results, improving access to care, implementing a standardized communications method, maintaining adequate staffing levels, and increasing patient and family engagement/activation [16].

### **OPERATIVE AND POSTOPERATIVE COMPLICATIONS**

Many of the sentinel events reported to the Joint Commission regarding operative and postoperative complications occurred in relation to nonemergent procedures, such as interventional imaging and/or endoscopy, tube or catheter insertion, open abdominal surgery, head and neck surgery, orthopedic surgery, and thoracic surgery [17]. The majority of the reporting healthcare facilities cited miscommunication as the primary root cause. Other identified causes include failure to follow established procedures, incomplete preoperative assessment, inconsistent postoperative monitoring procedures, and failure to question inappropriate orders. In order to reduce the risk, reporting facilities have identified a number of strategies, including improving staff orientation and training, increasing educational opportunities for physicians, clearly defining expected channels of communication, and monitoring consistency of compliance with procedures. Healthcare facilities should review postoperative patient monitoring procedures to ensure an adequate level appropriate to the needs of the patient, regardless of the setting (e.g., operating room, endoscopy suite, radiology department) [17]. Based upon these findings, it is clear that direct communication among healthcare providers is key to preventing operative and

postoperative complications. Healthcare facilities should provide more staff education regarding preventative measures, and healthcare providers can do their part by engaging in a healthy and mutual respect for all of the members of the healthcare team [17].

## **PATIENT SUICIDE**

Of the estimated 30,000 suicides that occur every year in the United States, 5% to 6% occur in hospitals [60]. Times of care transition are particularly risky, with a 200% increase in risk in the week after discharge from a psychiatric facility; the elevated risk continues for four years [18]. Other risk factors include previous suicide attempt or self-injury, mental or emotional disorders, history of trauma or loss, serious illness or chronic pain, substance use disorder, social isolation, and access to lethal means.

The most common root cause documented for patient suicide reported between 2010 and 2014 was shortcomings in assessment, most commonly psychiatric assessment [18]. In addition, nearly 25% of behavioral health facilities accredited by the Joint Commission were found noncompliant with the requirement to conduct a adequate suicide risk assessment in 2014.

The Joint Commission has recommended a number of risk reduction strategies, including [18]:

- Review each patient's personal and family medical history for suicide risk factors.
- Screen all patients for suicide ideation, using a brief, standardized, evidence-based screening tool.
- Review screening questionnaires before the patient leaves the appointment or is discharged.
- Establish a collaborative, ongoing, and systematic assessment and treatment process with the patient involving the patient's other providers, family, and friends, as appropriate.

- To improve outcomes for at-risk patients, develop treatment and discharge plans that directly target suicidality.
- Educate all staff in patient care settings about how to identify and respond to patients with suicide ideation.
- Document decisions regarding the care and referral of patients with suicide risk.

A simple review of these measures demonstrates that healthcare providers can avoid the devastating impact of an inpatient suicide by implementing fairly routine preventative strategies, such as removing harmful items and careful screening through the admission and discharge process.

## **PATIENT FALLS**

Patient falls are a constant challenge in healthcare facilities. Patients who are at highest risk include the elderly, those who have an altered mental status due to chronic mental illness or acute intoxication, and those who have a history of prior falls. It is obvious from these factors that a thorough and complete patient history may be the key to identifying those at risk. The root causes of those patient falls that healthcare facilities identified as sentinel events and reported to the Joint Commission included inadequate assessment, communication failures, lack of adherence to protocols and safety practices, inadequate staff orientation, supervision, staffing levels or skill mix, deficiencies in the physical environment, and lack of leadership [19]. Risk reduction strategies to these root causes are fairly straightforward, although in practice, preventing falls is difficult. The most important are the use of a standardized assessment tool to identify fall and injury risk factors, assessing an individual patient's risks that may not have been captured through the tool, and interventions tailored to an individual patient's identified risks [19].

Because patient falls often result in morbidity, mortality, immobility, and early nursing home placement for patients, it is imperative that health-care facilities initiate adequate fall prevention programs, which will ultimately reduce injuries. Failure to do so will result in a spiraling increase in the number of falls in healthcare facilities, particularly among the elderly who are at highest risk. As more Americans live beyond 65 years of age, the need to develop mobility protocols and programs to reduce the risk of falls and injuries for the older adult grows more urgent.

## MEDICATION ERRORS

Unquestionably, medication errors are one of the most common causes of avoidable harm to patients. These errors may occur at three critical points: when ordered by a physician, dispensed by a pharmacist, or administered by a nurse.

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as [20]:

“any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such events may be related to professional practice, health-care products, procedures, and systems, including prescribing; order communication; product labeling; packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

A number of medication errors can be linked to the prescriber who continually uses potentially dangerous abbreviations and dose expressions. Despite repeated warnings by the Institute for Safe Medication Practices about the dangers associated with using certain abbreviations when prescribing medications, this practice continues. To eliminate this factor, there are fairly simple steps that can eliminate much confusion. Prescribers should [21]:

- Avoid the use of the symbol “U” or “u” but rather spell “units” when ordering drugs, such as insulin.
- Spell out medication names completely rather than using abbreviations and acronyms.
- Avoid using abbreviations for “daily” (QD), “every other day” (QOD), or “four times daily” (QID), which are easily confused.
- Use leading zeros before a decimal point (e.g., 0.2 mg instead of .2 mg), and do not use trailing zeros (e.g., 2 mg instead of 2.0 mg).
- Write out “morphine sulfate” and “magnesium sulfate” instead of using the abbreviations (MS, MSO<sub>4</sub>, MgSO<sub>4</sub>).

The Institute for Safe Medication Practices publishes a list of error-prone abbreviations, symbols, and dose designations online at <https://www.ismp.org/Tools/errorproneabbreviations.pdf>.

Other factors contributing to prescriber errors are illegible or confusing handwriting and, a frequently cited cause of many adverse and sentinel events, the failure of healthcare providers to assess risk and prevent errors. Addressing illegibility may include developing appropriate policies and procedures, tracking and trending patterns, and evaluating results through peer review committees. Improving communication might include developing protocols for the use of verbal orders to assure that those from an onsite practitioner would be limited to an emergency situation only. No verbal orders should be taken for certain medications, such as for chemotherapy, and all verbal orders should be repeated for clarification and, whenever possible, reiterated to a third person. Another method of improving communication might involve reviewing the hospital formulary in collaboration with the Pharmacy and Therapeutics Committee of the medical staff to limit, where appropriate, the number of therapeutically and generically equivalent products [22].

It has been estimated that between 0.2% and 10% of prescriptions are dispensed incorrectly [23]. The most common type of medication error is wrong drug (43.8%), followed by wrong dose (31.5%), failure to consult with prescriber (4.9%), and compounding error (3.7%) [24]. Safe medication dispensing practices may include a number of risk reduction strategies to reduce the incidence of errors that may cause harm to patients [22; 25; 61]:

- Ensure that appropriate and current drug reference texts and/or online resources are immediately available to pharmacy personnel.
- Ensure that essential patient information, such as allergies, age, weight, current diagnoses, pertinent lab values, and current medication regimen, is available to the pharmacist prior to the dispensing of a new medication order.
- Require clarification of any order that is incomplete, illegible, or otherwise questionable using an established process for resolving questions.
- Whenever possible, dispense dosage units in a ready-to-administer form.
- Dispense single-dose vials and ampoules rather than multidose vials.
- Select oral rather than injectable routes, when possible.
- Require that a pharmacist double-check all mathematical calculations for neonatal and pediatric dilutions, parenteral nutrition solutions, and other compounded pharmaceutical products.
- Create an environment for the dispensing area that minimizes distractions and interruptions, provides appropriate lighting, air conditioning, and air flow, safe noise levels, and includes ergonomic consideration of equipment, fixtures, and technology.

- Require that a second pharmacist double-check the accuracy of order entry and dose calculations for all orders involving antineoplastic agents and other high-risk drugs dispensed by the pharmacy.
- Enhance the awareness of look-alike and sound-alike medications, and use warning signs to help differentiate medications from one another, especially when confusion exists between or among strengths, similar looking labels, or similar sounding names.
- Separate look-alike and sound-alike medications in pharmacy dispensing areas or consider repackaging or using different vendors.
- Follow-up and periodically evaluate the need for continued drug therapy for individual patients.

Once again, communication is likely the key to avoiding dispensing errors. Pharmacists should work closely with their staff to ensure that proper protocols are followed, and most importantly, when questions arise regarding a prescription, the pharmacist should take the time to contact the prescriber directly to obtain clarification.

The healthcare provider who has the responsibility to administer a medication has the final opportunity to avoid a mistake. In most cases, particularly in inpatient settings, this responsibility falls to the nurse. Nurses are often taught in nursing school to review the five “rights” prior to administering any medication: the right patient is given the right drug in the right dose by the right route at the right time [26]. Medication errors generally fall into four categories, which mimic these five “rights.” The first is the failure to follow procedural safeguards, such as ensuring that essential patient information, including allergies, age, weight, and current medication regimen, is available. The second is unfamiliarity with a drug. In one case, a jury determined that a nurse was negligent for giving a drug without having reviewed the literature, which stated that the necessary precautions for the administration of the

drug required the specialized skill of an anesthesiologist. The third category of drug administration is failure to use the correct mode of administration. A nurse in Delaware was held liable for administering a medication by injection after an order had been written to change the route to oral. The final category involves failure to obtain clarification if an order is incomplete, illegible, or otherwise questionable. In a case tried in Louisiana, a nurse was held liable for administering a medication that a physician ordered, notwithstanding that the dose was excessive. The nurse's administration of the drug led to the patient's death [27].

In addition, healthcare facilities should implement appropriate guidelines, policies, and procedures to ensure safe medication administration practice. These policies should require that staff members who administer medications [25; 61]:

- Are knowledgeable about the drug's uses, precautions, contraindications, potential adverse reactions, interactions, and proper method of administration
- Resolve questions prior to medication administration
- Only administer medications that have been properly labeled with medication name, dose to be administered, dosage form, route, and expiration date
- Utilize a standard medication administration time schedule and receive education on how and when to incorporate newly started medication orders safely into the standardized schedule
- Have a second person verify a dosage calculation if a mathematical calculation of a dose is necessary
- Receive adequate education on the operation and use of devices and equipment used for medication administration (for example, patient-controlled anesthesia pumps and other types of infusion pumps)

- Have another person double-check infusion pump settings when critical, high-risk drugs are infused
- Document all medications immediately after administration

Finally, healthcare facilities should have proper quality assurance measures in place to monitor medication administration practices. Included among these would be protocols and guidelines for use with critical and problem-prone medications to help optimize therapies and minimize the possibility of adverse events and to integrate "triggers" to indicate the need for additional clinical monitoring [25].

It is important to note that the pediatric population is especially vulnerable to medication errors. When children are prescribed adult medications, care must be taken to adjust dosage according to weight, requiring the physician to use pediatric-specific calculations. Also, many healthcare settings are not trained to care for the pediatric patient. Intolerance due to physiologic immaturity is also a factor in adverse response to medications, and in many cases, this population cannot communicate their discomfort due to adverse reactions. Risk reduction strategies include standardizing and effectively identifying medications and processes for drug administration, ensuring pharmacy oversight, and using technology, such as medication dispensing programs, infusion pumps, and bar-coding, judiciously [28].

### COMMON MISDIAGNOSES

As Florida healthcare professionals, it is important to be aware that in addition to wrong-site/wrong-procedure surgery, several medical conditions also continue to be misdiagnosed. As of 2016, the Florida Board of Medicine has determined the five most misdiagnosed conditions to be [29]:

- Cancer
- Neurologic conditions
- Cardiac-related issues

- Infectious/communicable diseases
- Pulmonary-related issues

It is important to be aware of the possibility of misdiagnosis and incorporate this knowledge into practice.

### **Cancer**

The early detection and diagnosis of cancers is crucial for selecting the appropriate treatment approach and to ensure an optimum outcome. However, an estimated 12% of cancer patients are initially misdiagnosed, and the missed or delayed diagnosis of cancers remains a significant cause of medical malpractice claims [30; 31]. The causes of missed diagnoses vary widely among cancers in different parts of the body. In many cases, patients who do not fit the typical profile for a specific cancer (e.g., young age) may be underdiagnosed, and it is important that cancer is considered as part of the differential diagnosis in ambiguous cases [31; 32; 33]. In order to prevent missed or delayed cancer diagnosis, practitioners may take steps to ensure adherence to clinical guidelines for screening and diagnosis, use tools to facilitate communication, and engage strategies to ensure appropriate follow-up [62].

### **Neurologic/Spinal Cord-Related Conditions**

Delayed or missed diagnoses of neurologic conditions may result in serious morbidity and mortality. Headaches are a common presenting condition in acute and primary care, and an estimated 5% of all patients admitted to emergency departments have neurologic symptoms [63]. Acute headache with neurologic symptoms may be misdiagnosed as stroke [36]. In addition, missed spinal fracture diagnoses are one of the leading causes of malpractice claims against radiologists [42].

One of the most common neurologic conditions is headache; however, it has been estimated that 50% of migraine patients remain undiagnosed or misdiagnosed, and only a small number (8% to 10%) of individuals with migraine take migraine-specific medications such as triptans or ergotamines

[48; 49]. Patients suffering from daily migraines may be misdiagnosed with chronic sinusitis or rhinitis and repeatedly and unsuccessfully treated with broad-spectrum antibiotics [50; 54]. The diagnosis of migraine is based solely on a constellation of signs and symptoms, and a comprehensive medical and neurological examination is required to exclude secondary headache [55]. Useful evidence-based clinical guidelines for migraine screening have been developed and are summarized in the mnemonic POUND: pulsatile headache; one-day duration (4 to 72 hours); unilateral location; nausea or vomiting; and disabling intensity [56]. Competence of the clinician and effective communication with the patient play a crucial role in the diagnosis of migraine.

### **Cardiac- and Stroke-Related Issues**

The clinical presentation of chest pain has many possible etiologies, ranging from benign (e.g., panic/anxiety, pneumonia, peptic ulcer, gastroesophageal reflux disease, and pericarditis) to life-threatening (e.g., pulmonary embolism, acute coronary syndrome [ACS], aortic dissection, and pneumothorax). In many cases, it is best to rule out the more urgently threatening possibilities before testing for other causes.

Of the potentially life-threatening causes of chest pain, ACS is the most prevalent. Although a large percentage of individuals with suspected ACS will be seen initially in emergency departments, patients in any healthcare setting, regardless of other diagnoses, may abruptly develop chest pain suspicious for ACS. When a patient presents with clinical signs suspicious for myocardial infarction, immediate medical intervention is directed at confirming a diagnosis and stratifying the person's risk for adverse events such as cardiac arrest and severe/significant damage to the myocardium [41]. It is important to note that while some patients will present with classic ACS-related chest pain (tightness, sensation of pressure, heaviness, crushing, vise-like, aching pain in the substernal or upper left chest), many patients, particularly women and older patients, will present with "atypical"

ACS-related chest pain [45; 46]. Words commonly used to describe “atypical” chest pain associated with ACS include numbness, tingling, burning, stabbing, or pricking. Atypical chest pain location includes any area other than substernal or left sided, such as the back, area between shoulder blades, upper abdomen, shoulders, elbows, axillae, and ears [43; 44; 45; 46]. Aside from atypical clinical presentation, other possible causes of missed ACS diagnosis include failure of interpretation of the history, failure to correctly interpret the electrocardiogram, failure to perform an electrocardiogram when necessary, and lack of proper use of cardiac enzyme test [47].

Stroke is among the most common cardiovascular conditions, and missed or delayed diagnosis of these patients drastically reduces survival rates. If a patient presents with classic signs of stroke and has one or more cardiovascular risk factors, the diagnosis of stroke can be straightforward. In a study conducted by the American Heart Association in 2013, 22% of strokes diagnosed and treated in two hospitals were initially misdiagnosed [34]. Certain symptoms were associated with a greater likelihood of missed diagnosis, including nausea/vomiting, dizziness, and a positive stroke history. In addition, posterior cerebral artery strokes were more commonly misdiagnosed than anterior strokes [34]. Even if classic signs of stroke are present, certain patients (e.g., women, minorities, younger adults and children) are at increased risk for missed diagnosis [64].

Identifying more unusual stroke cases may be a challenge. In fact, an estimated 25% of patients initially diagnosed with stroke are later found to have a different condition (or “stroke mimic”) [35]. The most common stroke mimics are seizures/post-seizure symptoms, systemic infection, brain malignancy, and toxic-metabolic disturbances [37]. If fever and headache are present, the actual underlying disease may be infective endocarditis or viral encephalitis (usually caused by herpes simplex virus) [35; 36]. Approximately one-third of stroke mimics are seizures or post-seizure symptoms [36].

Patients experiencing seizure/post-seizure symptoms are more likely to have a history of seizure/epilepsy and loss of consciousness than patients with stroke [38].

Because the temporal window for effective stroke treatment is short, it is imperative that evaluation and diagnosis are performed promptly and accurately. Regardless of the degree of the neurologic deficits, an individual with suspected stroke or transient ischemic attack should be triaged as if he or she were a serious trauma patient [39]. If possible, the individual should be taken to a designated stroke center [40].

### **Infectious/Communicable Diseases**

Acute infection was the most commonly misdiagnosed disease in one study, with the potential adverse outcomes of sepsis, organ damage, and even death [57]. The presentation of infectious diseases may be atypical in certain populations (e.g., the elderly), making detection even more difficult. Diseases with general symptoms and varied presentations (e.g., Lyme disease) also present complicated clinical pictures. Adherence to established guidelines for the diagnosis and treatment of specific infectious diseases and attentive patient assessment and history are recommended in order to improve diagnostic accuracy.

### **Pulmonary-Related Issues**

Pulmonary issues can be difficult to diagnose, as the presenting symptoms tend to be similar and in some cases definitive diagnostic tests are unavailable or underutilized. One example is pulmonary hypertension, which, depending on the severity of symptoms, may have a similar presentation to obstructive sleep apnea, hypothyroidism, scleroderma, mitral stenosis, or dilated cardiomyopathy. In one study, half of patients referred to pulmonary hypertension centers were referred late in the course of the disease, when treatment is unlikely to be effective [58]. Improved clinician education regarding the signs/symptoms of pulmonary hypertension as well as appropriate testing and treatment is necessary.

## OTHER CONSIDERATIONS FOR PATIENT SAFETY

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The most important issue to improving patient safety is being aware of the particular safety hazards that may exist for various patient populations and on particular specialty units. In addition, education of the patient and the family should be a priority.

Infants and young children are not developmentally or cognitively able to participate in care and decision making, thus putting them at higher risk, especially for medication errors. In addition, when a medication error occurs in this population, infants and young children are at higher risk because of their physical immaturity and increased sensitivity to the effects of drugs. The family or guardian of a pediatric patient should be encouraged to ask questions, especially if something seems wrong. In addition, a meta-analysis found that computerized provider order entry with clinical decision support reduced pediatric medication errors by 36% to 87% [51]. As such, the adoption of electronic support systems may help to reduce or eliminate these errors.

An estimated 30% of individuals 65 years of age or older who are living in the community fall each year [52]. Older patients may have poor vision, as a result of cataracts, glaucoma, and/or macular degeneration, and cardiovascular problems, which might result in syncope or postural hypotension. These conditions may affect patients' balance and stability. Bladder dysfunction, such as nocturia, may cause an elderly patient to have to ambulate more during the night in an unfamiliar environment, thereby increasing the risk of a fall. Lower extremity dysfunctions, such as arthritis, muscle weakness, or peripheral neuropathy, may make it more difficult to ambulate at any time. In addition to being at greater risk for falls, the elderly are also more prone to medication errors as their ability to understand instructions or to recognize an unfamiliar medication may be affected by dementia or

other cognitive disorders. Interventions that can help prevent falls in the elderly include exercise programs, tai chi, vision improvement (e.g., first cataract surgery), and multifactorial assessment and intervention [52].

There are also unique factors that increase the risk of medical errors on specialty units. For instance, in critical care units, patients may be suffering from environmental psychosis, which could inhibit participation in their care. This is also true of lethargic and comatose patients. These patients are at particular risk because they cannot participate in the identification process. On psychiatric wards, patients may be suicidal or depressed, which may cause them to act out or attempt to harm themselves or others. Psychiatric patients may also experience orthostatic side effects due to antidepressants, which may increase the incidence of falls. Obstetrical patients are at higher risk for falls because they may have decreased sensation and mobility due to administration of epidural anesthesia, and they may also suffer from excessive blood loss, which could lead to postural hypotension [59]. Again, the key is identifying the unique needs of the particular population.

With regard to education, a number of organizations have developed guidelines to facilitate the role of patients as their own safety advocates. These guidelines are not intended to shift the burden of monitoring medical error to patients. Rather, they encourage patients to share responsibility for their own safety. As healthcare professionals, we should ensure that all of our patients are familiar with these guidelines. The Agency for Healthcare Research and Quality has developed a "Patient Fact Sheet" that outlines 20 tips for patients to help prevent medical errors [53]. Although some of these suggestions may seem extreme, many patients now desire to have a more active role in their care. Some of these items have become routine or are currently required, such as consultations by pharmacists when a patient picks up a prescribed medication.



## USE OF AN INTERPRETER

As a result of the evolving racial and immigration demographics in the United States, interaction with patients for whom English is not a native language is inevitable. Because patient education is such a vital aspect of preventing medical errors, it is each practitioner's responsibility to ensure that information and instructions are explained in such a way that allows for patient understanding. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required.

Interpreters are more than passive agents who translate and transmit information back and forth from party to party. They should be professionally trained in ethics, accuracy, completeness, and impartiality. Furthermore, it is the interpreter's role to negotiate cultural differences and promote culturally responsive communication and practice. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers, who ultimately enhance the clinical encounter. In any case in which information regarding diagnostic procedures, treatment options, or medication/treatment measures is being provided, the use of an interpreter should be considered.

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## CONCLUSION

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Although the United States has one of the top 40 healthcare systems in the world, it is apparent that the numbers of medical errors are at unacceptably high levels. The consequences of medical errors are often more severe than the consequences of mistakes in other industries. They may lead to death or to serious and long-term disability, which underscores the need for aggressive action in this area. As a starting point, we should become an active part of the solution. This will only happen if all healthcare professionals voice their concerns when they identify problems in a system or process. In addition, we should actively participate in the root cause analysis process, understanding that the goal is not to assign blame, but rather to identify how we can improve the process to provide the best quality care to our patients. Medical errors are costly, not only because patients may lose their lives or livelihoods, but also because patients lose trust in the system and colleagues lose faith in each other. To preserve the integrity of our system, we must correct this problem, and the solution begins with each of us.

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