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GENERAL INFORMATION

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GENERAL INFORMATION
This self-instructional monograph is designed to provide essential information on Medical Errors Prevention for physicians across all specialties. It is also appropriate for medical students, residents and other allied healthcare professionals who are involved in patient care.

This activity consists of a 34-page handbook, key references, a post-test and participant evaluation form. Upon completion of this activity participants have the option of completing the post-test to qualify for continuing medical education credit. A score of 70% or greater on the post-test is required to receive credit.

This course fulfills the Prevention of Medical Errors education requirement for Florida licensed physicians.

TARGET AUDIENCE
Physicians

OBJECTIVES
At the completion of this activity, participants will be able to:
1. Explain the scope of the problem of medical errors
2. Define medical error, differentiating preventable from non-preventable
3. Define root cause analysis and know its use in preventing medical errors
4. Determine which adverse event-associated injuries must be reported to the Florida AHCA within 15 days of occurrence
5. Identify the root causes for the six most common types of sentinel events
6. List the five most misdiagnosed medical conditions in the state of Florida

ACCREDITATION
The University of Miami Leonard M. Miller School of Medicine is accredited by the Accreditation Council for continuing Medical Education (ACCME) to provide continuing medical education for physicians.

CREDIT DESIGNATION
The University of Miami Leonard M. Miller School of Medicine designates this enduring material for a maximum of 2 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

FACULTY DISCLOSURE
Dr. Rogers has indicated that he has no relevant financial relationships with commercial interests.

Applying for Continuing Medical Education (CME) Credit
- Read the monograph
- Complete the post-test* with a score of 70% or greater.
- Complete the online evaluation and registration process*.

* Post-test, evaluation and registration process
A link to the Post-test, evaluation and registration process appears at the conclusion of this monograph.

Fees
UM Physicians..........................Complimentary
All others.................................$50

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INTRODUCTION: BACKGROUND AND SCOPE OF THE PROBLEM

In an effort to reduce the number of preventable medical errors in the State of Florida, the Florida Legislature (2001) (Statutes 465.013) has mandated that all healthcare professionals applying to be licensed to practice medicine be required to complete a 2-hour ACCME-accredited course on the topic of prevention of medical errors; that the course be repeated upon first renewal of licensure and every six years thereafter [1]. The course you are preparing to take has been designed to achieve a specific set of learning objectives which will enhance your understanding of the magnitude of the problem of preventable medical errors; to understand better their root causes through the process of root cause analysis; to make you aware of the five most commonly misdiagnosed conditions in Florida; to sensitize you to your responsibility as a member of the medical staff of the facility in which you practice to work closely with hospital administration and the risk management department and to assume some degree of responsibility to help reduce the incidence of medical errors in your unique setting.

LEARNING OBJECTIVES

1. Explain the scope of the problem of medical errors
2. Define medical error, differentiating preventable from non-preventable
3. Define root cause analysis and know its use in preventing medical errors
4. Determine which adverse event-associated injuries must be reported to the Florida AHCA within 15 days of occurrence
5. Identify the root causes for the six most common types of sentinel events
6. List the five most misdiagnosed medical conditions in the state of Florida

Once you have completed the course, you will be asked to take a self-assessment examination which will be online and consist of fifteen (15) questions; to obtain formal certification that you have passed the course; you must answer a minimum of ten correctly.

A set of memorable axioms follow in the table below:

<table>
<thead>
<tr>
<th>MEDICAL ERRORS PREVENTION: MEMORABLE AXIOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• As important as making a correct diagnosis and instituting appropriate therapy.</td>
</tr>
<tr>
<td>• One preventable medical error is one too many.</td>
</tr>
<tr>
<td>• They can and must be prevented:</td>
</tr>
<tr>
<td>• Be mindful of predisposing circumstances/conditions.</td>
</tr>
<tr>
<td>• Consider their prevention a shared responsibility.</td>
</tr>
<tr>
<td>• Take on the role of activist in the office, hospital, or clinic setting where you practice.</td>
</tr>
<tr>
<td>• Know and play by the rules.</td>
</tr>
</tbody>
</table>
We are all responsible for doing what we can to prevent preventable medical errors and reduce their incidence in our State. Of special interest is that little progress has been made over the past decade. The Institute of Medicine (1999) reported an annual incidence of deaths caused by medical errors to range from 44,000 to 98,000. The lower incidence exceeds annual deaths due to motor vehicle accidents, breast cancer, and AIDS [2]. There are other estimates (Health Grades 2004) as high as 185,000 deaths per annum [3]. The JCAH (2010) estimated that 1 of every 7 hospitalized Medicare beneficiaries experienced 1 adverse event/medical error each month. When balanced against the millions of hospital admissions, it would be easy to dismiss the incidence of deaths caused by medical errors as being relatively insignificant [4]. One serious injury or death occurring as a result of a preventable medical error is one adverse event too many.

### MEDICAL ERRORS

**SCOPE OF THE PROBLEM**

- IOM (1999) 44-98k deaths from ME on annual basis; serious injuries as well
- HealthGrades (2004) 195k
- Balanced against admissions of 33-38 million
- Joint Commission (2010) 135k/1 million or 1/7 Medicare beneficiaries→1 AE/month

### WHAT IS CONSIDERED A MEDICAL ERROR?

What exactly is considered a MEDICAL ERROR? The definition is straightforward, easy to remember and can be classified as (1) an error of execution or (2) an error of planning [5].

### MEDICAL ERROR: A DEFINITION

“the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” (Institute of Medicine- 2000)

Classification of medical error:
- “error of execution”, e.g. did not proceed as intended
- “error of planning”, e.g. original intended action was incorrect

Medical errors may occur along the continuum of medical care from diagnosis to treatment; they are not intentional, do not always arise to the level of malpractice or negligence, and do
not necessarily result in injury to the patient. Those that do are referred to as adverse or sentinel events and must be subjected to rigorous root cause analysis and a response [6]. Even under circumstances in which a medical error did not rise to the level of an adverse or sentinel event, there is often something to be gained by a thorough analysis of the error, why it occurred and what can be done to present a recurrence, and, quite possibly, an adverse or sentinel event.

**MEDICAL ERROR: OCCURRENCE AND TYPES**

- Medical error(s)→injury = Sentinel Event (SE) or Adverse Event (AE)
- Potential to occur at any stage in patient care: Diagnosis→Treatment
- May cause no injury
- Not intentional
- Do not necessarily rise to level of malpractice or negligence

Sentinel or adverse events are the result of medical errors, often preventable, that result in injury or death to the patient, and cannot be attributed to the patient’s underlying medical condition [6].

**THE “SENTINEL EVENT”**

“An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof”

Or the risk thereof: Recognition of a variation in process which if recurrent would carry a significant risk for the occurrence of an adverse outcome

Can reasonably be said not to be related to underlying medical condition

Was the adverse or sentinel event preventable?

Root Cause Analysis can provide the answers.

The question which must be addressed is whether the acknowledged medical error was preventable. A thorough and credible root cause analysis often provides the answer and signals a need to modify practices and systems in the patient care setting in which the error occurred [7].
ROOT CAUSE ANALYSIS: Definition and Utilization

Root cause analysis should be undertaken with objectivity and not with the idea of impugning anyone or any system in place at the time. The JCAH has defined root cause analysis as (Joint Commission on Accreditation of Healthcare Organizations: Root Cause Analysis in Health Care: Tools and Techniques, 2000):

 ROOT CAUSE ANALYSIS (JCAH): WHAT IS IT?  

“A PROCESS FOR IDENTIFYING THE BASIC OR CAUSAL FACTORS THAT UNDERLIE VARIATION IN PERFORMANCE, INCLUDING THE OCCURRENCE OR POSSIBLE OCCURRENCE OF A SENTINEL EVENT”

Applying the “Golden Rule”, those with the gold make the rules. Accreditation status is accorded healthcare facilities by the Joint Commission which holds accredited facilities responsible for establishing and maintaining a safe environment for patients. To that end, the Joint Commission has identified a subset of sentinel events subject to their review [6]:

1. When the event has resulted in death or permanent loss of function and does not seem related to natural course of the patient’s or underlying condition or
2. The event is one of the following:
   a. The suicide of the patient being cared for in a staffed around-the-clock setting or within 72 h of discharge;
   b. Surgery on the wrong patient or wrong body part;
   c. The unintended retention of a foreign object in a patient who has undergone surgery or another procedure;
   d. A hemolytic transfusion reaction involving the administration of blood or blood products having major group blood incompatibilities;
   e. The unanticipated death of a full-term infant;
   f. The occurrence of severe neonatal hyperbilirubinemia (bilirubin > 30mg%);
   g. The discharge of an infant to the wrong family;
   h. Abduction of a patient receiving care, treatment, and services;
   i. The rape of a patient;
   j. Prolonged fluoroscopy with excessive rads delivered to a single field or the administration of radiotherapy to the wrong body region or > 25% above the planned dose.

The Joint Commission further requires that accredited healthcare organizations (1) have in place processes to recognize these events; (2) conduct thorough and credible root cause analyses which focus on process and systems factors; (3) and are able to provide a risk-reduction strategy and internal corrective plan with built in methods for assessing the effectiveness of these strategies and plans to actually reduce further risks and the incidence of adverse events [8].
## ROOT CAUSE ANALYSIS: IMPORTANT ELEMENTS (JCAH)

- A **thorough** and **credible** process in place to:
  - facilitate recognition of **sentinel events**
  - Conduct a thorough and credible root cause analysis focusing on **process** and **systems**
  - document a **risk-reduction strategy**
  - document an **internal corrective** action
  - Identify changes which can be made in systems or processes → risk for recurrence
  - minimize individual blame or retribution

Of interest is that the Joint Commission considers a root cause analysis to be acceptable if it focuses on **systems** and **processes**, and **not exclusively on individual performance** and is both **thorough** and **credible** [9]. Furthermore, it should think of sentinel or adverse events as the result of **special causes** in clinical processes as well as **common causes** in organizational processes. The suggested framework for a root cause analysis and action plan initiated in response to a sentinel event is designed to address the following questions: **What happened? Why did it happen? What were the most proximate factors? What systems and processes underlie the proximate factors?** The provision of answers for which correctable actions can be undertaken depend on a **level of analysis** which focuses on the following:

1. The sentinel event
2. The process or activity in which it occurred
3. Human factors
4. Equipment factors
5. Controllable environmental (factors which directly affected outcome)
6. Uncontrollable external factors (outside the control of the organization)
7. Human resource issues (staff qualifications, competence, actual performance, numbers, ideal v actual levels, adequacy of orientation and continuing education procedures)
8. Information management issues (availability, completeness, unambiguousness, accuracy)

9. Environmental management issues (appropriateness for processes being conducted, systems to identify environmental risks, testing and planning of emergency and failure-mode responses)

10. Leadership issues: Corporate culture

11. Encouragement of communication

12. Clear communication of priorities

ROOT CAUSE ANALYSIS: ASSURING THOROUGHNESS

- A process which considers human and other factors responsible for the SE or AE;
- Asks “why” did it happen;
- Considers improvements in processes or systems to reduce recurrences;
- Analysis concludes that no improvements in processes and/or systems would reduce risk for recurrences.

A credible and thorough analysis of each of the factors enumerated above gives way to findings, the identification of root causes, an answer to the question “Why?”, and whether action needs to be taken. The actions taken should state clearly the risk reduction strategy being employed; and for each, measures of effectiveness must be included along with dates of implementation, planned follow up, and the associated measure of effectiveness. To be considered credible, the root cause analysis process must (1) involve the organization’s leadership and include the participation of individuals involved directly or indirectly in the process and/or systems under review; (2) the analysis must be internally consistent, not contradict itself or leave important questions incompletely addressed; (3) findings of “not applicable” or “no problem” must be accompanied by an explanation; and, finally, (4) should
include reference to relevant literature. This process is to be completed within 45 days from the date the organization involved becomes aware of the sentinel event [8,9]

ROOT CAUSE ANALYSIS: ASSURING CREDIBILITY

- Health care organization’s leadership and individuals most closely involved in areas under review must participate in analysis;
- Must be internally consistent, i.e. not contradict itself or leave difficult questions unanswered;
- Must provide explanation for findings dismissed as not relevant;
- Must include relevant literature

ROOT CAUSE ANALYSIS REPORT TO JOINT COMMISSION

- MUST INCLUDE THE FOLLOWING:
  - Internal correction action plan that:
    - Identifies changes able to be implemented
    - Identifies persons responsible for implementation
    - Establishes timeline for action to be implemented
    - Establishes evaluation methodology to assure effectiveness of action plan
FLORIDA LAW

In addition to what has already been discussed regarding the reporting of adverse incidents (sentinel events) to the Joint Commission, Florida law mandates the reporting to its Agency for Health Care Administration (AHCA) within 15 calendar days from their occurrence a set of serious adverse events associated with and occurring possibly as a result of medical intervention and which have resulted in an adverse outcome [10].

**MEDICAL ERRORS PREVENTION: FLORIDA LAW**
(Florida Statute 395.0197)

- Adverse (sentinel) events must be reported to organization leadership.
- Licensed facilities (hospitals) must have a risk management program and an incident reporting system.
- Incident reports submitted within 3 business days; some →AHCA (Agency for Health Care Administration) within 15 d.

To assure that this occurs, the JCAHO accredited facility must have in place a well-developed risk management program which includes an incident reporting system requiring all healthcare providers and employees to report adverse incidents to the risk manager or his or her designee within 3 business days of the incident. Florida law defines an adverse incident 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 [10]. The following injuries resulting from an adverse event must be reported to the Florida AHCA:

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 following discharge from the facility

6. When informed consent was not obtained for a non-emergent medical intervention which required specialized medical attention or surgical intervention;

7. Any condition requiring transfer of the patient to a facility providing a more acute level of care, the result of the adverse event and not the pre-existing condition;

8. Regarding a surgical procedure, was it:
   a. performed on the wrong patient?
   b. the wrong surgical procedure?
   c. performed on the wrong site?
   d. unrelated to the patient’s diagnosis or condition?
   e. a surgical repair of damage resulting from a planned surgical procedure?
   f. performed to remove a foreign object remaining from a prior procedure?

**FLORIDA STATUTE: MANDATORY REPORTING REQUIREMENT**

- SURGERY-RELATED ADVERSE EVENTS:
  - Wrong patient
  - Wrong site
  - Wrong surgery
  - When unrelated to 10 condition (25%)*
  - Performed to remove unintended retention of foreign object (21%)*
  - When required to repair damage occurring during surgery unrecognized as a surgical risk

*AHCA (2011) figures
Each reported incident is reviewed by the AHCA which determines the penalty to be imposed on the party held responsible for the adverse event. The organization feels that all healthcare professionals who practice in licensed facilities share the responsibility to ensure that risk management systems are in place to detect and report adverse incidents in an accurate and expedient manner [7,10].

### FLORIDA LAW: WHAT FACILITIES AND HEALTH CARE PROFESSIONALS NEED TO KNOW

- Defines adverse or sentinel event as a controllable medical error the result of medical intervention and separate from the condition which prompted the intervention.
- One that results in death, disfigurement, neuropathology, brain or spinal damage, osseous pathology, transfer to another facility, the need for unplanned medical or surgical intervention (15 day mandatory reportable events)

### REDUCING AND PREVENTING ERRORS

An analysis of sentinel events reported to the Joint Commission from 2004 to 2012 indicated that 6994 sentinel events impacting 7061 patients resulted in serious injury or death. Six major causes of these sentinel events were identified [11].
MAJOR CAUSES OF 6994 SENTINEL EVENTS AFFECTING 7061 PATIENTS:

1. Wrong patient, wrong site, wrong surgical procedure
2. Delays in treatment
3. Operative and postoperative complications
4. Patient suicide
5. Patient falls
6. Medication errors

These events are more likely to occur in error-prone situations and in healthcare facilities providing care to special populations, (i.e. the elderly, those with diminished cognitive function, developmental or learning disabilities, psychiatric patients, infants and young children). It has been determined as well that a better informed, educated public is more likely to become more involved in its own health care as relates especially to medication use and events impacting on surgery (peri-operative, pre-operative, operative, and postoperative). The Joint Commission (www.jointcommission.org) provides public education through their “Speak Up” program.

In the sections which follow, interventions will be discussed which may prevent the six commonest medical errors detailed earlier which account for close to 2/3rds of reported sentinel events.

1. **Wrong-site surgery**

This important common error has been the subject of a Joint Commission sentinel event alert. This error is most common during orthopedic procedures, followed in incidence by urological and then neurosurgical procedures. A generic set of risk factors includes: (1) more than one surgeon involved because of multiple procedures or transfer to the care of another surgeon; (2) the performance of multiple procedures on the same patient during a single operation; (3) pressures imposed by time constraints; and (4) circumstances peculiar to the patient which altered usual, preferred positioning during a given surgical procedure.

The American Academy of Orthopedic Surgery has issued a set of corrective measures to reduce the risk of errors which include marking the correct surgical site with indelible pen along
with the surgeon’s initials; writing “NO” on the side not to be operated on; and the use of radioopaque markers and intraoperative radiographs to determine the exact vertebral level during spinal surgery. As mentioned earlier, root cause analysis should focus on systems and processes and not exclusively on individual performance. All personnel involved in the operating room setting should monitor procedures to verify compliance, especially during high-risk surgical procedures [12,13].

Because of the high prevalence of wrong-site, wrong-procedure, and wrong-person surgeries, the Joint Commission, along with 50 healthcare professional organizations, convened two summits, one in 2003 and the second in 2007. A Universal Protocol was developed during the first summit, and included the following recommendations:

1. a pre-procedure verification process;
2. marking the operative/procedure site with an indelible marker;
3. taking a “time out” with all perioperative/periprocedure personnel immediately preceding the performance of the operation/procedure;
4. adapting these requirements to all procedure settings, including bedside

<table>
<thead>
<tr>
<th>SENTINEL EVENTS: STRATEGIES TO REDUCE RECURRENCES</th>
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<tbody>
<tr>
<td>• SURGICAL ERRORS</td>
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<tr>
<td>– Conduct a pre-procedure verification process,</td>
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<tr>
<td>i.e. correct procedure on the right patient</td>
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<tr>
<td>– Mark the operative/procedure site with</td>
</tr>
<tr>
<td>indelible marker</td>
</tr>
<tr>
<td>– Have a brief “time out” with all operative</td>
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<tr>
<td>team members regardless of procedure setting</td>
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<tr>
<td>to review the verification process</td>
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</table>

Despite this protocol, the incidence rose for wrong-site surgeries, and the second summit (2007) was convened. Failure to consistently follow the 2003 recommendations led to the adoption of a “zero tolerance” policy along with a clarification that the Universal Protocol policy applied to all types of procedures, often including those many would not have considered a procedure, per se, i.e. the administration of regional anesthetics and radiological interventions. An updated version of the Universal Protocol was revised for 2010 [15].
2. **Delays in Treatment**

According to the Joint Commission, more than half of all sentinel event cases that resulted in patient death or permanent injury were due to delays in treatment in the emergency room setting, attributed most commonly to misdiagnosis in addition to delayed test results, physician availability, delays in following orders regarding patient care, incomplete treatment, and, strangely enough, difficulty in locating the entrance to the emergency department [16]. Once again, a breakdown in communication usually with or between physicians, was identified as a root cause; included were insufficient or inadequately trained staff, overcrowding of the ER facility, and lack of specialists when required. To remedy the remediable, Joint Commission recommended (1) implementing processes and procedures that improved timeliness, completeness, and accuracy of communication; (2) implementing face-to-face interdisciplinary change-of-shift debriefings; (3) taking steps to reduce reliance on verbal orders; and (4) requiring a procedure of “read back” or verification when verbal orders are utilized [16].

Effective strategies to reduce recurrences require that root causes be determined. Identifiable, many but not all easily remediable, causes include:

<table>
<thead>
<tr>
<th>SENTINEL EVENTS: STRATEGIES TO REDUCE RECURRENCES</th>
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<tbody>
<tr>
<td>• DELAYS IN TREATMENT: CAUSES</td>
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<tr>
<td>– Misdiagnoses</td>
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<tr>
<td>– Physician availability, i.e. numbers and types</td>
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<tr>
<td>– Delayed following of orders</td>
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<tr>
<td>– Delayed test results</td>
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<tr>
<td>– Breakdown in inter-professional</td>
</tr>
<tr>
<td>communication</td>
</tr>
<tr>
<td>– Overcrowding in ER settings</td>
</tr>
<tr>
<td>– Verbal orders&gt;written orders</td>
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</table>

3. **Operative and Postoperative Complications**

Interesting and surprisingly, studies by the Joint Commission revealed that most of these complications occur in nonemergent procedures [17]:

1. interventional imaging and/or endoscopy ➔ perforation of a viscus
2. tube or catheter insertion (NG tube ➔ lung; central venous catheter ➔ artery)
3. open abdominal surgery (fluid overload, respiratory failure)
4. head and neck, orthopedic, and thoracic surgery
OPERATIVE AND POSTOPERATIVE COMPLICATIONS: OCCURRENCES

MOST COMMONLY RECOGNIZED CAUSES:
• Vast majority in non-emergent procedures
• Catheter insertion; head and neck, open abdominal, ortho, thoracic surgeries
• Miscommunication usually responsible
• Failure to follow established list guidelines
• Failure to question incompletely understood or inappropriate orders

Miscommunication (insufficient, inaccurate, infrequent) among and between physician and non-physician support personnel in the pre-operative, intra-operative, and post-operative arenas, whether in the operating room, endoscopy suite, radiology department, or at the bedside, has been targeted as the major root cause of complications. Other identified risk factors include [17]:

1. Inadequate supervision of house staff (when applicable),
2. deficiencies in conferring privileges and credentialing,
3. incomplete preoperative assessment,
4. failure to follow established procedures,
5. inconsistent postoperative monitoring procedures, appropriate to the needs of the patient,
6. failure to question “inappropriate” orders, and
7. inadequate support staff orientation, training, and continuing education.
OPERATIVE AND POSTOPERATIVE COMPLICATIONS:
STRATEGIES TO REDUCE RECURRENCES

- Improve staff orientation and training
- Establishing effective channels of communication
- Enhanced communication between providers of health care of patients
- Increased focus on preventative measures
- Encouraging mutual respect between and among professionals

4. **Patient Suicide**

The majority of inpatient suicides take place in psychiatric hospitals (JCAHO 1998) followed in decreasing incidence in general hospitals and residential facilities. Root causes identified by reporting facilities included [18]:

1. The environment (inadequate security, the presence of non-breakaway bars, rods, safety rails, inadequate testing of breakaway hardware);
2. Inadequate or incomplete suicide assessment on admission;
3. Incomplete reassessment at regular intervals to identify the presence of contraband;
4. Factors related to staff (inadequate numbers, insufficient training or orientation, incomplete competency reassessments);
5. Too infrequent or incomplete patient observation; and
6. Lack of effective communication among caregivers and unavailability of information when needed.
PATIENT SUICIDE: OCCURRENCES

- Settings: Psychiatric hospitals > General hospitals > Residential facilities; 75% by hanging, 25% by jumping from roof or room
  - Inadequate security
  - Failure to accurately assess suicide risk
  - Incomplete assessment of individual for harboring contraband
  - Poorly trained or insufficient numbers of staff
  - Suboptimal frequency of patient observation

Risk-reduction strategies were directed to remedy the identified root causes. In addition, these strategies included engaging family and friends regarding the process of detecting contraband and educating them regarding the identification of suicide risk factors [18].

PATIENT SUICIDE: STRATEGIES TO REDUCE RECURRENCES

- Settings: Psychiatric hospitals > General hospitals > Residential facilities; 75% by hanging, 25% by jumping from roof or room
  - Inadequate security
  - Failure to accurately assess suicide risk
  - Incomplete assessment of individual for harboring contraband
  - Poorly trained or insufficient numbers of staff
  - Suboptimal frequency of patient observation
5. **Patient Falls**

They provide a constant challenge to health care facilities. The elderly, those with altered mental status on the basis of intoxication or chronic mental illness, and a history of prior falls are red flags for identifying patients at high risk. Identified root causes of these sentinel events include the processes of care, the care givers, the environment where care is provided, and the entire organizational culture.

<table>
<thead>
<tr>
<th>PATIENT FALLS: OCCURRENCES</th>
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<tbody>
<tr>
<td>• Elderly, altered mental status, prior Hx, acute intoxication</td>
</tr>
<tr>
<td>• Incomplete admission data on fall Hx</td>
</tr>
<tr>
<td>• Failure to communicate fall risk assessment factors to all covering staff, changing shifts, etc.</td>
</tr>
<tr>
<td>• Staff unawareness of falls as major preventative sentinel event → morbidity or mortality</td>
</tr>
<tr>
<td>• Infrequent observation of at risk patients</td>
</tr>
<tr>
<td>• Reduced use of restraints without alternatives</td>
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</table>

The Florida Hospital Association has recommended that facilities establish a comprehensive, interdisciplinary program to prevent falls; such a program should have the following components: (1) have in place fall prevention protocols applied to patients screened and determined to be at greatest risk; (2) reporting falls and measuring fall rates; and (3) use gathered information to modify fall prevention protocols [19]. As the population ages with more Americans living well beyond age 65, hospital facilities should have in place programs to guard against falls and to introduce activities designed to enhance mobility in a safe environment while the elderly patient and others at high risk are hospitalized [19].
PATIENT FALLS: STRATEGIES TO REDUCE RECURRENCES

- RECOGNITION OF RISK FACTORS PREDISPOSING TO FALLS AND IMPLEMENTATION OF REMEDIES TO REMOVE OR MODIFY THOSE RISK FACTORS
- INCREASED AWARENESS BY ALL HEALTH PROVIDERS THAT FALLS ARE A MAJOR CAUSE OF PREVENTABLE MEDICAL ERRORS

6. Medication Errors

Common and unavoidable, they seem to occur at three critical points in the care of the patient: when ordered by the physician (or authorized healthcare professional), dispensed by the pharmacist, or administered by a nurse.

MEDICATION ERRORS: REASONS FOR OCCURRENCES

- WHICH AREAS ARE AT RISK FOR COMMITTING A MEDICATION ERROR?
  - PHYSICIAN(S) - PRESCRIBERS
  - PHARMACIST(S) – “OFF-SITE” DISPENSERS; PHARMACY→PATIENT UNIT
  - NURSE(S) – “ON-SITE” DISPENSERS; NURSE→PATIENT

Medication error has been defined by the National Coordinating Council for Medication Error Reporting and Prevention as: “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing: order communication;
The majority of medical errors are related to the administration of the wrong medication, the correct medication in the wrong dose, or the correct medication administered at the wrong time [21].

Factors related to prescribing of the wrong medication include

1. drug interactions
2. duplicate therapy
3. incorrect indication
4. failing to recognize contraindications

Factors related to the wrong dosage include:

1. misplacement of decimal points
2. incorrect calculations
3. incorrect units of measure
4. miscopying of doses
5. not adjusting to the patient’s altered physiologic status, i.e. alertness, unstable vital signs, dehydration, impaired renal function, etc.

Factors related to errors of dosing frequency include:

1. incorrect frequency for a dose form
2. misinterpretation of abbreviations (QD read as QID)

The use of dangerous abbreviations and dose expressions contributes to the number of medication errors. The Joint Commission has addressed this in their Sentinel Event Alert, Issue 23: Medication Errors Related to Potentially Dangerous Abbreviations (http://www.jointcommission.org/SentinelEvents/SentinelEventsAlert/sea_23.htm). They recommended that prescribers take the following precautionary steps:

- Avoid the use of the symbol “u”; when ordering drugs administered in unit dosages such as insulin, spell out “units”.
- Spell out medication names completely rather than using abbreviations or acronyms.
- Avoid using abbreviations such as QD for “daily”; QOD for “every other day”, and QID for “four times daily” which are easily confused. Write out the word “discharge” or “discontinue” rather than using the abbreviation “D/C”.
- Precede a decimal point with a 0 (e.g. 0.2mg rather than .2mg) and avoid the use of “trailing” zeros (e.g. 2mg instead of 2.0 mg to avoid confusing 2.0mg with 20mg).
Other factors contributing to prescriber errors include [19]:

1. Illegible or confusing handwriting
2. Overuse of verbal orders, especially when there is no procedure or system in place to assure verification
3. Failure to restrict the use of verbal orders for certain medications such as chemotherapy.
4. Failure to involve the facility’s Pharmacy and Therapeutics Committee to interact with the prescriber staff to limit, where appropriate, the number of therapeutically and generically equivalent products.

MEDICATION ERRORS: RISK REDUCTION STRATEGIES FOR PHYSICIANS

- Avoid use of abbreviations
- Spell out names of medications
- Put 0s before decimal points, i.e. 0.2mg
- Write legibly; print if necessary
- Limit use of verbal orders; confirm by repetition
- Effective communication to nurse(s), especially when ordering an uncommon medication and prescribing an unusual dose.

A national observational study (2003) which focused on prescription dispensing accuracy estimated that between 0.2% and 10% of prescriptions are dispensed incorrectly [22]. Based on this report and many other related publications, a number of risk reduction strategies have been suggested to assure safe dispensing practices in order to reduce the incidence of errors that may harm patients [23-25]:

1. Assure that current drug reference texts are immediately available to prescribing professionals.
2. Be certain that the dispensing pharmacist has available essential patient information (e.g. vital statistics, current medication regimen, current diagnosis, etc).
3. Have in place a process for clarification of any questionable order and resolution of differences of opinion.
4. Whenever possible, dispense dosage units in a ready-to-administer form.
5. Rely more on single-dose vials and ampoules rather than multidose vials.
6. Assure that the pharmacist re-check all mathematical calculations for neonatal and pediatric solutions and other compounded pharmaceutical products.
7. Involve a second pharmacist to verify that a prescribing order is correct, especially when involving high-risk drugs and antineoplastic agents.
8. Enhance an awareness of look alike and sound alike medications and have in place preventative steps to avoid dispensing errors.

### MEDICATION ERRORS: RISK REDUCTION STRATEGIES FOR PHARMACISTS

- Ready availability of drug reference sources (books, online, etc)
- Availability of detailed patient data
- Clarify questionable orders
- When possible, dispense dosage units
- Check and re-check mathematical calculations
- Distraction and interruption-free work area
- Pharm backup to re-check orders (dose, high-risk meds) and calculations
- Awareness of similar sounding or looking medications

Very often, especially in inpatient settings, a prescribed medication is administered by a nurse who often employs the five “rights” before doing so: the right patient, the right medication, in the right dose, by the right route, and at the right time [26]. It has been determined that medication errors fall into four categories which, can be shown to be related to the five “rights” detailed above: (1) failure to follow procedural safeguards related to the patient (e.g. weight, allergies, current medications); (2) unfamiliarity with the medication being dispensed; (3) failure to use the correct mode of administration (e.g. oral, IV, etc); and (4) failure to clarify a confusing order (e.g. incomplete, illegible, or questionable for other reasons). Nurses can be held legally responsible by virtue of a shared responsibility in administering a medication ordered by a physician and dispensed by a pharmacist [27]. A system in place that emphasizes reviewing the five “rights” prior to administering a medication and the four categories in which medical errors can be compartmentalized goes a long way toward assuring that the incidence
of medical errors leading to the occurrence of adverse events which cause patient harm will be reduced substantially.

### MEDICATION ERRORS: RISK REDUCTION STRATEGIES FOR NURSES

- ADHERE TO FIVE “RIGHTS” PRINCIPLE:
  1. **Right** patient (✓ and re-✓ pt. information)
  2. **Right** drug (assure familiarity with drug)
  3. **Right** dose (clarify abbreviations, amount, ✓ mathematical calculations when converting adult to pediatric doses; or when based on pt. weight)
  4. **Right** route (Consult PDR to confirm)
  5. **Right** time (Clarify illegible orders)

In a preceding section of this manuscript, *Reducing and Preventing Errors*, reference is made to special populations at greater risk of sustaining medical errors. It is worthwhile to list these representative samples again, including some not detailed in the earlier section:

1. elderly patients
2. psychiatric patients
3. patients with diminished cognitive function, developmental or learning disabilities
4. infants and young children
5. individuals with hearing or visual difficulties
6. comatose patients
7. heavily sedated members of the general population
MEDICAL ERROR PREVENTION: RISK REDUCTION STRATEGIES FOR HIGH RISK PATIENTS

- Infants and children (open lines of communication with parents/guardians)
- The elderly and falls (↓vision, meds, balance, nocturia, muscle weakness, arthritis)
- Dementia (age, illness, or drug-related)→medication errors
- Special care units (lethargy, coma)
- Focus on identifying unique needs of patients placing them at ↑risk for ME/SE

The pediatric population is at high risk for sustaining injury from medication errors. Pediatric-specific calculations are required to adjust medication dosage according to weight. Healthcare professionals trained to care for pediatric patients must be on site in the facility where health care is delivered. Intolerance to medications is common due to physiologic immaturity. Furthermore, it is difficult for a child to communicate symptoms attributable to adverse drug reactions. Risk reduction strategies must be in place targeted at identified root causes [28].

COMMON MISDIAGNOSES

Misdiagnosis is an obvious contributor to the occurrence of medical errors. Continuing medical education is a requirement especially for the five most commonly misdiagnosed conditions. Recognizing this, the Florida Board of Medicine (2010) has determined that the most commonly misdiagnosed conditions as determined in the last licensing biennium are[29]:

- Cancer
- Neurological conditions
- Acute abdomen
- Late recognition of surgical complications
- Conditions related to pregnancy
1. **Cancer**

   It is well recognized and accepted that early diagnosis is essential to assure an appropriate treatment approach and a better outcome. Regrettably, an estimated 12% of cancer is misdiagnosed, and the missed or delayed diagnoses account for a large number of medical malpractice claims [30-33]. There are many reasons underlying misdiagnoses: (1) atypical or ambiguous presentations; (2) not considered because of the patient’s young age; (3) a low index of suspicion; and (4) diagnosis considered unlikely because of the absence of risk factors.

2. **Stroke and Related Conditions**

   Effective treatment requires rapid recognition and diagnosis of the third leading cause of death in the United States and an important cause of disability. Most are ischemic, caused by thrombosis, embolus, or hypertensive vasospasm. Each may produce a transient ischemic attack (TIA), the result of a temporary disruption of cerebral blood flow, presenting with focal neurologic symptoms including speech slurring of a duration usually less than 30 minutes. Attacks lasting longer than 1 hour are indicative of brain infarction. Treatment undertaken within 3-4 hours of onset increase the likelihood of successful clot dissolution (thrombolytic agent rt-PA {alteplase}) once brain imaging is negative for hemorrhage, and prevention of infarct; this fact underlines the importance of a high index of suspicion and rapid transportation to an emergency room setting equipped to handle such a problem [34]. Stroke must be considered as a diagnostic possibility, irrespective of age if symptoms are compatible; the diagnoses of stroke may be missed in up to 14% of adults less than 50 years of age [36]. The American Heart Association recommends that all such patients receive a battery of standard
tests and undergo a baseline set of procedures [35]. All such tests should be available to a community and in a hospital setting 24 hours a day, seven days a week.

3. **Acute Abdomen**

   This complaint accounts for approximately 5% of visits to ERs and 1.5% of visits to primary care physicians [30]. There are numerous causes to consider. A careful history and physical examination are essential to determine the need for immediate hospitalization, a surgical consultation, and the ordering of an EKG as baseline or to exclude an atypical presentation of ACS. The mode of onset, antecedent symptoms suggesting biliary tract or peptic ulcer disease, the radiation pattern, the character of the pain (e.g. colicky or constant), the appearance of the patient are all factors that facilitate a rational differential diagnosis and the selection of appropriate confirmatory tests. Special consideration has to be paid to this condition in children, the elderly and pregnant women [37].

4. **Surgical Complications**

   Zahn and Miller (2003) presented data indicating that postoperative complications accounted for up to 22% of “preventable” deaths [38]. Not all of these are avoidable. Surgery undertaken for the right reasons, performed by a credentialed, experienced surgeon who knows when to call for assistance in the operating room, and which reveals what was suspected and is appropriately remedied reduces the likelihood of postoperative complications. Baseline (pre-operative) and serial examinations performed in the recovery room by personnel trained to know what to look for as the patient is able to be aroused are likely to detect early complications and facilitate appropriate diagnostic evaluations. The same can be said for follow up on a daily or more frequent basis in the in-hospital; premature discharge should be avoided when in doubt about the explanation for unexpected findings.

5. **Conditions Related to Pregnancy**

   When encountering a woman of child bearing age, no matter the setting or circumstances, a gravid state and/or stage of pregnancy must be high index of suspicion and rapid transportation to an emergency room setting equipped to handle such a problem [34]. Stroke must be considered as a diagnostic possibility, irrespective of age if symptoms are compatible; the diagnoses of stroke may be missed in up to 14% of adults less than 50 years of age [36]. The American Heart Association recommends that all such patients receive a battery of standard tests and undergo a baseline set of procedures [35]. All such tests should be available to a community and in a hospital setting 24 hours a day, seven days a week.

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percentage of female patients (0.15-2.2%) had previously undiagnosed pregnancy at the point
of undergoing surgery. Confirmation or exclusion should be based on hormonal assays in urine
and human chorionic gonadotropin test results. Efforts should be undertaken to obtain
informed prior to testing, and the patient’s privacy concerns should be addressed and
respected. The patient’s consent or lack of same should be noted in the record [39-41].

Ectopic pregnancy may present with a set of symptoms common to a variety of causes
for an acute abdomen due to pelvic pathology; failure to consider this diagnosis can have dire
consequences for the patient who may experience rupture and death [42].

MEDICAL ERRORS: RISK REDUCTION
STRATEGIES IN PREGNANCY

- Exclude pregnancy in all women of child-bearing years
- Especially important when awareness of pregnancy → alteration in management
- Use of informed consent, notations in medical record (agree or decline testing)
- Ectopic pregnancy → 9-15% of 1st trimester maternal deaths (broad range of DDxs)
THE ROLE OF PATIENTS AS THEIR OWN SAFETY ADVOCATES

Guidelines have been developed by a number of organizations to encourage patients to share in the responsibility toward insuring their own safety. The Agency for Healthcare Research and Quality has developed a “Patient Fact Sheet” which includes 20 tips for patients to help reduce the incidence of medical errors [43]. These are guidelines only, not intended to shift the responsibility to patients for reducing medical errors. The informed patient who is able to become involved in his or her own care with the assistance of loved ones and friends and who asks the right questions and accepts only those answers which make sense increases the likelihood of a better outcome.

USE OF AN INTERPRETER

From time to time the services of a skilled interpreter may become both necessary and desirable to assure that effective communication is occurring between healthcare professionals providing care and the patient receiving that care. It is essential to be confident that instructions and information conveyed to the patient are understood. It is important for the physician “in charge” to respect the interpreter as a professional, a member of an interdisciplinary team providing care, who has been trained to negotiate cultural differences and be able to do so ethically, accurately, and with impartiality, able to translate and transmit important information expeditiously when required. The role of the interpreter is critical in circumstances when there is high risk for the occurrence of medical errors (e.g. obtaining informed consent for procedures, making decisions about treatment options, understanding the purpose of recommended therapies, etc).

<table>
<thead>
<tr>
<th>THE INTERPRETER: USE AND ROLE</th>
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<tr>
<td>• The need arises from time to time</td>
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<tr>
<td>• Explain in understandable terms and verify recipient’s understanding</td>
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<tr>
<td>• Skilled interpreter (practitioner&gt;&lt;patient; negotiate cultural differences)</td>
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<tr>
<td>• Essential when informed consent required</td>
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<tr>
<td>• Should enhance clinical encounter and be considered and treated as team member</td>
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CONCLUSIONS
Medical errors, adverse events, contribute significantly to morbidity and mortality. They are usually unanticipated and, more often than not, preventable. A careful study of the circumstances surrounding the care of the patient is undertaken when it is felt that the error was preventable, i.e. a sentinel event. A carefully performed root cause analysis is undertaken to identify factors which contributed to the occurrence of the event. The findings generated by the analysis provide information useful to improve systems and processes in the health care facility providing care. The major objectives of the root cause analysis are to identify and correct problem areas and not to assign blame. The Joint Commission has and continues to play an important role in the establishment of reporting guidelines and the publication of sentinel alerts. The Florida legislature has mandated additional reporting requirements for a specific set of medical errors. All healthcare professionals should be increasingly sensitive to the issue of medical errors, alert to circumstances which increase the risk for their occurrence, and work as a team to reduce the risks when identified. We should strive to encourage our patients to assume some responsibility for their own safety as well; education systems are available to make our patients better informed. We must work together so that the public we serve know of our concerns for their safety and trust the system in which healthcare is delivered.

MEDICAL ERRORS PREVENTION:
TAKE HOME POINTS

- No healthcare professional or institution in which healthcare is delivered intends to make a medical error whether or not it results in serious injury.
- Healthcare professionals and the institutions in which they deliver health care have a shared responsibility to insure a safe environment for patients in whatever setting they receive care.
- The accreditation process conducted by the JCAH serves an educational function.

EVALUATION AND SELF-ASSESSMENT EXAMINATION

REFERENCES


34. Hankey GJ. Patients with suspected TIA and stroke should be referred, assessed, and treated with the same urgency as patients with suspected acute coronary syndrome. *Lancet*. 2005;365:2065.


