This course is intended for the reader to be able to achieve the following objectives:
1. Define factors that contribute to the occurrence of medical errors
2. Define root cause analysis
3. Define sentinel event
4. Understand why it is critical to report medical errors
5. Review laws relating to patient safety
6. Identify how to improve patient outcome from prevention of errors
7. Understand public awareness of medical errors

Statistical Data

It is estimated that 44,000 to 95,000 people die every year from medical errors. Taking in to consideration even the LOWEST estimate, medical errors account for more deaths annually than those caused by motor vehicle crashes, breast cancer, and even AIDS. Every year
over one million people in the United States suffer from preventable injuries caused by medical errors.

Research has documented that most medical errors can be prevented. The Institute of Medicine (IOM) estimates that medical errors cost the United States 39.7 billion dollars a year. (ARHQ, 2000) We all remember the incident in Florida where the man had the wrong leg amputated. This is one of many incidents that happen throughout the medical community and are not made public knowledge often times. As a result from strong publicity, the Institute of Medicine’s committee instituted a report: To err is human: Building a safer health care system which highlights the problem of medical errors in the United States, with an emphasis on how to prevent them. Fear of becoming a victim of a medical error may have led patients to delay medical attention, which in turn may actually allow their symptoms to become worse.

Two key studies, conducted by Brennen and colleagues in 1991 and Thomas in 1999, suggested that adverse events occur approximately 3-4% of patients. Leape reported in 1994 that the average intensive care unit patient experienced almost two errors per day! It is predicted that 20% of these errors were potentially life threatening. To put this into a realistic perspective, if these amount of reported statistics of errors applied to the airline or banking industry, it would be equivalent to two dangerous landings per day at O’Hare International Airport, and 32,000 checks per HOUR deducted from the wrong bank account!!

Many medical errors are associated with the use of medications, and are potentially preventable. The Institute of Medicine estimates that the number of lives lost to preventable medication errors alone, represents over 7,000 deaths annually. (More than the number of Americans injured on the job annually) A 1995 study by Bates has suggested that the problem associated with improper administration of medications accounts for at least 10% of all hospital admissions, and significantly contributes to increased morbidity and mortality in the USA. Leape’s study in 1999 suggested that hospitals in New York State indicated that drug complications represent 19% of all adverse events, and that 45% of these adverse events were caused by medical errors.

However, the IOM report concludes that the majority of medical errors are the result of systemic problems rather than poor performance by individual providers, and has spawned a whole new approach to preventing medical mistakes and improving patient safety. One example came from a study reported by Rebillot, 2000 reporting that a hospital with 310 beds thought its facility was safe. That is, until they did an audit of assessing and reviewing for medical errors. The result showed 200-230 actual or potential errors for every 100 records reviewed. Each patient entering the facility would be at risk for two to three errors during their stay.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reports an alarming increase in surgery on the wrong body parts or on the wrong patient. In 1998, there were 15 ‘wrong site’ cases reported. In just one month, November 2001, 11 cases were reported. 108 cases were reported in the two year span of 2000-2001. 76% involved operating on the wrong body part, 13% operating on the wrong patient, and the remaining 11% involved the wrong surgical procedure. (Tanner, 2001)
Most studies of medical errors have been done in hospital facilities. However, medical errors can and do occur in any situation where there is a healthcare professional/patient involvement.

Defining Medical Errors

The Institute of Medicine defines medical errors as, “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.” 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 and negligence.

There are two types of errors to define.
1. Error of planning- Is when the original intended action is not correct
2. Error of execution- Is when the correct action does not proceed as Intended.

Errors can include problems with practice, procedures, products, and systems. Errors are important because of their impact on patient safety. Medical errors are adverse events that are preventable with our current state of medical knowledge.

Consideration of errors is usually expanded beyond preventable adverse events that lead to actual patient harm to include near misses, also referred to as close calls. A near miss is an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or by timely intervention.

The definition of a medication error is when a patient receives a medication that is:
   - Not ordered by the physician
   - Not as specified by the manufacturer
   - Not in accordance with accepted national, state, and association of professional nursing standards and principles.

The definition of a significant medication error is one that causes the patient discomfort, or puts the patient’s health and safety at risk.
There are three guidelines for determining significance:
1. Patient’s condition (missing a dose of pain medication which puts the patient in severe discomfort)
2. Drug category- (such as a drug that requires titration)
3. The frequency of the error (if repeated can become significant)

A medical error is something that happens that was not planned, as part of the normal medical care or when a plan of care was not put into place correctly to begin with. These medical errors can occur anywhere, at anytime in the medical setting.

Different Stages of Medical Errors

There are different stages in which a medication error can happen.
   Prescribing of medication
   Dispensing of medication
   Administration of medication
   Monitoring the effects of the medication

In the prescribing stage of medications, many potential problems can arise.
   Ordering the incorrect dose
   Ordering the incorrect drug
   Ordering the wrong interval or schedule
   Ordering the wrong route of administration
   Ordering the wrong rate
   Ordering the wrong dose form (tabs, liquid)
   Handwriting that is illegible
   Incomplete orders
   Ordering and not being alert to allergies
   Ordering and not being aware of pre-existing medical conditions
   Ordering without reviewing and being aware of current medications patient is taking resulting in adverse reactions.
In the prescribing stage, prevention would include: educating the prescriber, educating the nurse, completing a thorough assessment of the patient’s history including allergies and current medications, clarifying orders that are illegible, and a review by the consultant pharmacist of medication profiles.

In the dispensing phase, some potential problems include:
- Dispensing the wrong drug
- Dispensing the wrong dose
- Inaccurate directions for use of medications
- Failure to educate patient on use of medication
- Dispensing an expired medication
- Failure to assess, review the patient medication profile
- Dispensing without knowing patient allergies
- Dispensing without knowing patient conditions, and medical history (such as why the drug is prescribed)

Prevention tips related to the dispensing stage would include:
- Checking the expiration dates on drugs
- Checking the integrity of the drug
- Review patient medication profile
- Be clear of proper use of the drug
- Clear concise instructions for medication usage
- Clarifying all questionable orders
- Knowing what the drug is used for
- Know patient allergies
- Know patient history

Potential problems related to administration of medications include:
- Follow the five rights to medication administration
- Right patient, right drug, right dose, right route, and right time
  - Educate the patient as to why he is receiving the medication and be aware of the patients right to refuse any medication. Be aware that if a patient refuses a medication, it is not a medical error. If a nurse leaves the medication at the bedside, and it is thrown out without the nurse knowing, this can be considered a medication error.
- Omitting medications
- Administering an unauthorized medication
Not shaking a medication that should be ( can lead to overdose or under dose)
Crushing medications not intended to be crushed

Potential problems with the Monitoring stage of Medications
Laboratory tests need to be monitored and reported
Side effects of medication
Monitor effectiveness of therapeutic action of medication
Complying with a pain management program
Assess and monitor vital signs

Where Do Medical Errors Occur?

Hospitals
Outpatient settings
Physician offices
Pharmacies
Nursing homes
Clinics
Home health

Types of events that occur

Types of medical errors can include surgical errors, medication errors, equipment failure, patient abduction, patient assault, suicide, wrong blood transfusions, falls, failure to order and interpret labs, diagnosing and treatment orders, and the list goes on and on?????.

There are two specific kinds of factors that impact the incidence of medical errors.
1. Individual factors
2. System failure factors

In individual factors, they could be related to:
Distractions
Stress
Complacency
Increased workload
Lack of education
Lack of common sense
Failure to follow policy and procedures

System failures can include poor policy and procedures, poor tracking systems to identify cause and prevention of errors, and breakdown in communication and education regarding these systems.

Situations that will contribute to more errors, are an environment that is conducive to interruptions, distractions, very noisy, tense/stressful, poor communication, and a lax environment.

It has been determined that most errors do not occur from individual negligence or mistake, but a system error in which there were several small occurrences that took place leading to an event.

Root Cause Analysis

A "root cause" is defined as "the most fundamental reason an event has occurred". (NCPS, 2001)
There are three levels of analysis when looking at the root cause of an error.

The first level is the direct cause or injury analysis. It defines how the injury was caused. (such as a reaction to a medication)

The second level is the event or special cause analysis. This level looks at surface causes or specific unsafe behaviors that result in an accident. Proximal cause would be included in this level. Proximal cause is the cause closest to the accident.

The third level would include systems analysis or root cause analysis. This analysis traces various causes to common behaviors and conditions that ultimately result in an accident. The analysis looks at policies, procedures, programs, and processes.
One major study has shown that 3/4ths of all adverse drug events were failures at the system level.
Analysis of the underlying cause and effect is achieved by a series of "why" questions. Root cause analysis needs to be an interdisciplinary approach involving clinicians, those who are familiar with the event, those who work with the processes and systems every day, and those in the management team.
Root cause analysis identifies changes that need to be made in order to prevent reoccurrence and improve patient safety.
The Joint Commission requires a root cause analysis to be completed on any serious or sentinel event. (those that threaten life, limbs, body function, or produces psychological harm)

In order for root cause analysis to be acceptable, it must include:
- Determination of human and other factors
- Identification of risk factors
- Analysis of underlying systems through series of ?why? questions
- Determination of related systems and processes
- Determination of improvement processes that would decrease likelihood of reoccurrence.

Root cause analysis is a tool that helps identify and clarify the bottom line reason that causes an error. Root cause analysis continually digs deeper by asking ?Why? over and over. The rule of thumb is to ask why five times, or until no additional logical answers can be identified. When you get to a point where there is no further logical answer to ?why?, you have reached a root cause.

What Are Sentinel Events?

Sentinel Events are unexpected events that result in (or could result in) the serious injury or death of a patient or resident. Serious injury can be a physical or psychological injury. It includes a loss of a limb or organ, or a major permanent loss of body function. Sentinel event related to death is a death that is unrelated to natural or expected course of a patient?s or resident?s health problems.

Every healthcare worker plays an important role in helping to prevent negative incidents in health care. This includes:
- Manufacturers
- Physicians
- Nurses
- Pharmacists
- Data entry staff
- technicians consultant pharmacists
- Support staff
- Administrative staff
Regulatory bodies and professional organizations focus a lot of attention on patient and resident safety. The Joint Commission has standards relating to root cause and sentinel events, as discussed earlier.

The public places their trust in healthcare workers. Patients, residents and their families need and deserve to know they will receive safe, high quality care when they go to a healthcare facility.

Sentinel events take on many forms.

Such as:
- Wrong site surgery (wrong part, or wrong patient)
- Hemolytic transfusion reactions (patient receives wrong blood type transfusion)
- Death of a patient or resident in restraints (such as suffocation, strangulation, or fire)
- Suicide of patient or resident
- Assault or rape (committed by another patient, resident, or staff member)
- Infant abduction (or discharge to home to wrong family)

An unexpected death, serious injury, or major permanent loss of body function may also result from:
- Medication errors (such as giving wrong patient the wrong drug, or right drug in wrong dose, wrong time, or wrong way)
- Treatment delays (such as delays in hooking up monitors or reacting to signs of distress)
- Complications during or after surgery (such as bleeding, infection, or surgical objects left inside the patient)
- Equipment misuse (poor equipment or malfunction)
- Patients leaving facility (without permission- lack of supervision and/or security)

A sentinel event requires immediate attention. REPORT IT AND DOCUMENT objectively by describing the event in detail. Fill out an incident report.

Reporting sentinel events helps everyone.
Always follow your facilities policies and procedures for informing patients before you inform them of any mistake. Many patients and families are grateful to be informed and being honest. They may be less likely to file a lawsuit. ALWAYS INFORM YOUR SUPERVISOR FIRST BEFORE TALKING TO A PATIENT OR FAMILY ABOUT AN ERROR OCCURANCE. Make certain you complete an incident report.

The purpose of reporting is to protect other patients from a similar occurrence, improve patient care. It is NOT to blame the person making the error.
Every sentinel event requires a root cause analysis to be done. This helps to uncover the factors that led to the event. No system is perfect, but working toward perfection is a must for providing quality patient and resident care.

Responsibilities In Reporting

There are two types of reporting:

Voluntary and Mandatory

Voluntary reporting focuses on safety, and improving patient outcome. Voluntary reporting deals with potential error or minimal patient harm. There are not any penalties or fines associated to the healthcare provider.

Mandatory reporting is to make the healthcare worker take responsibility for reporting errors/events that result in serious harm or death. (sentinel event)

Remember the three R?s to reporting:
   - Rapport
   - Report
   - Record

Florida Law

As healthcare professionals we have an obligation to report these types of events to supervisors to ensure safety measures are put into place to prevent further problems. In Florida, certain serious adverse incidents must be reported to AHCA. (Agency for Health Care Administration). Florida law requires that licensed facilities, such as hospitals and nursing homes, establish an internal risk management program, develop and implement an accident reporting system, which imposes an affirmative duty on all healthcare providers and employees of the facility to report adverse incidents to the risk manager. The risk manager must receive these reports within three days of the incident, and depending on the type of incident, the risk manager must report the incident to AHCA within 24 hours of the report.

Under Florida law, an adverse incident is defined as: an event in which healthcare personnel could exercise control, and the
accident/incident could have been prevented?

For other types of adverse incidents, Florida Law requires that the facility report the incident to AHCA within 15 days of the incident. Failure to report the incident in the obligated time frame can result in fines up to $25,000 per violation.

Safety Needs of Special Populations

Special populations include children and elderly, pregnant women, immigrants, cognitively disabled, mentally ill, physically disabled and low income and uninsured individuals.

What do they all have in common?

They are vulnerable, may not have adequate support systems, may not be able to advocate or speak for themselves, incapable to make decisions, and/or may be financially dependent.

Educating The Public

We as healthcare professionals must stress the importance of preventing medical errors by encouraging them to ask questions, and have an active part in their health care.

Such as:

- Inform regarding look alike medications
- Name brand vs. generic brand (many patients have duplicated prescriptions, and are unaware they are taking the same drug twice due to different brand names)
- Some cannot afford the medications and therefore do not get the prescriptions filled

CONCLUSION

Although the United States provides some of the best healthcare in the world, it is apparent that the number of medical errors are at an unacceptably high number. The consequences of medical errors are higher than errors in other industries. We must become active in finding solutions to problems. This will only happen if all healthcare professionals voice their concerns when they identify problems in a system or
process. We must fully understand that the goal is not to assign blame, but to correct problems to prevent reoccurrence of the same. Safe patient outcome is the ultimate goal in preventing medical errors. Medical errors are costly, not only because our patients may lose their lives or livelihoods, but also because our patients lose trust in the healthcare system, and our colleagues lose faith in one another. To restore the faith, and prevent potential life threatening errors, it begins with each and every one of us to be informed, know how to report, and talk responsibility for errors. The solution is then further found by investing the cause and preventing another patient from being the next victim of medical errors.

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