

# Medical Errors Biennium 2008 - 2010

This course meets the 2-hours Medical Errors continuing education requirement for healthcare providers in the state of Florida.

## Objectives:

- Explain the document of the Institute of Medicine
- Describe Types of Medical Errors
- Describe Causes of Medical Errors
- Explain the Prevention of Medical Errors
- Discuss the Position of the Joint Commission
- Explain the Root Cause Analysis
- Explain the role of the Patient and the Caregiver in Medical Errors

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## Background

In 1999 the Institute of Medicine (IOM) presented a report titled *To Err Is Human: Building A Safer Health System*. This report was focusing its attention to the issues of medical errors and patient safety, stating that in the United States an estimated 44,000 to 98,000 people died unnecessary in hospitals due to medical errors.

In comparison to other causes of death in the United States, medical errors are the eighth leading causes of death. It is even higher than auto accidents, which is estimated at 43,458, breast cancer at 42,297 and AIDS at 16,516. The amount of death estimated due to medication errors alone in the U.S. is about 7,000 people per year, calculating this to be 16 percent higher than death associated to work-related injuries.

As a result of the IOM report, President Clinton ordered the Quality Interagency Coordination Task Force (QuIC) to make recommendations on improving health care quality and protecting patient safety responding to the report. According to the CDC (2001), the statistics showed that in the United States five other causes led to more deaths than medical errors:

Heart Disease	700,000
Cancer	554,000
Stroke	164,000
Chronic lower respiratory disease	123,000
Accidents	102,000

## Types of Medical Errors

Adverse Event – undesirable and unintentional, though not necessarily unexpected, results of medical treatment. An example of an adverse event is discomfort in an artificial joint that continues after the expected recovery period, or a chronic headache following a spinal tap. A medical error, on the other hand, is an adverse event that could be prevented given the current state of medical knowledge.

The QuIC task force expanded the IOM's working definition of a medical error to cover as many types of errors as possible. Their definition of a medical error is as follows: "The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems." A useful, brief definition of a medical error is that it is a preventable adverse event (QuIC, 2000). In reality, medical errors cannot be set to one specific classification as this may cover various areas. The report presented by QuIC in 2000 listed five different classifications in order to narrow down the areas of incidence. These include:

- type of health care given (medication, surgery, diagnostic imaging, etc.)
- severity of the injury (minor discomfort, serious injury, death, etc.)
- legal definitions (negligence, malpractice, etc.)
- setting (hospital, emergency room, intensive care unit, nursing home, etc.)
- persons involved (physician, nurse, laboratorian, pharmacist, patient, etc.)

According to Frey (Frey, 2009), “the importance of these different ways to classify medical errors is their indication that different types of errors require different approaches to prevention and problem solving. For example, medication errors are often related to such communication problems as misspelled words or illegible handwriting, whereas surgical errors are often related to unclear or misinterpreted diagnostic images”.

### **A. Laboratory Errors:**

There are two types of errors that can be reflected within the clinical and anatomical laboratories. Medical error has been defined as “A commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, regardless of whether there were any negative consequences.” (Pai, 2005). The commission error involves action, and the omission error involving inactions. The commission errors can be related to errors such as a test specimen being mislabeled, blood samples being drawn from the wrong patient, and even incubating test or specimens at the incorrect temperature. On the other hand, omission errors may include errors such as omitting a reagent in a test, failure to communicate the results of a critical test, and forgetting to collect a specimen at a specified time. The recognized errors discovered in laboratory practices vary between laboratories and depend on many factors, not least of which is the competence of the pathologist and technicians.

Causes for Laboratory Errors:

- Humans?
- Reagents?
- Instruments?
- Other?

### **Types of Laboratory Errors**

The mistakes occurring in the laboratories are based in the levels of pre-analytic, analytic and post-analytic. It is difficult to pinpoint at what level laboratory errors occur. The outsider or clinicians attributes laboratory errors to the analytical level. However, many studies have shown that 68 to 87% of the laboratory errors occur at the pre-analytic and post-analytic level. According to Pai (2005), In the clinical laboratory “variables such as time of sample collection and length of time of application of a tourniquet can affect haematological and biochemical values. Drug interactions may interfere in various analyses and have been known to confound the best of clinicians. In the era of automation, there are fewer analytic errors”. Some literature have reported that in surgical pathology the errors are more frequently in the post-analytical level giving as example a faulty transcription or understanding of the report.

#### **a. Pre-Analytical Errors**

Preanalytic medical errors begin with the patient and the places he or she receives medical care the bedside, chair-side, hospital, clinic--wherever the patient is located.

The possibility for these errors continues through the ordering processes for medical tests or procedures.

Preanalytic medical errors also happen with the systems, processes, and procedures involved in the collection of test samples from patients.

These medical errors occur during the time before the laboratory is directly involved in assaying and analyzing test samples.

- Sample identification - Wrong patient
- Order/Entry Errors - Wrong test
- Sample integrity/timing - Wrong timing
- Phlebotomy technique - Wrong collection procedure  
Wrong tube, container, additive

#### b. Analytical Errors

Medical errors also occur in the analytic processes and systems of patient care.

Analytic errors begin with problems in the transportation of medical samples for testing. These occur between the patient's location and the testing facility. They happen during the time between specimen collection and arrival in the testing facility.

The possibility for analytic medical error continues through the analytic processes and procedures of medical testing.

Analytic medical error also includes systems, processes, and procedures involved in the transmission and reporting of test results.

These medical errors occur during the time the laboratory is directly involved in receiving, analyzing, and reporting test samples.

- Wrong transport storage or temperature
- Delay in transport
- Sample mixup during transport
- Acceptance of unacceptable samples that are insufficient, hemolyzed, or clotted
- Centrifugation, mixing, and other test sample preparation errors
- Wrong test procedures
- Test control errors
- Sample mixup during testing
- Outdated reagents
- Wrong reagents
- Test result mixup
- Transcription errors
- Data reporting process errors and result report delays

#### c. Post-Analytical Errors

Errors also occur after analyses are completed and reported. Postanalytic errors begin with the medical professionals who receive test results, and they include interpretation of the results.

These errors can occur at--the bedside, chair-side, hospital, clinic-- wherever the patient and the

medical professional are located. The possibility for postanalytic medical error continues

through diagnosis and treatment procedures and processes. These medical errors occur during the time after the laboratory reports test results.

These medical errors occur during the time after the laboratory reports test results.

- Wrong test value associated with patient
- Wrong test interpretation
- Wrong diagnosis
- Wrong treatment
- Accessioning--name on specimen and tube do not match, put different numbers on form and tube
- Specimen Analysis--misidentify patient, misread results
- Enter Results in computer--enter the incorrect result
- Report Results--report to wrong provider

### **Headlines of Laboratory Errors**

*“Laboratory Errors Suspected as Cause of Two Deaths”* Emergency Medicine News

In June, the hospital laboratory did not verify the new reagent used in the PT measurement device, and as a result, the ISI used to calculate the INR was incorrect for the reagent used. The World Health Organization recommends use of the INR to standardize PT results from various manufacturers' devices and testing reagents

*“Suit Says Transplant Error Was Cause in Baby's Death”* NYTimes

A laboratory mixed up the blood types of the baby's parents and incorrectly identified the father as a suitable donor of a partial liver when; in fact, the mother should have been the donor.

Although subsequent blood tests revealed the father's true blood type, hospital personnel did not notice the mismatch. Mother and baby had Type O blood; the father is Type A.

*“Hospitals move to cut dangerous lab errors”* Pittsburg, Post Gazette

Diagnosed with a deadly neuroendocrine cancer at age 34, Kim Tutt was told she might have just months to live. After five surgeries to excise a cyst under her gum, remove her lower jaw and teeth, and reconstruct her face with bone taken from her lower leg, the Tyler, Texas, mother of two heard some shocking news: The slides from the biopsy of her cyst had been contaminated by cells from another patient, and she had never had cancer in the first place.

*“Allegations of medical lab errors mounting”* The Boston Globe

When the 47-year-old woman from Ohio got back the results of her breast biopsy from Magee-Womens Hospital in 1999, she faced few medical options. The lab found invasive cancer requiring immediate surgery. She promptly underwent a mastectomy, followed by two months of painful radiation treatments, unaware that there had been a mistake. It turned out that the hospital lab had mistakenly switched biopsy specimens. She had no cancer. The positive reading belonged to a 64-year-old Pennsylvania woman.

### **B. Medication Errors:**

These are errors that may occur outside of hospitals. The administration or dispense of prescriptions account for a major percentage of Medical Errors. In 1999 the The Massachusetts State Board of Registration in Pharmacy reported that an estimated 2.4 million prescriptions are filled incorrectly each year in that state—this is only one of 50 states.

### **C. Near Misses:**

When a reference is made to near misses “Close calls” the identification is made to medical events that avert unwanted consequences. A person or something identifies and corrects harmful influences before they cause adverse events.

#### **D. Medical Negligence:**

Unfortunately, adverse events do occur in healthcare situations. They may or may not be preventable and they may or may not involve medical negligence. Medical negligence is the legal term describing the adverse events involving patient care that fails to meet specific, established standards. Medical negligence occurs when a medical professional does or does not perform the correct action, resulting in great patient harm (an adverse event).

## **Causes of Medical Errors**

The mere mention of medical errors makes one wonder about the involvement of such errors. Most people believe that medical errors usually involve drugs, such as a patient getting the wrong prescription or dosage, or mishandled surgeries, such as amputation of the wrong limb. The truth is that the causes of medical errors are complex and not yet completely understood. Some causes that have been identified include the following:

#### **Communication Errors**

One widely publicized case from 1994 involved the death of a Boston newspaper columnist from an overdose of chemotherapy for breast cancer due to misinterpretation of the doctor's prescription; the patient was given four times the correct daily dose, when the doctor intended the dosage to be administered instead over a four-day period. Other cases involve medication mix-ups due to drugs with very similar names. The Food and Drug Administration (FDA) has identified no fewer than 600 pairs of look-alike or sound-alike drug names since 1992.

The increasing specialization and fragmentation of health care. The more people involved in a patient's treatment, the greater the possibility that important information will be missing along the chain.

#### **Human errors resulting from overwork and burnout**

For some years, hospital interns, residents, and nurses have attributed many of the errors made in patient care to the long hours they are expected to work, many times with inadequate sleep. With the coming of managed care, many hospitals have cut the size of their nursing staff and require those that remain to work mandatory overtime shifts. A study published in the *Journal of the American Medical Association* in October 2002 found a clear correlation between higher-than-average rates of patient mortality and higher-than-average ratios of patients to nurses.

#### **Laboratory Errors**

Most laboratory errors are the result of human action or a human interaction with an instrument of reagent. Daily Quality Control is intended to verify that instruments and reagents are working properly. Errors related to equipment and reagents are often the result of humans failing to detect problems through QC.

#### **Manufacturing/Blood Transfusion Errors**

Instances have been reported of blood products being mislabeled during the production process, resulting in patients being given transfusions of an incompatible blood type.

#### **Equipment Failure**

A typical example of equipment failure might be intravenous pump with a malfunctioning valve, which would allow too much of the patient's medication to be delivered over too short a time period.

## **Diagnostic Errors**

A misdiagnosed illness can lead the doctor to prescribe an inappropriate type of treatment. Errors in interpreting diagnostic imaging have resulted in surgeons operating on the wrong side of the patient's body. Another common form of diagnostic error is failure to act on abnormal test results.

## **Poorly designed buildings and facilities**

Hallways that end in sharp right angles, for example, increase the likelihood of falls or collisions between people on foot and patients being wheeled to an operating room.

No matter how we view medical errors when they happen they can be attributed to one or more of the categories:

- Diagnoses
- Treatments
- Performance
- Communications
- Systems
- Medications

## **Where do Medical Errors Occur?**

Medical errors are not just an association with a hospital setting. There are many non-hospital sites where medical errors may occur and these include:

- Non-hospital Laboratories
- Nursing homes
- Home health care
- End-of-life care
- Doctor's offices
- Urgent Care centers

## **Cost of Medical Errors**

In terms of health-care costs, the IOM report estimated that medical errors cost the United States about \$37.6 billion each year; about half this sum pays for direct health care.

## **Prevention of Medical Errors**

All available research reflects that medical errors in their majority can be prevented. One of the studies indicates that 70 percent of adverse events found in a review of 1,133 medical records were preventable 6 percent were potentially preventable; and 24 percent were not preventable. A study, based on a chart review of 15,000 medical records in Colorado and Utah; found that 54 percent of surgical errors were preventable.

In the laboratory, maintaining a good communication between clinicians and pathologists can be a source to reduce all levels of errors. Understanding the various available tests and work together as to a diagnosis and course of treatment may be the key to error reduction. The communication can be based on:

- a. Making requisitions and reports clear and standardized
- b. Inclusion of a comment on the report
- c. Follow process with a call

According to Pai (2005), "Errors in clinician interpretation may be the result of a misunderstanding or unfamiliarity with terminology. It is a fairly common practice in surgical pathology to include a comment in the final report that may clarify a point or increase the doctor's understanding of the report".

## Ways of thinking about Medical Errors

### a. Who to blame for Medical Errors?:

In the report by Frey (2009), explains that "one subject that has been emphasized in recent reports on medical errors is the need to move away from a search for individual culprits to blame for medical errors. This judgmental approach has sometimes been called the "name, shame, and blame game." It is characterized by the belief that medical errors result from inadequate training or from a few "bad apples" in the system. It is then assumed that medical errors can be reduced or eliminated by identifying the individuals, and firing or disciplining them. The major drawback of this judgmental attitude is that it makes health care workers hesitate to report errors for fear of losing their own jobs or fear of some other form of reprisal. As a result of underreporting, hospital managers and others concerned with patient safety often do not have an accurate picture of the frequency of occurrence of some types of medical errors". The IOM report concluded that the majority of medical errors were not the fault of the individual practitioners, but the fault of systemic processes!

### b. What being done?

The QulC presented the recommended report to the president urging the adoption of model borrowed from industry that incorporates systems analysis. The use of an industrial model is found to be a continuous quality improvement model (CQI). At the arising of medical errors concerns, many hospitals implemented error-reduction programs based on CQI concepts and have found that a non punitive system of reporting errors can be implemented busting the trust of the employee and the reporting of medical errors. The report of the QulC focused on concepts to create a national focus on patient safety, performance standards and expectation for safety and the implementation of safety systems in health care organization. The report of the IOM published a follow-up report: *Crossing the Quality Chasm: A New Health Care System for the 21st Century* and a National Initiatives known as The National Summit on Medical Errors and Patient Safety Research.

## Root Cause Analysis

Situations which are recurring with the greatest frequency and consume the most resources to rectify are the candidates for root cause analysis

- ❖ Root Cause Analysis: Identifying possible problems to be analyzed
  - Look for recurring problems. If something happens multiple times, consider reviewing the process and look for ways to make changes that will prevent the problem from occurring
- ❖ Root Cause Analysis: Evaluate the Process

- Once problems are identified, review the entire process and look for opportunities for errors to occur. It is important to include the people who perform the process since they know it best.
- ❖ Root Cause Analysis: Identify Potential Changes
  - Identify changes that could be made to prevent errors from occurring again
- ❖ Root Cause Analysis: Is it more cost effective to keep putting out the fires?
  - Once possible solutions are identified, you must consider the cost versus the cost of an error. In some cases costs of making a change may be much more that the cost of an error. For example, a scale in the doctors' office consistently gives weights that are off by 5 pounds. For an adult it would not be a big problem but what about for a child? How about an infant?
- ❖ Root Cause Analysis
  - Is it more cost effective to keep putting out the fires?
    - In some cases the cost of a solution might be much more than the cost of dealing with the errors
      - Example-a robotic instrument can be purchased that will process 100 specimens per hour with virtually 0% errors. The cost is 20 times the cost of employing 2 technologists to process the specimens. If the technologist makes an average of 2 errors per month, is it enough to justify the additional cost? What would your decision depend on?

## Joint Commission & Medical Errors

The Joint Commission (JACHO) was founded in 1951 in order to seek a continuous improvement in health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. The Joint Commission evaluates and accredits more than 17,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is the nation's oldest and largest standards-setting and accrediting body in health care.

**Position Statement:** The Joint Commission on Accreditation of Healthcare Organizations is committed to improving patient safety through its accreditation process. Meaningful improvement in patient safety will eventually be reflected by a significant reduction in the number of medical/health care errors that result in harm to patients.

### Steps to achieve goals outlined in position statement:

1. Identification of the errors that occur.
2. Analysis of each error to determine the underlying factors -- the "root causes" -- that, if eliminated, could reduce the risk of similar errors in the future.
3. Compilation of data about error frequency and type and the root causes of these errors.
4. Dissemination of information about these errors and their root causes to permit health care organizations, where appropriate, to redesign their systems and processes to reduce the risk of future errors.

5. Periodic assessment of the effectiveness of the efforts taken to reduce the risk of errors.

### **JACHO Sentinel Event Policy:**

In support of its mission to continuously improve the safety and quality of health care provided to the public, The Joint Commission reviews organizations' activities in response to sentinel events in its accreditation process, including all full accreditation surveys and random unannounced surveys and, as appropriate, for-cause surveys.

- A sentinel event is an unexpected occurrence involving 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.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.
- The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

### **JACHO 2010 Laboratory National Patient Safety Goals**

The purpose of the National Patient Safety Goals is to improve patient safety. The Goals focus on problems in health care safety and how to solve them.

Goal – Improve the accuracy of patient identification.

A. Use of Two Patient Identifiers (NPSG.01.01.01)

**Identify patients correctly:** Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the medicine and treatment meant for them.

Goal – Improve the effectiveness of communication among caregivers.

A. Timely Reporting of Critical Tests and Critical Results (NPSG.02.03.01)

**Improve staff communication:** Quickly get important test results to the right staff person.

Goal – Reduce the risk of health care–associated infections.

A. Meeting Hand Hygiene Guidelines (NPSG.07.01.01)

**Prevent infection** Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization.

## **Improvement for Medical Errors**

Current proposals for reducing the rate of medical errors in the American health care system include the following:

- Adopt stricter standards of acceptable error rates.
- Standardize medical equipment and build in mechanical safeguards against human error.
- Improve the working conditions for nurses and other hospital staff.
- Make use of new technology to improve accuracy in medication dosages and recording patients' vital signs.
- Develop a nationwide database for error reporting and analysis.
- Encourage patients to become more active participants in their own health care.
- Address the fact that both patients and physicians have emotional as well as knowledge-related needs around the issue of medical errors.

# The Role of the Patient

Medical Errors have been the number one issue in patient care. Patients can take an important role in reducing the rate of medical errors. The QulC task force initiated awareness that will help patients improve the safety of their health care. One of these fact sheets, entitled "Five Steps to Safer Health Care," gives the following tips:

- Do not hesitate to ask questions of your health-care provider, and ask him or her for explanations that you can understand.
- Keep lists of all medications, including over-the-counter items as well as prescribed drugs.
- Ask for the results of all tests and procedures, and find out what the results mean for you.
- Find out what choices are available to you if your doctor recommends hospital care.
- If your doctor suggests surgery, ask for information about the procedure itself, the reasons for it, and exactly what will happen during the operation.

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# TEST

1. Types of Laboratory Errors includes all, except:
  - a) Pre Analytical Errors
  - b) Analytical Errors
  - c) Post Analytical Errors
  - d) Enzymatic Errors
2. Daily quality control is intended to verify that instruments and reagents are working properly:
  - a) True
  - b) False
3. In the United States, approximately \_\_\_\_\_ died due to medical errors:
  - a) 44,000 – 98,000
  - b) 10,000 – 30,000
  - c) 110,000 – 144,000
  - d) 144,000 – 150,000
4. Which of the following is considered to be a cause of Medical Errors?
  - a) Communications
  - b) Manufacturing
  - c) Diagnostic
  - d) All of the above
5. The position statement for The Joint Commission includes identification of the errors that occur:
  - a) True
  - b) False
6. JACHO 2010 Laboratory National Patient Safety Goal includes:
  - a) Use of two patient identifier
  - b) Communication between caregiver
  - c) Reduce the risk of healthcare associated infections
  - d) All of the above
7. As a patient responsibility it is important that they keep a list of their medications:
  - a) True
  - b) False
8. Medical Errors are the \_\_\_\_\_ leading cause of death in the United States.
  - a) Second
  - b) Four
  - c) Sixth
  - d) Eighth
9. An Analytical Error can begin in the transportation of medical samples for testing:
  - a) True
  - b) False
10. According to the IOM report Medical Errors in the United States is costing about \_\_\_\_\_ a year:
  - a) 37.6 million
  - b) 37.6 billion
  - c) 37.6 trillion
  - d) 376 million

# Answer Sheet

Title: **Medical Errors Biennium 2008 - 2010**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

FL Licensure #: (TC, TN, SU) \_\_\_\_\_

Note: Circle the correct answer.

- |            |          |          |          |          |
|------------|----------|----------|----------|----------|
| <b>1.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>2.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>3.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>4.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>5.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>6.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>7.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>8.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>9.</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |
| <b>10.</b> | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> |

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