

**Prevention of Medical Errors**  
**Florida Osteopathic Medical Association**  
**Mid-year Seminar**  
**September 14-17, 2017**  
**Grand Hyatt Tampa Bay, Florida**

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# Florida Board of Osteopathic Medicine Requirements

- Two hour Prevention of Medical Errors course.
- Include a study of root cause analysis, error reduction and prevention, and patient safety.
- Address medication errors, surgical errors, diagnostic inaccuracies, and system failures, and
- Provide recommendations for creating safety systems in health care organizations.
- Must include information relating to the five most mis-diagnosed conditions during the previous biennium, as determined by the Board.

# Objectives

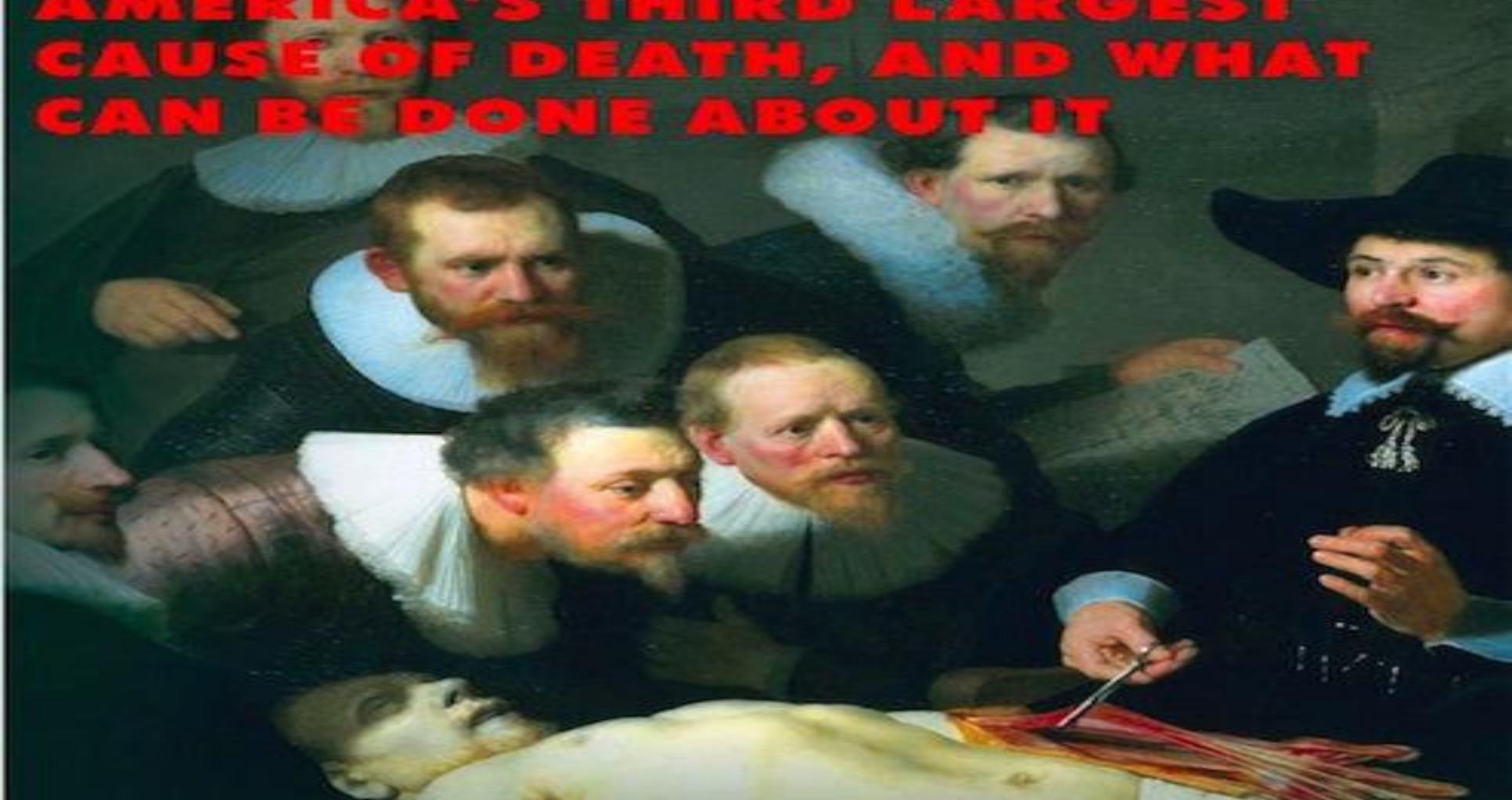
## Review and Discuss

- Myths of Medical Errors.
- Medical Errors – overview.
- Florida Board of Osteopathic Medicine Most Common Misdiagnosed Conditions.
- Root Cause Analysis.
- What Physicians can do to Improve Prevention of Medical Errors.

# Medical Errors - How Common?

# KILLER CARE

**HOW MEDICAL ERROR BECAME AMERICA'S THIRD LARGEST CAUSE OF DEATH, AND WHAT CAN BE DONE ABOUT IT**



# IOM

## “TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM”

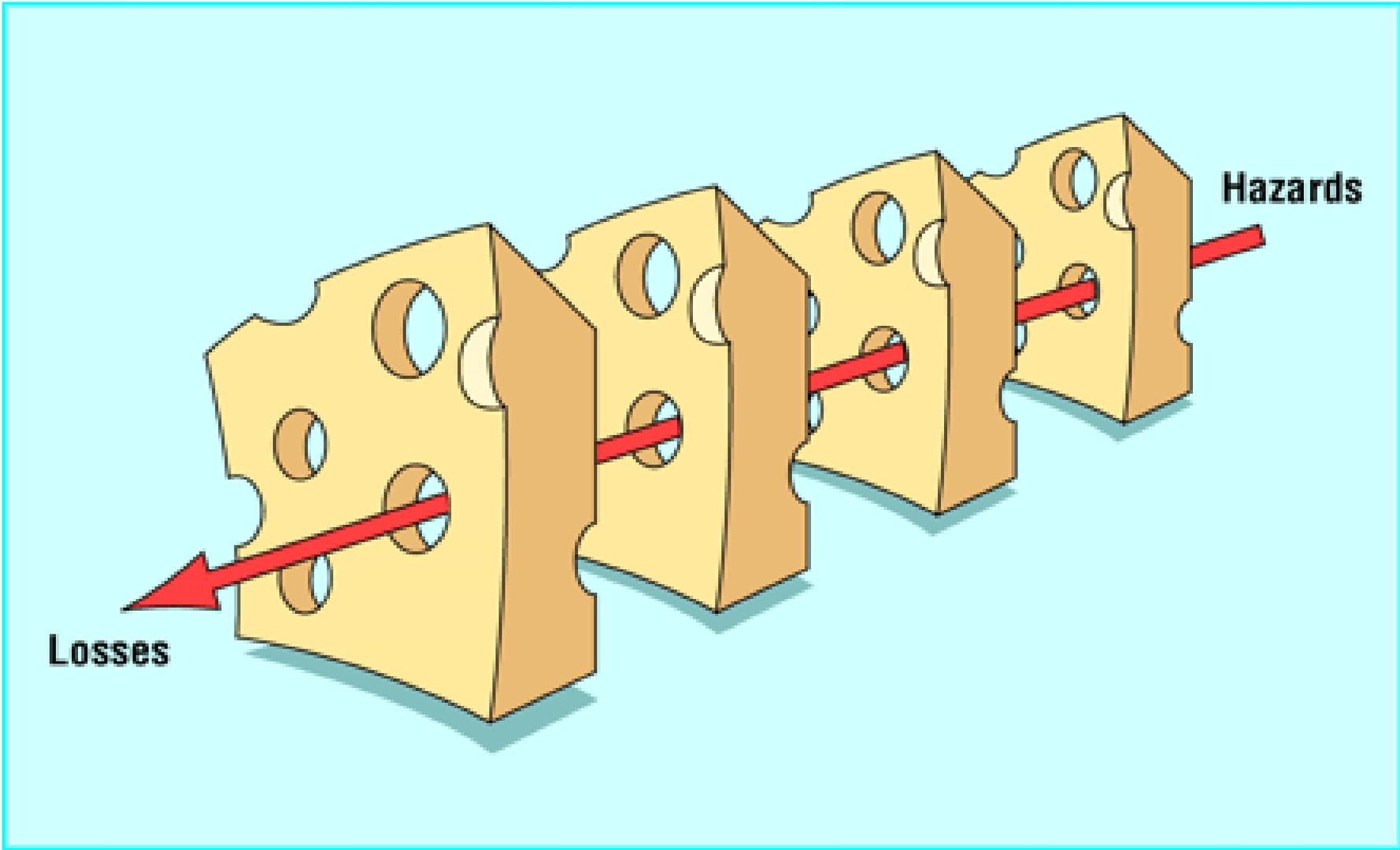
- **Debate after the IOM report about the accuracy of its estimates.**
- **Whether the deaths of 100,000, 200,000 or 400,000 is unknown - but at any level significant issue.**
- **Action and progress on patient safety is frustratingly slow.**

November 29, 1999

Journal of Patient Safety: September 2013 - Volume 9 - Issue 3 - p 122–128, doi: 10.1097/PTS.0b013e3182948a69

Campbell EG, Regan S, Gruen RL, et al. Professionalism in medicine: results of a national survey of physicians. *Ann Intern Med.* 2007; 147: 795–802.

Junya Z, Struver S, Epstein A, et al. Can we rely on patients' reports of adverse events? *Med Care.* 2011; 49: 948–955.



# Top Myths About Diagnostic Errors Held by

Patients

Physicians

Healthcare Systems

# Top Myths about Diagnostic Errors Held by Patients

1. No news is good news.
2. My doctors are talking to one another.
3. My doctor is different.
4. Somebody is in charge of my diagnosis.
5. There is always an answer.
6. My hunches don't count as much as my physician's.
7. I would be disloyal to my physician if I ask for a second opinion.
8. My insurance won't pay for a second opinion.
9. The more tests I have, the better.
10. Diagnosis errors won't happen to me.

# Top Myths about Diagnostic Errors Held by Physicians

1. It won't happen to me.
2. I can trust my intuition.
3. Physicians know what they know and know what they don't know.
4. I communicate effectively with my patients.
5. I'm a good listener.
6. Most diagnostic errors involve rare or uncommon diseases.
7. I always make a complete differential diagnosis.
8. If I made a diagnostic error, I'd find out about it.
9. I speak personally with the Radiologist about important tests.
10. I have a reliable system in place to track requested tests.

# Top Myths about Diagnostic Errors Held within Healthcare Systems

1. They don't happen here.
2. If something went wrong, I would hear about it.
3. We are already dealing with the problem.
4. They are too complex to understand.
5. That's the physician's problem.
6. We open ourselves to liability if we look too hard at diagnosis errors.
7. There's nothing we can do.
8. Only physicians have a role in diagnosis.

# General Types Medical Errors (IOM)

Diagnostic

Treatment

Performance

Communications

Systems

Medication

# Wide Spectrum of Medical Errors

- Lost blood sample for tumor marker - guide Tx/Prognosis
- Wrong side mastectomy – Chairman of Surgery.
- Wrong side thoracotomy – Chief of Thoracic Surgery.
- Jaw Pain interpreted as dental – teeth extracted – Patient MI and died.
- Death following Ketorolac -Tromethamine.
- Physician incorrectly given diagnosis of metastatic cancer – devastating emotionally.

# Wide Spectrum of Medical Errors

- Asthma in six month expectant woman.
- Loss of hand – arterial stick – no Allen test
- Spine surgery performed with “clean” not “sterile” tools.
- Lumbar puncture ordered on incorrect patient.
- EMR and Missed Pulmonary Nodule .
- Pneumonia vs. Mitral Regurgitation?

# Diagnostic Errors

- Wrong, delayed or missed.
- Cognitive and system errors.
- Failure to employ indicated tests.
- Use of outmoded tests.
- Failure to act on results of monitoring or testing.
  - “We will call you if there is a concern – no need to call us”

# Diagnostic Errors

- Harmful, under-recognized, under-studied and not integrated into quality assurance measures or activities.
- Occurs 5-15% of the time.
- Autopsy data , self -reports of diagnostic error, Patient self-reports of experiencing diagnostic error, Databases of reported error, Peer reviewed journal studies.

# Diagnostic Errors As Cause of Death?

- Many error unknown: decline in autopsy, patient goes elsewhere.
- Harvard Study diagnostic errors - 17% of adverse events (Physician Insurer, PIAA 2010)
- Malpractice claims involving death - diagnostic error is the top allegation at 26%

# Diagnostic Errors

## Hospital More than Clinic?

- Frequency in claims:
  - #1 cause of claims in ambulatory care and
  - #2 in hospitals (after improper performance of a procedure) - totals fairly close.
- More common diagnosis - missed (not the rare ones) !

# Causes of Diagnostic Error?

- Multi – Factorial Usually six factors on average in IM.
- Physician knowledge is least often the problem.
- More often due to cognitive error, systems errors including communication errors.
- Most common - combination of cognitive and systems errors.

# Cognitive vs System Errors

## Cognitive Error

Occurs in physician's processing of information –  
thinking process:  
latching on prematurely to a diagnosis and  
abandoning the search evidence to the contrary

## System Error

Occurs between the inter-related pieces in healthcare systems:  
physicians –

others involved in care  
“dropping the ball” in the referral -  
consultation process or in the “hand-off” process.

Lost or unreported test results, etc.

# Cognitive

Occurs in physician's processing of information - thinking process: latching on prematurely to a diagnosis and abandoning the search for evidence to the contrary.

# System Errors

Occurs between the inter-related pieces in healthcare systems: physicians – others involved in care

“dropping the ball” in the referral - consultation process or in the hand-off process.  
Lost or unreported test results.

# Diagnostic Errors Common in all Specialties

## #1 Cause of Claims Primary Care Specialties

- Internal Medicine
- Family Medicine
- General Practice
- Pediatrics
- Radiology
- Emergency Medicine
- Most of the Medical Sub-specialties.

## #2 Cause of Claims in Surgical Specialties

- OB-GYN
- General Surgery
- Orthopedics
- Most of the Surgical Sub-specialties

(it is most often a close, not a distant second place)

Diagnosis Subject to Error?

# Diagnosis Subject to Error?

- Rare disease?
- Common - MI, Cancer, CVA
- Acute MI - adult primary care specialties: PC, EM, Cardiology.
- Stroke diagnostic error – 9% of time
- Breast cancer - dominant diagnostic error.
- FP - MI, breast ca, appendicitis, colorectal ca, lung ca.
- P E, aortic dissection not known as autopsy rate declined so these and others are under-detected at an unknown rate.

# Florida Board Of Osteopathic Medicine

## Five Most Misdiagnosed Conditions:

1. Inappropriate prescribing of opioids in patients in whom there have been misdiagnosis or failure to diagnose addiction, psychiatric conditions and diversion;
2. Failure or delay in diagnosing cancer.
3. Retained foreign objects in surgery and wrong site/patient surgery.
4. Surgical complications/errors and pre-operative evaluations;  
and
5. Prescribing, dispensing, administering, or using non-FDA approved medications and devices.

# Most Misdiagnosed Conditions:

*Florida Board of Medicine*

- Neurological conditions.
- Urological complications.
- Pregnancy-related conditions.

# Inappropriate Prescribing of Opioids

- Misdiagnosis
- Failure to diagnose addiction.
- Psychiatric conditions.
- Diversion.

# State Opioid Prescribing Policy: Florida

# Florida Opioid Prescribing Policy

## Documentation!!!

- Assess the patient.
- Adequate rationale for opioids?
- Establish treatment goals.
- Abuse – must screen/monitor for addiction potential
- Deviation from “contract” (must have documentation)
- Blind acceptance.
- System failure (testing results).
- Unsupported clinical rationale for OPIOIDS.
- Diversion.

# Failure or Delay in Diagnosing Cancer

# Failure or Delay in Diagnosing Cancer

Estimated Number\* of New Cancer Cases and Deaths by Sex, US,

New Cases **2015** Deaths

	Both Sexes	Male	Female	Both Sexes	Male	Female
<b>All Sites</b>	1,658,370	848,200	810,170	589,000	312,000	277,280
<b>Digestive</b>	291,150	163,000	128,000	149,300	86,540	62,760
<b>Colon</b>	93,090	45,890	47,200	49,000	26,100	23,000
<b>Respiratory</b>	240,390	130,260	110,130	162,460	89,750	72,710
<b>Lung</b>	221,200	115,610	105,590	158,040	86,380	71,660
<b>Breast</b>	234,190	2,350	231,840	40,730	440	40,290
<b>Prostate</b>	220,800	220,800		27,540	27,540	

# Florida Board of Osteopathic Medicine

## Breast Cancer

- One in eight women.
- Most commonly diagnosed cancer in women.
- Leading cause of death.
- Rare in men BUT can occur.

# Breast Cancer

- Mammography became a common diagnostic tool in the 1960s.
- Key method for detecting breast cancer early, when it is easier to treat.
- 2005, about 68% of all US women between 40 and 64 years of age had had mammography in the past 2 years, according to insurance studies. All US states except Utah require private health insurance plans and Medicaid to pay for breast cancer screening.
- Standards for the timing of mammography vary by organization and by patient history. The US Preventive Services Task Force currently recommends that low-risk women older than 50 years receive mammography once every 2 years. ACOG currently recommends annual mammograms for all women 40 and older.

# Breast Cancer

- Failure to engage high risk groups
- Failure to exam
- Poor follow up on palpable findings\*
- Questionable mammogram – dense breast tissue – no breast ultrasound!
- Failure to workup mammographic abnormalities
- Consistency with American College of Radiology Standards
- Technical or technician performance issues
- Loss of reports! Therefore, no follow-up.
- Interpretative errors (most common reason for claims)
- Communication errors

# Four Patients

- 58 Yr. Old B/F - wife of a patient – asks in passing about “coughing up blood”.
- 66 Yr old W/F fell on vacation struck face now coughing up blood.
- 42 yr old W/F – lifted case of beer out of trunk pain right upper posterior shoulder.

# Failure or Delay in Diagnosing Cancer

## Lung Cancer

- Lung cancer - most common cancer worldwide.
- Most patients present because of symptoms
- Hemoptysis, unexplained, change in cough
- Incidental finding on chest imaging.
- Delay in diagnosis
- Failure to follow through
- Communication between consultants

# Cancer Misdiagnosis in General – Causes?

- Miscommunication, - lab failing to accurately report biopsy results to physician or in a timely fashion or office failing to inform the patient about test results.
- Lab errors, including mishandling samples, misreporting results or incorrectly interpreting tests.
- Failure to “see the big picture” that could indicate cancer when synthesizing all the data about a patient.
- (Anemia – RA)
- The failure to follow up on diagnostic results, including failing to refer the patient to consultant for evaluation and treatment.

# Cancer Misdiagnosis in General – Causes?

- Not screening a patient who is at-risk for a certain type of cancer.
- Discounting - potential for cancer because of the patient's characteristics, such as assuming a woman is too young to develop breast cancer, rectal bleeding in young patient etc.
- Many cases of negligent cancer misdiagnosis or delayed diagnosis involve a series of system or process breakdowns.

# Wide Spectrum of Medical Errors

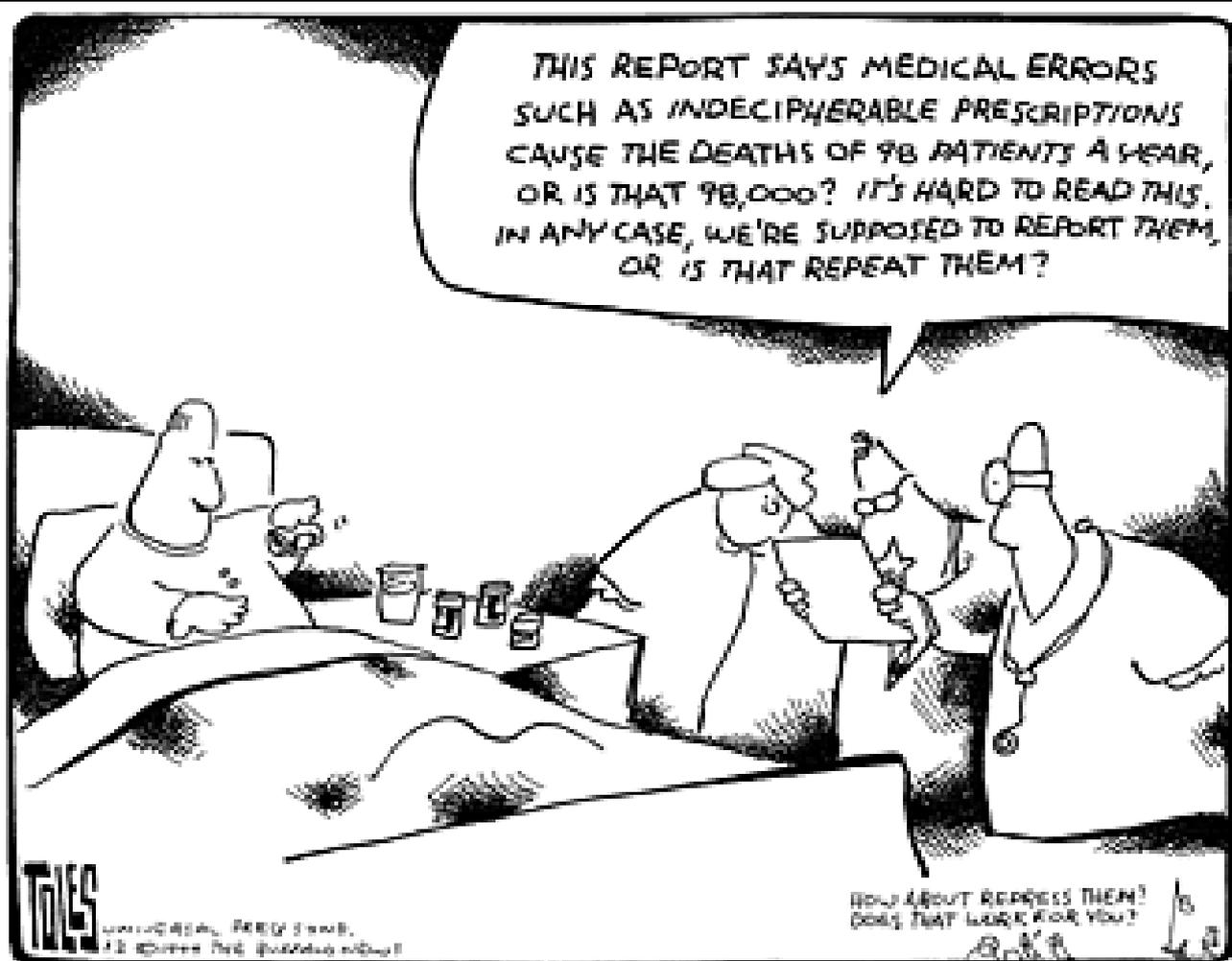
- Asthma in six month expectant woman.
- IV Lidocaine for Medication Administration.
- Lumbar puncture ordered on incorrect patient.
- EMR and Missed Pulmonary Nodule .
- NSAID and the Asthmatic

# Treatment Errors

- Medication errors are major concern.
- Error in the performance of an operation, procedure, or test.
- Error in administering the treatment.
- Error in the dose or method of using a drug.
- Avoidable delay in treatment or in responding to an abnormal test.
- Inappropriate (not indicated) care.

# How to Reduce Medical Errors

- Increase awareness of whole team (patient and team).
- Awareness of cognitive errors - differentials.
- Aware of system failures, conflicts.
- EMR – problematic for some physicians.
- Attention to process in office/hospital.
- Assure every member of team are committed to culture of patient safety and patient coming first.



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# Medication Errors

- 7,000 + fatalities secondary medication errors
- Look-alike/sound-alike drug list
- Hand written RX – legibility
- Abbreviations
- Cross checking drug interactions
- Multiple pharmacies
- Allergies
- Communication with patient
- Patient knowledge of their medication

# Polypharmacy

## National Health & Nutrition Examination Survey

- 13,869 aged 65 or older –1988-2010.
- Rx verified by medication containers.
- No. of meds increased from two to five.
- No. of medication > five – tripled (12.8 to 39.0).
- Increase in # of medication in patient with:
  - increase in BMI
  - Higher income – poverty ratio
  - Former smoker

# Preventive/Other Errors

- Failure to provide prophylactic treatment.
- Inadequate monitoring or follow-up of treatment.
- Failure of communication.
- Equipment failure
- Other system failure

# EMR ISSUES

- Failure of system design
- Does not function as a “folder/file/chart”
- Confusing interface
- Lack of patient/physician contact
- Incorrect information entered
- Tedious data entry
- Difficulty reviewing prior data timely
- System failure unable to access data
- Other issues
- Scribes?

# Systems Errors

- Complex environment
- Organized practices vs disorganization
- Reporting
- Recording
- Human factor

Retained Foreign Objects

Wrong Site/Patient Surgery

# Retained Foreign Bodies

## Unintended Retention Foreign Objects (URFOs)

- After invasive procedure
- Can Cause Death
- Survivors – emotional/physical harm
- Liability – estimated \$200,000.00/incident

# Most Common URFOs

- Soft goods, such as sponges and towels.
- Small miscellaneous items, including un-retrieved device components or fragments (such as broken parts of instruments), stapler components.
- Parts of laparoscopic trocars, guidewires, catheters, and pieces of drains.
- Needles and other sharps .
- Instruments, most commonly malleable retractors.

# URFOs

## Root Cause Analysis 2005 -2012

- 772 URFOs reported to Joint Commission's Sentinel Event data base.
- Sixteen deaths
- 95% of incidents required additional care and/or extended hospital stays.
- Operating rooms, Cath labs, Endo lab, ambulatory surgery centers, interventional radiology

# US Department of Health and Human Services Retained Objects

- Involves up to 1 in 5000 persons.
- 2008 study published in Annals of Surgery found that mistakes in tool and sponge counts happened in 12.5% of surgeries.
- Nursing and surgical groups recommend that each member of the surgical team play an equal role in assuring accuracy of the counts.
- Recently, manufacturers have made sponges with threads visible on x-rays, radiofrequency identification systems, and bar coding to alert staff about missing sponges.

# Most Common Root Causes Reported to Joint Commission

- Absence of policies and procedures.
- Problems with hierarchy and intimidation.
- Failure in communication with physicians.
- Failure of staff to communicate relevant patient information.
- Inadequate or incomplete education of staff.

# Wrong-Site Surgery Defined

- Wrong patient
- Wrong body part
- Wrong side
- Wrong procedure
- Unnecessary/unauthorized procedure
- Wrong level of the correctly identified site

# Wrong Site Surgery “Sentinel Events”

- Wrong-site surgery is considered indicative of serious underlying patient-safety problem.
- Largely preventable patient safety incidents that should not occur if the available preventive measures were implemented.
- Unexpected - resulting in serious physical, emotional injury, risk - to a patient.
- Not related to the natural course patients illness and being the most frequent sentinel event accounting for 13.4% of such events reviewed by the Joint Commission between 1995–2010.

# Wrong Site Surgery

- 9,744 paid settlements for surgical “never events” in the United states from 1990 – 2010 to \$1.3b.
- Mortality occurring in 6.6% of the patients.
- Permanent injury in 32.9%.
- Temporary injury in 59.2%.
- Cost of these events to the healthcare system and the enormous harm to the patients call for vigorous attention.

# Standards of Practice for Surgery/Procedure-64B15-14.006

- Responsibility of the treating physician or an equivalently trained DO or MD practicing within a Board approved GME program to explain the procedure to and obtain the informed consent of the patient.
- Not necessary to witness signature
- Except in life-threatening emergencies - once the patient has been prepared for the elective surgery/procedure and the team has been gathered in the surgery/procedure room and immediately prior to the initiation of any procedure, the surgery/procedure team will pause and the physician(s) performing the procedure will verbally confirm the patient's identification, the intended procedure and the correct surgical/procedure site.
- Physician performing the surgery/procedure shall not make any incision or perform any surgery or procedure prior to performing this required confirmation.
- Notes of the surgery/procedure shall specifically reflect when this confirmation procedure was completed and which personnel on the surgical team confirmed each item

# Standards of Practice for Surgery/Procedure

## 64B15-14.006

- **Confirmation of the patient's identity shall be made by using two or more of the Two or following corroborating patient identifiers:**
  1. Name.
  2. Assigned identification number.
  3. Telephone number.
  4. Date of Birth.
  5. Social security number.
  6. Address.
  7. Photograph.
- **Applicable to anesthesia**
- **If the physician(s) leave(s) the room where the procedure is being performed, upon his or her return, the pause set forth in paragraph (b) above must be performed again.**
- **(3) Management of postsurgical care.**
- **(4) The operating surgeon can delegate discretionary postoperative activities**
- **Delegation ..... if the other practitioner is supervised by the operating surgeon or an equivalently trained licensed allopathic or osteopathic physician or a physician practicing within a Board approved postgraduate training program.**

# Wrong-Site Surgery 2004-20012

## Causes and Remedies Reported by JCAHO

- Leadership
- Communication
- Human Factors
- Information Management
- Operative Care
- Assessment
- Physical Environment
- Patient Rights
- Anesthesia Care
- Continuum of Care

# Root Cause Analysis

Joint Commission Requirement for Sentinel Event

- Sentinel Event - unexpected occurrence - death or serious physical or psychological injury, or the risk thereof.
- Sentinel Event and Error - not synonymous.
- Sentinel event may not be triggered by an error and an error may occur - not cause a sentinel event.
- RCA looks beyond immediate result - identifies chain of events/contributing factors that led to adverse event.

# Root Cause Analysis

## Joint Commission Requirement for Sentinel Event

- **Review process relies heavily on the repeated use of the word - “Why?” - to dig deeper in an effort to find the most basic issue or contributing factor.**
- **Focused framework to analyze errors, identify what , why, and prevention.**
- **Avoids the tendency of assigning individual blame.**
- **An RCA must be credible and thorough to be effective.**

# Root Cause Analysis Must Be Credible and Thorough

Goal is to avoid the culture of blame.

To encourage open examination.

Foster patient safety

# Root Cause Analysis

- Communication
- Lines of authority – clear?
- Highly variable physical settings
- Variable healthcare process
- Time pressured environments
- System deficiencies
- Vulnerable defense barriers
- Human fallibility

## **Revealing their medical errors: Why three doctors went public.**

**<http://m.amednews.com>**

**“To err is human. To tell the world about the cases  
when things went  
wrong requires courage”**

# National Patient Safety Goals

- Correct patient- ID patient and surgeon
- Correct surgery, mark site pre-
- Correct site- marked pre-op
- Correct anatomical place
- Pause before surgery to assure correct patient, procedure and site.
- Hand cleaning guidelines from the CDC or WHO.
- Use proven guidelines to prevent infections that are difficult to treat.
- Use proven guidelines to prevent infection of the blood from central lines.
- Use proven guidelines to prevent infection after surgery.
- Use proven guidelines to prevent infections of the urinary tract that are caused by catheters.

# Preventing Medical Errors

Physician Leadership

Culture

Competence

Empathy

Humility

Principles

Policies

Procedures

Practices

# Bottom Line

- Safety is everyone's concern.
- Past events reviewed changes made.
- Root Cause Analysis is in place and implemented.
- Messengers are rewarded not “shot”
- Protocols exist.
- Procedures are established and agreed upon

# Bottom Line

- All humans will error – it is part of human condition.
- We may not change the human condition.
- We cannot Name, Blame, Shame – does not work.\*
- We can change conditions under which people work.

# Disclosing Medical Errors

- Physician's duty to inform the patient of a medical error. Under Florida Statute 456.0575
- Practitioner must inform the patient, or the patient's legal representative, in person about adverse incidents that result in serious harm to the patient.
- Notification of outcomes of care that result in harm to the patient governed by the disclosure statute shall not constitute an acknowledgment of admission of liability, nor can such notification be introduced as evidence.

# Adverse Incident Reporting

Florida Statute 395.0197(5) states:

**(5) For purposes of reporting to the agency pursuant to this section, the term “adverse incident” means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which: (a) Results in one of the following injuries:**

- 1. Death;**
- 2. Brain or spinal damage;**
- 3. Permanent disfigurement;**
- 4. Fracture or dislocation of bones or joints;**
- 5. Resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;**
- 6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent;  
or**
- 7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient’s condition prior to the adverse incident.**

# Disclosing Medical Error

- Obtain legal/risk management advise
- Communicate
- Express concern – empathy
- No blame
- Present Plan
- Confirm Understanding
- Document above

# “Second Victim”

- 250 physician suicides annually .
- Physician who believe they have made an error three time more likely to attempt suicide.
- Emotional turmoil even if right in presence of bad outcome.
- Multiple hospitals have developed outreach for physicians.

*“All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride.” — Sophocles, Antigone”*

# FDA's MedWatch

- Gateway for medical product safety information
- Can send out urgent safety alerts via e-mail
- Allows adverse reporting of adverse events
- 1-800-FDA-1088
- <http://www.fda.gov/medwatch>

# Websites

[www.archive.ahrq.gov/patients-consumers/care-planning/errors/20tips/index.html](http://www.archive.ahrq.gov/patients-consumers/care-planning/errors/20tips/index.html)

[www.ismp.org/pressroom/Patient\\_Broc.pdf](http://www.ismp.org/pressroom/Patient_Broc.pdf)

<http://familydoctor.org/familydoctor/en/healthcare-management/self-care/medical-errors-tips-to-help-prevent-them.html>

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