

PREVENTION OF MEDICAL ERRORS
2017 UPDATE
FPMA SUMMER CONFERENCE
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- I have no relevant financial relationships to disclose.
- While the information in this power point presentation is believed to be accurate, it is general in nature and does not purport to be a legal opinion. Additionally, it is intended for informational purposes only and should not be construed or relied upon as legal advice.



Course Objectives:



- At the conclusion of this presentation, the participant will be able to:**
- Identify Risk Management measures designed to prevent medical errors & enhance patient safety.
 - Identify common medication errors.
 - Describe important strategies for preventing medication errors in the outpatient setting.
 - Discuss surgical errors, contributing factors, and solutions to prevent them.
 - Discuss errors of diagnosis, causes and prevention, illustrated with case studies.
 - Describe the elements of root cause analysis.
 - Discuss the five most misdiagnosed conditions during the previous biennium as determined by the Board of Medicine.
 - Meet the requirements set forth by Florida Statutes FS 456.013(7)

Five Most Misdiagnosed Conditions as Determined by the Florida Board of Medicine:
Chapter 64B8-13.005(1)(c)

1. Cancer related issues.
2. Neurological related issues.
3. Cardiac/stroke related issues.
4. Infectious/communicable diseases.
5. Pulmonary related issues.



Five Most Misdiagnosed Conditions as Determined by the Board of Osteopathic Medicine: Chapter 64B15-13.001(4)(f)

1. Inappropriate opioid prescribing in patients in whom there has been a misdiagnosis or a 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.
5. Prescribing, dispensing, administering, or using non-FDA approved medications and devices.

Why do Errors Occur?

- Most of medicine is complex and uncertain.
- All humans make errors: indeed, “the ability to make mistakes” allows human beings to function.
- Most errors result from “the system”--inadequate training, long hours, ampoules that look the same, lack of checks, etc.
- Healthcare has not tried to make itself safe.

Developing Risk-Reduction Strategies

- Identifying errors in system may indicate where changes need to be made.
- There are two objectives of safe system design:
 - Make it difficult for providers to make mistakes.
 - Permit the detection and correction of errors before harm occurs.

• Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995;274:35-41. <http://www.ncbi.nlm.nih.gov/pubmed/7791256>

How Do We Perceive an Error?



- An individual failing
 - Only the minority of cases amount from negligence or misconduct; so it's the "wrong" diagnosis
 - It will not solve the problem--it will probably in fact make it worse because it fails to address the problem
 - Doctors will hide errors
 - May destroy many doctors inadvertently (the second victim)

Program helps caregivers under stress after errors:

- After a medical error or patient harm, clinicians can suffer from stress and emotional harm, which can in turn further affect their ability to perform at work. Albert Wu, MD, a physician and researcher at the Johns Hopkins Bloomberg School of Public Health in Baltimore, calls this the "second-victim" phenomenon.
- Two Maryland hospitals — greater Baltimore Medical Center and the University of Maryland Medical Center in Baltimore — are implementing programs to help clinicians cope with the stress that comes after a medical error.
- To combat this issue, the hospitals' programs involve choosing a team of roughly 24 peer responders who are trained to counsel caregivers as they deal with the aftermath of a medical error, or another source of work-related stress.

The Baltimore Sun June 21, 2015

Communication:



DEFINITION OF COMMUNICATION:

Simple Definition of Communication:

: the act or process of using words, sounds, signs, or behaviors to express or exchange information or to express your ideas, thoughts, feelings, etc., to someone else.

Merriam Webster



Communication:

Communication can breakdown when there is a difference between the speaker's intention and the listener interpretation.

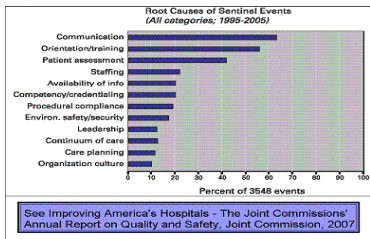
- Provider to provider
- Provider to patient and family
- Patient to family
- Patient and family to provider



WHAT DO WE KNOW ABOUT COMMUNICATION ?

- Speakers systematically overestimate how well their message is understood by listeners.
- Speakers also assume that the listener has all the same knowledge that they do (gets worse the better you know someone).

SENTINEL EVENTS:



HOW WELL DO WE LISTEN TO OUR PATIENTS?



The Effect of Physician Behavior on the Collection of Data:

- Determining the patient's major reasons for seeking care is of critical importance in a successful medical encounter.
- To study the physician's role in soliciting and developing the patient's concerns at the outset of a clinical encounter, 74 office visits were recorded.
- In only 17 (23%) of the visits was the patient provided the opportunity to complete his or her opening statement of concerns. In 51 (69%) of the visits the physician interrupted the patient's statement and directed questions toward a specific concern; in only 1 of these 51 visits was the patient afforded the opportunity to complete the opening statement.
- Physicians play an active role in regulating the quantity of information elicited at the beginning of the clinical encounter, and use closed-ended questioning to control the discourse. The consequence of this controlled style is the premature interruption of patients, resulting in the potential loss of relevant information.

• Ann Intern Med. 1984;101(5):692-696. doi:10.7326/0003-4819-101-5-692 HOWARD B. BECKMAN, M.D.; and RICHARD M. FRANKEL, Ph.D.

Communication is Key to "Medication Adherence"



- Generic prescription drugs made by different manufacturers may vary in color or shape, and switching among these drug products may interrupt medication use.
- To determine whether non persistent use of generic drugs among patients with cardiovascular disease after M.I. is associated with inconsistent appearance of their medications.
- Patients discharged after hospitalization for M.I. between 2006 and 2011 who initiated treatment with a generic B-blocker, angiotensin converting enzyme inhibitor, angiotensin II-receptor blocker or a statin.
- Variation in the appearance of generic pills is associated with nonpersistent use of these essential drugs after M.I. among patients with cardiovascular disease.
- INEFFECTIVE Communication is a significant factor contributing to poor drug adherence.
- Medication adherence is better if the physician has established a trusting relationship with the patient, and prioritizes the quality of communication.

Ann Intern Med 2014; Aaron Kesselheim M.D., JD, MPH et al

Communication is Critical to Patient Safety

Medical errors are a leading cause of death and injury in America, and an estimated 80 percent of serious medical errors involve some form of miscommunication, particularly during the transfer of care from one provider to the next.

A study published in the Journal of the American Medical Association demonstrates that standardizing written and verbal communication during these patient "handoffs" can substantially reduce medical errors without burdening existing workflows.



Study: 40% of critical information omitted during morning handovers

- Researchers observed third-year medical student and first and second-year residents during their morning handovers following an overnight shift. They found the on-call trainees omitted 40.4 percent of "clinically important issues" during these morning handovers.
- Additionally, the trainees did not document any of these issues in the patient's medical record 85.8 percent of the time.
- Researchers suggest training programs should utilize educational activities and workflow changes to improve handover communication regarding on-call issues, according to the study.

• JAMA Intern Med. Published online July 21, 2014. Megan K. Devlin, MD1; Natalie K. Kozij, MD1; Alex Kiss, PhD2; Lisa Richardson, MA, MD1,3,4; Brian M. Wong, MD1,5.

Effective Communication Among Health Care Professionals Is Challenging Due To A Number Of Interrelated Dynamics:

- Health care is complex and unpredictable, with professionals from a variety of disciplines involved in providing care at various times throughout the day, often dispersed over several locations, creating spatial gaps with limited opportunities for regular synchronous interaction.
- Care providers often have their own disciplinary view of what the patient needs, with each provider prioritizing the activities in which he or she acts independently.
- Health care facilities have historically had a hierarchical organizational structure, with significant power distances between physicians and other health care professionals. This frequently leads to a culture of inhibition and restraint in communication, rather than a sense of open, safe communication.

Effective communication among health care professionals is challenging due to a number of interrelated dynamics: Cont.

- Differences in education and training among professions often result in different communication styles and methods that further complicate the scenario and render communications ineffective.
- Although teamwork and effective communication are crucial for safe patient care, the educational curricula for most health care professions focus primarily on individual technical skills, neglecting teamwork and communication skills.

HIGH RISK SITUATIONS:

- Production/Time Pressure
- High Noise Levels
- High Acuity
- Multitasking
- Time Sensitive Conditions
- Rapid Turnover
- Frequent Interruptions
- New/Unknown Patients
- Undifferentiated Diagnosis
- Wide Clinical Variation
- Increasing Complexity



WHY CHANGE IS NEEDED:

- Failures in communication a leading cause of adverse events in healthcare.
- Issues around communication, continuity of care, or care planning cited as root cause in >80% of reported sentinel events.
- Australian review of 28 hospitals found communication errors associated with twice as many deaths as clinical inadequacy.
- Coverage by a second team of residents one of strongest predictors of adverse outcome.

Variation in survival rates for 4 high-risk surgeries among US hospitals:

- Survival rates for high-risk surgical procedures can vary from hospital to hospital by as much as 19 percent, according to a report from The Leapfrog Group.
- Pancreatectomy — 19 percent variation (predicted survival rates range from 81 to 100 percent)
- Esophagectomy — 10 percent (predicted survival rates between 88 to 98 percent)
- Abdominal aortic aneurysm repair — 13 percent (survival rates range from 86 to 99 percent)
- Aortic valve replacement — 5 percent (survival rates range from 92 to 97 percent)
- Most of the hospitals surveyed for the report did not meet Leapfrog's standard for each surgery.
- For instance, only 17 percent of surveyed hospitals fully met Leapfrog's standard for AVRs, 30 percent met the standard for esophagectomies and AAA repairs, and 42 percent met the standard for pancreatectomies

Leapfrog Group Study http://www.leapfroggroup.org/media/file/2014LeapfrogReport_HighRiskProcedures.pdf

Is Healthcare Safer Today Since The IOM Report in 1999?

Difficult to Assess:

- Lack of universal reporting system.
- Under reporting
- Lack of consensus regarding terminology/definitions of what constitutes an error.

Johns Hopkins study suggests medical errors are third-leading cause of death in U.S.

- Medical errors would rank as the third leading cause of death in the United States, after heart disease and cancer.
- Most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols.
- The researchers caution that most medical errors aren't due to inherently bad doctors, and that reporting these errors shouldn't be addressed by punishment or legal action.

BMJ May 3, 2016

Massachusetts Statewide Survey



- 23 percent of respondents reported being personally involved in a medical error in the past five years — and more than half resulted in a patient harm.
- The most common medical error uncovered by the survey was a perceived misdiagnosis (51 percent). The other common medical errors were:
 - Given the wrong test, surgery or treatment: 38 percent
 - Given wrong or unclear instructions about follow-up care: 34 percent
 - Given an incorrect medication: 32 percent
 - Contracted an infection as a result of a test, surgery or treatment: 32 percent
- 75 percent medical error events reported happened in a hospital.
- **52 percent believed the cause of medical errors were mistakes made by individual clinicians.**

Harvard School of Public Health. Commissioned by Betty Lehman Center for Patient Safety and Medical Error Reduction

Why are Errors Under Reported?

Historically a punitive approach has been taken leading to fear:

- Loss of reputation
- Loss of job
- Disciplinary action by professional board
- Malpractice
- Difficult to use reporting system
- Time constraints
- Sweep it under the rug mentality



Fix and forget or fix and report: a qualitative study of tensions at the front line of incident reporting

Usually, providers chose not to report a problem for the following reasons:

- The problem was a "near miss" and didn't need to be reported because no harm to the patient actually occurred.
- The problem was seen as a unique or one-time event.
- The problem was seen as inevitable or routine.

• BMI Qual Saf doi:10.1136/bmjqs.2014.003279 Published Online 6 March 2015

TYPES OF ERRORS: Medical Errors



DEFINITION:

MEDICAL ERROR: The failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.

DEFINITION OF NEAR MISS: Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.

ADVERSE EVENT: An injury caused by medical management rather by the underlying disease or condition of the patient.

- Preventable
- Not Preventable

Study: Risk of Patient Identification Errors

- Anyone on the patient's healthcare team can make an identification error, including physicians, nurses, lab technicians, pharmacists and transporters.
- Majority of wrong-patient events (72.3 percent) took place during patient encounters, while another 12.6 percent occurred during the intake process.
- More than half of wrong-patient events involved either diagnostic procedures 36.5 percent or treatment 22.1 percent) Diagnostic procedures cover laboratory medicine, pathology and diagnostic imaging. Treatment covers medications, procedures, and transfusions.
- No single strategy can prevent these events; instead, organizations must adopt a multipronged approach to prevent wrong-patient mistakes.

ECRI INSTITUTE 2016

Patient Identification Errors:

- Patient identification errors have serious implications.
- Organizations must improve staff members use of two identifiers.
- Investigating and addressing reasons staff do not follow policies.
- By actively involving patients.
- Using adjunct strategies including bar coding and alerts that flag mismatches between orders and the problem list.



Baystate Notifies Dialysis Patients of Infection Risk:



- Massachusetts Department of Public Health identified a serious lapse in protocol in the inpatient dialysis unit.
- Nurses occasionally forgot to change gloves while alternating contact between the patient and the dialysis machine.
- Due to multitasking nurses did not always re-glove between patients.
- Hospital said there was nearly zero risk of infection, but the hospital will pay for the testing of hepatitis B and C , and HIV, if requested by the patient.

Unrecognized Dementia Creates Potential for Medical Errors:

- PPSA analyzed hospital data from January 2005 to December 2014 and found **63 near misses** for adverse events related to staff unawareness of a patient's dementia.
- Failure to recognize the dementia.
- Failure to assess a patient's decision-making ability.
- Failure to identify someone capable of relaying reliable history or making decisions.
- Failure by the hospital to contact the surrogate.
- Failure to communicate the patient's cognitive limitations to all members of the care team.

Pennsylvania Patient Safety Advisory Report

What is a Sentinel Event?

- The Joint Commission developed a Sentinel Event Policy and database in 1996 of all reported events.
- Used to analyze events to provide information to healthcare organizations to defer future occurrences.

Joint Commission

Top 5 sentinel events in 2016:

1. Unintended retention of a foreign body.
2. Wrong-patient, wrong-site, wrong-procedure.
3. Falls
4. Suicide
5. Unassigned.

Surgical Errors:



Contemporary Bloodletting in Cardiac Surgical Care:

- Health care providers are seldom aware of the frequency and volume of phlebotomy for laboratory testing, bloodletting that often leads to hospital-acquired anemia. Our objectives were to examine the frequency of laboratory testing in patients undergoing cardiac surgery, calculate cumulative phlebotomy volume from time of initial surgical consultation to hospital discharge, and propose strategies to reduce phlebotomy volume.
- The total phlebotomy volumes approached amounts equivalent to 1 to 2 red blood cell units. Implementation of process improvement initiatives can potentially reduce phlebotomy volumes and resource utilization.



The Annals of Thoracic Surgery March 2015 Volume 99, Issue 3, Pages 779-784 Coleen G. Koch M.D. et.al.

Retention of Foreign Object:



Foreign Body:



Foreign Body Retention

- Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical examination, or other diagnostic procedures.



Foreign Body Retention:



RCA reveals that such errors are attributed to:

- Lack of clearly defined roles & responsibilities in the operating room.
- Fast-paced environment of an emergency room.
- Lack of sound count policies & procedures.
- Assumption that counts marked on prepackaged packages are correct.
- Lack of a standardized counting sequence.
- Failure to use x-ray detectable sponges.
- Lack of up-to-date and readily available policies & procedures for sponge, sharp, and instrument counts.

Foreign Body Retention: Plan of Action for Prevention



- Count sponges, sharps, and instruments.
- Sponges, sharps, and instruments should be separated, counted audibly, and concurrently viewed during the count procedure by two individuals.
- Do not assume that the count on prepackaged sponges and needles are accurate.
- Perform counts in the same sequence each time.
- All sponges should be x-ray detectable. (non x-ray detectable for dressings).
- Do not remove waste containers from the room until counts are completed and resolved.
- Check by two persons for the complete integrity of invasive catheters, drains, and monitoring lines at time of removal

Foreign Body:



Foreign Body:



Important risk factors leading to wrong-site surgery:

- **During surgical booking**
- Errors on the booking form or illegible information.
- An unapproved form was used for booking.
- The booking form was not received within 48 hours of surgery
- **During pre-op**
- Inadequate patient verification by surgeon.
- Inadequate patient verification by anesthesia provider.
- Documents like consent, history and physical, surgeon booking orders or O.R. schedule were missing or incorrect.
- **In the OR**
- Patient's name, identifier and intended procedure were not read.
- Team members did not stop talking and activities without being prompted from a team member.
- No one visually and verbally confirmed the correct site mark during time out.

Data from the Targeted Solutions Tool for Safe Surgery from the Joint Commission

Florida: Position on Wrong Site Surgery:

FAC 64B8-9.007
 (2) "...requiring the team to pause..."
 (b) "...record shall specifically reflect..."

Florida Statute 456.072(1)(bb)
 "Performing or attempting to perform..."
 "... includes the preparation of the patient."

Wrong Site Surgery:



Wrong Site Procedures:

- Wrong eye cataract procedure
- Wrong side craniotomy
- Wrong level spine surgery
- Wrong procedure on elbow
- Wrong eye procedure
- Insertion of a chest tube in the wrong lung
- Wrong lung biopsy
- Wrong finger procedure
- Wrong toe procedure
- Wrong side facial surgery
- Wrong side hernia repair



Mayo Clinic researchers link surgical errors with human behaviors:

They grouped the errors into four levels, made up of multiple factors.

- **Preconditions for action.** This includes poor hand-offs, distractions, overconfidence, stress, mental fatigue and poor communication.
- **Unsafe actions:** Including bending or breaking rules or failing to understand before acting.
- **Oversight and supervisory factors:** For example, inadequate supervision, staffing deficiencies and planning problems.
- **Organizational influences.** This could be culture or operational processes.

Mayo Clinic June 2015

Music in the Operating Room:



Music in The Operating Room:

"Music and Communication in the Operating Theatre"

- To observe the extent and the detail with which playing music can impact on communication in the operating theatre.
- According to the cited sources, music is played in 53-72% of surgical operations performed. Noise levels in the operating theatre already exceed World Health Organization recommendations. There is currently a divide in opinions on the playing of music in operating theatres, with few studies conducted and no policies or guidance provided
- This study was conducted between 2012–2013 in the UK. Video recordings of 20 operations over six months in two operating theatres were captured. The recordings were divided into music and non-music playing cases.

Conclusions:

- Music played in the operating theatre can interfere with team communication, yet is seldom recognized as a potential safety hazard. Decisions around whether music is played and around the choice of music and its volume, are determined largely by surgeons. Frank discussions between clinicians, managers, patients and governing bodies should be encouraged for recommendations and guidance to be developed

Journal of Advanced Nursing, Music and communication in the operating theatre; Sharon-Marie Weldon BSc MSc RN Senior Research Officer/Nurse et al

Risks Are High at Low-Volume Hospitals

- Patients at thousands of hospitals face greater risks from common operations, simply because the surgical teams doesn't get enough practice.
- As many as 11,000 deaths may have been prevented between 2010 and 2012 if patients who went to the lowest-volume fifth of the hospitals had gone to the highest-volume fifth.
- At 331-bed Lawnwood Regional Medical Center & Heart Institute in Ft. Pierce, Florida, the relative risk of dying following a hip replacement was nine times the national average.
- At 316-bed Jersey City Medical Center in New Jersey, the risk for patients who had heart bypass surgery (none involving valve replacement or repair) was four times higher than average.



U.S. News May 18, 2015.

Novel Study Shows Lower Surgical Mortality in Hospitals With Best Nursing Care:

- Patients undergoing surgery at hospitals Magnet-recognized for nursing excellence are more likely to have better outcomes at lower costs, according to research from University of Pennsylvania.
- Researchers compared more than 25,000 matched pairs of Medicare patients who underwent the same surgeries in over 300 hospitals to determine the impact a Magnet-recognition might have on outcomes.
- Magnet-designated hospitals had lower death rates after surgery, the and better outcomes weren't significantly more expensive.

JAMA Surgery January 20, 2016

"Flying right": Adapting aviation's 'sterile cockpit rule' to improve patient safety in the OR

- **Flying Like the Pros— Proactive Tips for Converting the OR into a Cockpit**
- 1. **Standardize the "Call for Quiet"**— Implement a phrase that all staff will use during the critical times of starting and ending a case. A phrase such as "Safety Silence" reminds all physicians and staff to cease all non-essential activity and conversation to create an environment that is entirely patient-centered.
- 2. **De-ice the OR**— Create an Atmosphere of Psychological Safety and Teamwork. Highly Reliable Healthcare Organizations (HRHOs) do not tolerate intimidating behaviors that cause tension and suppress the escalation of safety concerns. HRHOs value communication, teamwork, and the psychosocial climate that make both possible. Before starting the case, create an atmosphere of teamwork in service of patient safety by asking each team member to introduce themselves and by inviting anyone to escalate a patient safety concern at any time during the case.
- 3. **Tuning Up the Time Out**— Researchers from the Joint Commission cited team inattention during the Time-Out as a predominant risk for wrong site surgery. To improve team attention, consider structuring the Time-Out checklist as a series of questions, so that team members are forced to evaluate information before responding. Additionally, to increase engagement, assign each team member a brief, but specific task. When the entire team is engaged, the chances of catching an error increase greatly

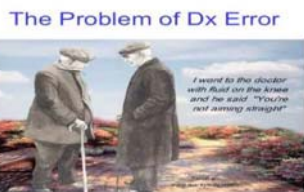
Written by Kimberly Danebrock, RN, JD, Risk Management & Patient Safety Specialist | Cooperative of American Physicians, Inc. CAP Assurance program | May 04, 2015

ELEMENTS OF A ROOT CAUSE ANALYSIS:

What is a Root Cause and Analysis?

- A process for identifying the causative factors involved in the occurrence of a sentinel event
- A root cause is the most basic reason for the failure or inefficiency of a process
- Focuses primarily on systems/processes not individuals
- Identifies changes that can be made in systems and processes either through redesign or development of new systems or processes and would reduce risk of such events occurring again.

Diagnostic Errors:

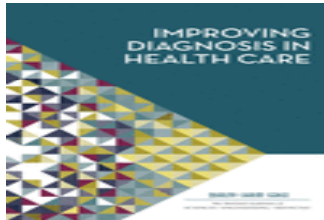


Diagnostic Errors:

- **Definition:**
- **Missed Diagnosis:** Where no diagnosis was ever made as judged from the eventual appreciation of more definitive information.
- **Delayed Diagnosis:** Unintentionally delayed where sufficient information was available earlier.
- **Incorrect Diagnosis:** Where another diagnosis was made before the correct one.

Source: Archives of Internal Medicine 2009

IOM Report:



The Washington Post:

Most Americans will get a wrong or late diagnosis at least once in their lives

By Lena H. Sun September 22, 2015

Most Americans who go to the doctor will get a diagnosis that is wrong or late at least once in their lives, sometimes with terrible consequences, according to a report released by an independent panel of medical experts.

This critical type of health-care error is far more common than medication mistakes or surgery on the wrong patient or body part. But until now, diagnostic errors have been a relatively understudied and unmeasured area of patient safety. Much of patient safety is focused on errors in hospitals, not mistakes in diagnoses that take place in doctors' offices, surgical centers and other outpatient facilities.

The new report by the Institute of Medicine, the health arm of the National Academy of Sciences, outlines a system-wide problem. **The report's authors say they don't know how many diagnostic errors take place. But the report cited one estimate that such errors affect at least 12 million adults each year, or about 5 percent of adults who seek outpatient care.**

Diagnostic Errors: Statistics

- 5% of U.S. adults who seek outpatient care each year experience a diagnostic error.
- Diagnostic errors contribute to approximately 10% of patient deaths.
- Diagnostic errors account for 6% to 17% of hospital adverse events.
- Diagnostic errors are the leading type of paid medical practice claims, and are almost twice as likely to have resulted in the patients death compared with other claims.

IOM 2015: "Improving Diagnostics in Health Care"

Economics of Diagnostic Errors:

- The costs of diagnostic error have not been determined, but are associated with unnecessary office and hospital visits, wrong treatments, unnecessary tests and procedures, readmissions and deteriorating health status.
 - In a recent review¹ of 25 years of malpractice claims, diagnostic errors were Leading type (28.6%)
 - Highest proportion of total payments (35.2%)
 - More often resulted in death than other allegation groups (40.9% vs 23.9%)
 - More outpatient than inpatient (68.8% vs 31.2%)
 - Responsible for payments of US\$38.8 billion (inflation-adjusted)

Saber Tehrani, A. S., Lee, H., Mathews, S. C., Shore, A., Makary, M. a, Pronovost, P. I., & Newman-Toker, D. E. (2013). 25-Year summary of US malpractice claims for diagnostic errors 1986-2010: an analysis from the National Practitioner Data Bank. *BMJ Quality & Safety*, (April), 1-9.

The Diagnostic Process:

The diagnostic process involves more than what's in the doctors head.

The process dimensions of the diagnosis:

- Problems with history, physical examination, or ordering diagnostic tests for further work-up.
- Diagnostic Tests: Labs/Pathology/Imaging.
- Follow-up and tracking of tests.
- Referrals and Specialty Consultations.

Cognitive Errors:

- Faulty knowledge 3%
- Faulty data gathering 14%
- Faulty synthesis 83%



HEURISTICS:



What Is a Heuristic?

- A heuristic is a mental shortcut that allows people to solve problems and make judgments quickly and efficiently. These rule-of-thumb strategies shorten decision-making time and allow people to function without constantly stopping to think about their next course of action. While heuristics are helpful in many situations, they can also lead to biases.
- While heuristics can speed up our problem and decision-making process, they can introduce errors. Just because something has worked in the past does not mean that it will work again, and relying on an existing heuristic can make it difficult to see alternative solutions or come up with new ideas.

• About.Com/Psychology

Premature Closure and Confirmation Bias

- Premature closure is narrowing the choice of diagnostic hypotheses too early in the process, such that the correct diagnosis is never seriously considered.
- Once our mind finds an adequate solution to whatever problem we are facing, we tend to stop thinking of additional, potentially solutions.
- Confirmation bias is the tendency to seek out data to confirm ones original idea, rather than to seek our disconfirming data.

Testing Related Diagnostic Error:

- An inappropriate test is ordered
- An appropriate test is not ordered
- An appropriate test result is misapplied
- An appropriate test is ordered, but a delay occurs somewhere in the total testing process
- The result of an appropriately ordered test is inaccurate

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Quality & Safety. 2013 August 16

Abnormal Test Results May Not Get to Patients

If you think your doctor will automatically tell you if you have an abnormal test result, think again. Researchers studying office procedures among primary care physicians found evidence **that more than 7 percent of clinically significant findings were never reported to the patient.**

The scientists, led by Dr. Lawrence P. Casalino, an associate professor at Weill Cornell Medical College, reviewed the records of 5,434 patients at 19 independent primary care practices and four based in academic medical centers. They extracted records that contained abnormal results for blood tests or X-rays and other imaging studies, and then searched for documentation that the patient had been properly informed of the problem in a timely way.

Then they surveyed the doctors with uninformed patients. Some told them that the patient had been informed, even though there was no documentation, while others believed the results were not significant and therefore required no notification.

New York Times:

Referrals and Specialty Consultations:

- Lack of appropriate action on requested consultations.
- Communication breakdown from consultant to referring physician.
- Patient compliance.

Case Study 1:

• A 64-year-old man with a history of stroke initially presented to his primary care physician (PCP) **complaining of burning pain and numbness in his left foot for one month**. Physical examination was notable for loss of sensation to his knee and a foot drop secondary to his prior stroke, but his pulses were intact with no other abnormalities noted. **The PCP attributed the pain and numbness to a peripheral neuropathy and referred him to podiatry**. The patient presented 4 more times to his PCP and twice to urgent care with a similar complaint of left foot pain. Each time he was referred to podiatry, but he never went to any podiatry appointments.

Case Study 1 cont.

• During these visits a complete extremity exam was not performed or documented, and the complaint was repeatedly attributed to his prior diagnosis of peripheral neuropathy. After multiple visits to his PCP and urgent care over a 2-month period, the patient presented to the emergency department with worsening symptoms. On examination his left lower leg was dusky in color, extremely tender to palpation, and his pulses could not be palpated. A computed tomography angiogram revealed complete occlusion of the left superficial femoral artery secondary to atherosclerotic peripheral arterial disease.

Case Study 1 cont.

The patient required emergent bypass surgery of the left leg by vascular surgery. Unfortunately, due to ischemia of his leg, he developed multiple infections postoperatively and ultimately required an above-the-knee amputation.

The vascular surgeons who cared for the patient believed the patient's chronic burning pain was likely due to progressive peripheral arterial disease and not to peripheral neuropathy.

Anchoring Bias:

- *Anchoring bias* is the tendency for clinicians to stick with the initial impression even as new information becomes available
- Anchoring bias seems strong in this case
 - Despite presenting 6 times over 2 months, the diagnostic impression did not change
 - In this case, progressive severe unilateral foot pain should have prompted consideration of other causes such as mononeuropathy, arthritis, or vascular insufficiency.

Multiple Cognitive Biases:

- Multiple cognitive biases contribute to anchoring
- *Confirmation bias* is the tendency to selectively seek information that supports initial impressions
 - Confirmation bias can be reduced by actively seeking information that could lead away from the initial or current impression
 - In this case, the physicians might have asked, "Is the other foot painful and numb?" as peripheral neuropathy is typically symmetric
 - Multiple physicians succumbed to common cognitive biases, which led to premature closure as well as anchoring on the diagnosis of peripheral neuropathy
 - More formal education, case conferences, real-time decision support, or application of a computerized diagnostic aid might have prevented this error and the subsequent adverse event

Anchoring Reduction:

Anchoring could be reduced if clinicians:

- Explicitly consider base rates (prior probabilities), sensitivity, and specificity of diagnostic tests and maneuvers when diagnosing common clinical conditions.
- Actively seek information that could refute the current provisional diagnosis.
- Frame their diagnostic thinking to avoid premature diagnostic labeling and share uncertainty.
- Use system-based interventions including structured diagnostic assessments, diagnostic decision support, or computerized expert diagnostic systems

Case Study 2:

- In 2009, the 53-year-old patient visited the defendant physician's clinic with a discolored nail of her great toe. PA allegedly assured the patient the discoloration was not cancer but a nail fungus and prescribed a medication and problem commonly persists and that a follow-up visit was not recommended.
- In 2012, the patient returned for an unrelated illness; she allegedly told the physician assistant who saw her that the discolored nail had become tender, and had drainage. The complaint about the nail was not documented and the plaintiff said no recommendations made.
- In 2013, the nail symptoms persisted and the patient was seen by another PA who noted the patient's multiyear history of nail discoloration/nail fungus. The PA diagnosed nail fungus and ordered a medication to treat it.
- Patient had an adverse reaction to the medicine and returned to the clinic, where she was seen by a different physician, who immediately suspected nail bed melanoma.

Problem List:

Failure to elicit history or key examination findings.

Complex systems and cognitive issues involved.

- Not black and white.
- Tension between under diagnosis and aggressive over-diagnostic pursuits.
- Chaotic clinical and inadequate time.

Overlooking critical information in EHR's.

Lack of feedback systems for improvement.

Meyer et.al JAMA I.M. 2013. Singh et.al JAMA 2013

Recommendations to Improve Diagnosing:

- Facilitate teamwork in the diagnostic process among healthcare professionals, patients, and families.
- Enhance healthcare professional education in the diagnostic process.
- **Ensure that health information technologies support the process.**
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses.
- Establish a work system and culture that supports the diagnostic process.
- Develop a nonpunitive reporting environment and medical liability system that brings improved diagnosis through learning from errors and near misses.
- Design a payment and care delivery environment that supports the diagnostic process.
- Dedicate funding for research on diagnosing and diagnostic errors.

Computer Assisted Systems:

- For this case, if one entered the following into a widely available computerized decision-support system: pain left foot, numbness left foot, foot drop, loss of sensation left leg
 - The program offered these top 5 diagnostic possibilities: compartment syndrome, tarsal tunnel syndrome, thromboangiitis obliterans, POEMS syndrome, and diabetic neuropathy
- In this case, a clinician might have been prompted to consider vascular causes of the patient's symptoms after seeing thromboangiitis obliterans on the computer-generated list

A Checklist for Diagnosis:

- Obtain **YOUR OWN** history
- Perform a focused, purposeful exam
- Take a "Diagnostic Time Out"
 - Was I comprehensive?
 - Did I consider the inherent shortcomings of using my intuition (heuristics)?
 - Was my judgment affected by bias?
 - Do I need to make the diagnosis now or can it wait?
 - What's the worst case scenario?
- Embark on the plan, but **ENSURE FOLLOW-UP & FEEDBACK**



Avoiding Malpractice Lawsuits:



Medical Malpractice: Contributing Factors

- Inadequate medical record keeping and insufficient documentation is a major factor in plaintiff awards and pretrial settlements.
- EMR functionalities.
- Claims and allegations by patients of improper treatment comprise the majority of law suits.
- Other allegations that may result in malpractice litigation include a diagnosis of post procedure infection, persistent pain and misdiagnosis.
- A key reason that a patient decides to pursue a malpractice case is the lack of communication from the provider after an unexpected outcome or undesirable result.

Tips to Avoid Medical Malpractice:

- Enhance the physician patient relationship.
- Listen to your patients and carefully document decision-making, including discussion of side effects and risks of all tests and treatments.
- Patients want a clear diagnosis, shared decision-making, and acknowledgment that their symptoms are real and concerns are valid.
- Post operative expectations.
- More care is not better care, as tests and treatments have associated harms that may lead to malpractice.
- Lack of follow up of abnormal test results often leads to malpractice litigation—don't order the test if you don't plan on following it up and acting on the results.
- Documenting what you did is as important as how it was performed.

What is Informed Consent?

- Informed consent is the **process** by which the treating health care provider discloses **appropriate information** to a **competent patient** so that the patient may make a **voluntary choice** to accept or refuse treatment. It originates from the **legal** and **ethical** right the patient has to direct what happens to her body and from the ethical duty of the physician to involve the patient in her health care.

Appelbaum PS. Assessment of patient's competence to consent to treatment. *New England Journal of Medicine*. 2007; 357: 1834-1840.

Doctrine of Informed Consent:

According to the doctrine of informed consent, a physician may be held liable for a patient's injuries, absent medical negligence, if those injuries arose from risks which the physician should have disclosed when securing the patient's consent to treatment. Additionally, some courts have held physicians liable for failing to disclose alternatives to the proposed treatment, abnormal conditions in the patient's body, and test results.

Montana Law Review Volume 48; Issue 1, Martin Struder

American Podiatric Medical Association Code of Ethics: ME2.0 Informed Consent

- **ME2.11** The podiatrist strives to ensure that the patient is cognizant of the nature of the illness or condition, the treatment proposal or its alternatives with reasonable explanations of expected outcomes, potential complications, and length of recovery.
- **ME2.21** The podiatrist provides truthful representations of their experience and outcomes.
- **ME2.31** The podiatrist strives to ensure that any economic benefit involving services, materials, medications, or facilities shall not interfere with their primary responsibility for the welfare of the patient and shall comply with applicable legal requirements.

APMA Code of Ethics – March 2013

What are the elements of full informed consent?

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in her health care decisions.

- The nature of the decision/procedure.
- Reasonable alternatives to the proposed intervention.
- The relevant risks, benefits, and uncertainties related to each alternative.
- Assessment of patient understanding.
- The acceptance of the intervention by the patient.

Standards of Disclosure:

- **Reasonable physician standard:**
- This standard allows the physician to determine what information is appropriate to disclose.
- This standard relies on expert medical testimony to establish the scope of legally adequate disclosure.
- This standard assumes that the physician knows best, and relatively low value on the autonomy of the patient.
- Many courts have rejected this standard to find one that is more compatible with patients' rights to make their own healthcare decisions.

Standards of Disclosure:

- **Reasonable patient standard:**
- This standard requires physicians to disclose all of the information that a reasonably prudent patient would consider material to the decision whether to accept treatment.
- Legally adequate disclosure under this standard includes more information than under the physician oriented standard.
- The precise scope of disclosure quite often evades definition.
- Some courts require full disclosure, most settle for reasonable disclosure.
- Duty to disclose is no longer limited to situations in which the physician performs treatment, but also arises when the patient wants to forego recommended tests.
- Expert testimony is of secondary importance though still necessary to establish the existence of risks, it is not necessary for establishing the standard of disclosure.
- It is for the jury to place themselves in the position of a patient and decide whether, under the circumstances, the patient should have been told.

Exceptions to the Doctrine of Disclosure:

- Performing emergency medical treatment when the patient is incapacitated and unable to give informed consent.
- Physicians may withhold information when candid disclosure would adversely affect a patient's condition.
- Courts will excuse inadequate disclosure when the risk is either known to the patient or is so obvious that knowledge is presumed.
- Usually not required to discuss risks inherent in common procedures that rarely materialize

Concluding Remarks:

- The loss of a loved one can be devastating.
- The knowledge that their death could have been prevented makes it harder still. Medical errors can result in severe patient injury or death, and they are preventable.
- Although some errors are minor, there is a huge spectrum—and many are fatal.
- The future is now!

Quote:



Perfection is not attainable, but if we chase perfection, we can catch excellence.

Vince Lombardi,
football coach



Quote:

"I don't want to make the wrong mistake"
Yogi Berra



Questions?