PREVENTION OF MEDICAL ERRORS

JOSEPH SOWKA, OD, FAAO

PURPOSE OF COURSE

- To reduce risk of medical errors occurring in optometrists’ offices
- To improve patient safety
- As of May 8, 2002 a new rule has been added to 64B13-5.001 (8). Licensees are required to complete a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process

PURPOSE OF COURSE

- The Florida State legislature mandated that all licensees must complete a two-hour course on prevention of medical errors
- The 2-hour course shall count towards the total number of continuing education hours required for the profession.
- Shall include a study of root cause analysis, error reduction and prevention, and patient safety

WHY WE ARE REALLY DOING THIS?

EPIDEMIOLOGY

- November 1999, the IOM revealed a hidden epidemic in the United States:
- Medical errors result in injury to 1 in every 25 hospital patients and an estimated 44,000 to 98,000 deaths each year. Even the lower estimate makes medical errors more deadly than breast cancer (42,297), motor vehicle accidents (43,458) or AIDS (16,516).
- ("To Err Is Human: Building A Safer Health System." Institute of Medicine. December 1999.)

EPIDEMIOLOGY

- Medical errors cost the economy from $17 to $29 billion each year.
- Agency for Healthcare Research and Quality (AHRQ) has shown that medical errors result most frequently from systems errors-organization of health care and how resources are provided in the delivery system.
  - Only rarely are medical errors the result of carelessness or misconduct of a single individual.
**EPIDEMIOLOGY**

- Medication errors are thought to cause 7,000 deaths annually – more than the 6,000 deaths that occur each year in the workplace. The annual cost of medication errors is at least $2 billion.

**EPIDEMIOLOGY**

- IOM reported only hospital errors
- Many errors occur outside the hospital.
- In an investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the State.

**1999 INSTITUTE OF MEDICINE (IOM) REPORT—IS LIMITED AND OUTDATED.**

- In 2008, 180,000 reported deaths due to medical error a year among Medicare beneficiaries alone.
- Classen et al described a rate of 1.13%. If this rate is applied to all registered US hospital admissions in 2013 it translates to over 400,000 deaths a year, more than four times the IOM estimate.

**1999 IOM report underestimates the magnitude of the problem**

- A 2004 report of inpatient deaths associated with the Agency for Healthcare Quality and Research Patient Safety Indicators in the Medicare population estimated that 575,000 deaths were caused by medical error between 2000 and 2002, which is about 195,000 deaths a year.

- In 2008, 180,000 reported deaths due to medical error a year among Medicare beneficiaries alone.

**Classen D, Resar R, Griffin F, et al. Global "trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs 2011;30:581-9**
TYPES OF MEDICAL ERRORS

- The IOM report defines an error as:
  - The failure of a planned action to be completed as intended (i.e., error of execution)
    - Tobrex instead of Tobradex
  - The use of a wrong plan to achieve an aim (i.e., error of planning)
    - NSAID or weak steroid on raging uveitis
    - Tobradex on dendritic or fungal keratitis

- An adverse event is an injury caused by medical management rather than the underlying condition of the patient (e.g., allergic response to a drug). An adverse event attributable to error is a preventable adverse event, also called a sentinel event, because it signals the need to ask why the error occurred and make changes in the system (prescribing drug to which patient is allergic because you didn’t ask).

WHY ERRORS HAPPEN

- Active Errors: Active errors occur at the level of the frontline operator, and their effects are felt almost immediately.
- Latent errors: Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations.

LATENT ERROR – SENTINEL EVENT

- High volume LASIK surgery
- Patient experiences acute anxiety and backs out on morning of surgery
- Patient data never removed from lineup
- Next patient undergoes LASIK with information from departed patient
- Four diopter myope now nine diopter hyperope

LATENT ERROR – SENTINEL EVENT

- Pt develops CN III palsy from aneurysm
  - Treatment choices: aneurysm clip or endovascular coil packing
- Successfully treated with aneurysm clip
  - All coils are inert and MRI safe; not all clips are MRI safe
- Radiologic tech doesn’t verify type of clip
- Pt undergoes F/U MRI with non-MRI safe clip in major medical center
- Clip displaces during MRI
- Patient has fatal hemorrhage during procedure
- Patient survived disease…but not the treatment

TOP 10 SENTINEL EVENTS-2013*

1. Wrong-patient, wrong-site, wrong-procedure — 60
2. Unintended retention of a foreign body — 56
3. Delay in treatment — 56
4. Fall — 48
5. “Other” unanticipated event (includes unexpected additional care/extended care, and psychological impact) — 40
6. Op/postop complication — 37
7. Suicide — 35
8. Criminal event — 26
9. Medication error — 20
10. Perinatal death/injury — 15

Joint Commission; *N= 393
TOP 10 SENTINEL EVENTS -2014*

1. Unintended retention of a foreign body — 57
2. “Other” unanticipated event — 53
3. Fall — 44
4. Suicide — 39
5. Wrong-patient, wrong-site, wrong-procedure — 35
6. Delay in treatment — 34
7. Criminal event — 29
8. Op/postop complication — 27
9. Perinatal death/injury — 17
10. Medication error — 12

Joint Commission; *N= 394

CONDITIONS THAT CREATE ERRORS

- Any given precondition can contribute to a large number of unsafe acts
  - training deficiencies can show up as high workload
  - undue time pressure
  - inappropriate perception of hazards
  - motivational difficulties
- Preconditions are latent failures embedded in the system

SURGICAL ERRORS

- Surgical adverse events accounted for two-thirds of all adverse events and 1 of 8 hospital deaths
- Wrong-site surgery was most common in orthopedic procedures. Risk factors contributing to the error included more than one surgeon involved in the case, multiple procedures performed during a single operating room visit, and unusual time pressures, particularly pressure to speed up preoperative procedures

DIAGNOSTIC INACCURACIES

- Incorrect diagnoses may lead to incorrect and ineffective treatment or unnecessary testing.
- Inexperience with a technically difficult diagnostic procedure can affect the accuracy of the results.
  - Study that demonstrated that measuring blood pressure with the most commonly used type of equipment often gives incorrect readings that may lead to mismanagement of hypertension.
DIAGNOSTIC INACCURACIES

• Types of Diagnostic Error
  - Misdiagnosis leading to an incorrect choice of therapy (Steroid Combo med on a dendritic or fungal keratitis)
  - Failure to use or order an indicated diagnostic test (VF, CV, eye not correctable to 20/20)
  - Misinterpretation of test results
  - Failure to act on abnormal results

SNATCHING DEFEAT OUT OF THE JAWS OF VICTORY

• Pt presents with reduced acuity (20/50)
• OD diagnoses CSC based upon OCT
  - Doesn’t dilate to confirm
• Case goes to trial - OD prevails
  - Poor expert witness for plaintiff
• Verdict gets overturned on appeal
  - Technicality
• Goes back into litigation

If you are going to use technology, please interpret results correctly

CONDITIONS THAT CREATE ERRORS

• Precursors or Preconditions
  - A need to have the right equipment, well-maintained and reliable
  - A skilled and knowledgeable workforce
  - Reasonable work schedules
  - Well-designed jobs
  - Clear guidance on desired and undesired performance
• Preconditions are latent failures embedded in the system

FACTORS AND SITUATIONS THAT INCREASE THE RISK OF ERRORS

• Fatigue
• Alcohol and/or other Drugs
• Illness
• Inattention/Distraction
• Emotional States
• Unfamiliar Situations
• Communication Problems
• Illegible Handwriting

MEDICATION ERRORS

• Problems related to the use of pharmaceutical drugs account for nearly 10 percent of all hospital admissions, and significantly contribute to increased morbidity and mortality in the United States (Bates. 1995).
### SIX RIGHTS
- Right Patient
- Right Drug
- Right Dose
- Right Dosage Form
- Right Route
- Right Time

### TOP 10 MEDICATION ERRORS
1. Sound-a-like Drugs
2. Lack of Drug Knowledge
3. Dose Calculation Errors
4. Decimal Point Misplacement
5. Wrong Dosage Form
6. Wrong Dosage Frequency
7. Use of Abbreviations
8. Drug Interactions
9. Renal Insufficiency
10. Incomplete Patient History

### SOUND-A-LIKE MEDS
- Vexol (rimexolone) Ophthalmic drops
  Vs.
- Vosol (acetic acid) Otic drops

### CASE
- A pediatric ophthalmologist prescribed **TOBREX** (tobramycin) 0.3% ophthalmic drops for a one-month-old infant with a dacryocystitis (one drop TID to the left eye). The physician indicated this drug by checking off a space on a preprinted prescription order form which listed 12 different ophthalmic drops including **TOBRADEX** (tobramycin and dexamethasone) which appeared on the line above Tobrex.
SAME DRUG – DIFFERENT DIRECTION

- Prescribed Tobradex
- Patient fails to improve
- Produces bottle of Tobrex
- Ask to see medications at follow-up

TOBRADEX AGAIN?!

- Pt diagnosed with infectious keratitis
- Doctor prescribes tobrex and gatifloxacin
- Techs E-prescribe in office
  - Tobrex not in system, but Tobradex is…
  - Tech assumes they are the same- never asks doctor
- Pt has fungal keratitis…

SOUND-A-LIKE MEDS

- Zymar (gatifloxacin) Ophthalmic drops
  Vs.
  - Zymase (amylase, lipase, protease) capsules for digestion

SOUND-A-LIKE MEDS

- Ocuflox (ofloxacin 0.3%) Ophthalmic drops (Allergan)
  Vs.
  - Ocufen (flurbiprofen 0.03%) Ophthalmic drops (Allergan)

SOUND-A-LIKE MEDS

- Vesneo Vs. Visine
  - Vyzulta Vs. Cymbalta
U.S. outpatient pharmacies filled 3.9 billion prescriptions in 2009, according to most recent figures from Wolters Kluwer Pharma Solutions. Overall, the dispensing error rate is 1.7 percent, which translates into more than 66 million drug mistakes a year.

Due to a doctor’s illegible handwriting, a woman in Scotland who was prescribed the ocular lubricant VitA-POS was given the erectile dysfunction cream Vitaros instead. The patients suffered eye pain, blurry vision, redness, and yes—swelling. The dispensing pharmacist didn’t stop to question why an erectile dysfunction drug was prescribed to a woman, which should have at least given him a reason to double check.

Takeda agreed to change the name of its new heartburn drug Kapidex after reports of confusion with the prostate cancer drug Casodex. In some cases, women received a cancer drug intended only for men.

AcetaZOLAMIDE (Diamox) vs.
AcetoHEXAMIDE (Dymelor)
Type 2 diabetes treatment
**SOUND-A-LIKE MEDS**
- Most often involved in look-alike, sound-alike errors?
  - Pharmacy technicians: 38%
  - Pharmacists: 24%
  - Registered nurses: 20% percent
  - Physicians: 7%

**SOUND-A-LIKE MEDS**
- Effort to use a combination of upper- and lower-case letters to differentiate drugs, called “Tall Man lettering.”
- Using that system, the potentially confusable drugs “prednisone” and “prednisolone” would be written as “predniSONE” and “prednisoLONE” to tell them apart

**SOUND-A-LIKE MEDS**
- Refresh Liquigel
  - Vs.
- RePhresh Vaginal Gel

**COMPUTERIZED DRUG ORDERING**
- A physician selected OCCLUSAL-HP (17% salicylic acid for wart removal) instead of OCUFLOX (ophthalmic ofloxacin) from an alphabetical product list in a computerized prescriber order entry system and sent the prescription to a hospital outpatient pharmacy with directions to “use daily as directed.”

**LOOK-A-LIKE PACKAGING**
*The problem of packaging similarities with ophthalmic medications is related in part to FDA approval of a color-coding system by pharmacologic class, making all products within a class the same color.*

**LOOK-A-LIKE PACKAGING**
Sulfacetamide, Tobramycin, Neomycin, Ocufloxacin
LOOK-A-LIKE MEDS
Dexacidin vs. Vasocidin

LOOK-A-LIKE MEDS
B&L Products

LOOK-A-LIKE PACKAGING
Generics are no different

LOOK-A-LIKE MEDS
- Precision Glucose Control Soln vs. Timolol

LOOK-A-LIKE PACKAGING
Ophthalmic vs. Otic

LOOK-A-LIKE PACKAGING
Ophthalmic vs. Otic
LOOK-A-LIKE PACKAGING

FML Forte

Vs.

Pred Forte

LOOK-A-LIKE PACKAGING

ALREX vs. NAIL GLUE

ERROR PREVENTION

- Identification and Evaluation of Error
- Hospital Mortality and Morbidity Meetings
  - Recourse free error reporting protocol
- Automated Equipment
  - Recall system
  - Medication ordering systems/software
- Professional Continuing Education

DOCTOR-PATIENT COMMUNICATION

- Know all your patient’s medications, vitamins and herbs
- Question about allergies and past adverse reactions to medications
- Write prescriptions legibly so patients and pharmacists can read them

FLORIDA PRESCRIBER LAW

- Florida Statute 456.42 A written prescription for a medicinal drug issued by a healthcare practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in both textual and numerical formats, and the directions for use of the drugs; must be dated with the month written out in textual letters; and must be signed by the prescribing practitioner on the day when issued.
PATIENT EDUCATION
- DO NOT rely on the Pharmacist!
- What is the medicine for?
- How is it supposed to be taken?
- What side effects are likely?
- What to do if side effects occur?
- Drug interactions?
- What food, drink or activity should be avoided or included?
- Have patient check meds from pharmacy
- Which generics are not acceptable
- Encourage Patient’s questions!

PATIENT SAFETY
- Stress dose adjustment in children and elderly patients
- Limit Access to high hazard drugs
- Use protocols for high hazard drugs
- Computerized drug order entry
- Use pharmacy-based IV and drug mixing programs
- Standardize drug packaging, labeling, storage
- Use “unit dose” drug systems (packaged and labeled in standard patient doses)
  - Medrol dose pack; Z-Pak

PROFESSIONAL COMMUNICATION
- Inter and Intra professional communication
- Communicate with patient’s other healthcare providers to coordinate care.

ROOT-CAUSE ANALYSIS
- Understanding Why Errors happen
- JCAHO requires that a thorough, credible RCA be performed for each reported sentinel event.
  - What Happened?
  - Why did it happen?
  - What do you do to prevent it from happening again?

ROOT-CAUSE ANALYSIS
- Includes experts from all services involved
- Those who are most familiar with situation
- Asking WHY at each level of cause and effect
- Identification of changes needed
- As great a degree of impartiality as possible
- Ultimately, Root cause analysis is a tool for identifying prevention strategies.
It is a process that is part of the effort to build a culture of safety and move beyond the culture of blame.

PATIENT/OFFICE SAFETY
- Standards for Healthcare Professionals
- Licensing, Certification and Accreditation
- Role of Professional Societies
- Infection Prevention
  - Tonometer tip, gonioprism, etc.
- OSHA
- CPR/EMS
- Handling common medical emergencies
  - Vasovagal Syncope
HOW DO HOSPITAL OR CLINIC SYSTEMS MONITOR FOR MEDICAL ERRORS TO PROTECT PATIENT SAFETY?

- Monitor vulnerable populations
  - Patients who may receive less contact with healthcare professionals; patients with limited English proficiency who may lack the ability to interpret complex medical instructions; and patients with low health literacy who may struggle to adequately communicate with members of the healthcare team, fill out complex forms, and understand concepts related to risk and probability

- Promote interdisciplinary collaboration
  - Decentralize the pharmacy, positioning pharmacists as permanent resources in particularly vulnerable hospital departments, such as the ER, or otherwise, rotating them between these departments on a regular basis.

- Engage patients in safety
  - Empower patients to be their own strongest advocates—providing literature with tips they may not have considered (e.g., make sure your doctor knows about medications you’re taking; for healthcare procedures, obtain vocal agreement from you, your doctor, and the person who is administering the procedure on what’s about to be done, etc.), increasing their interface with pharmacists who are best equipped to answer their questions and concerns related to their medications (a huge component of medical errors), and encouraging them to educate themselves on their condition and the different treatment options available to them.

- Encourage a high reliability culture
  - Healthcare leaders may help ensure staff members are comfortable coming forward with knowledge of medical errors that have already occurred.

REPORT OF ADVERSE INCIDENTS IN THE PRACTICE OF OPTOMETRY

- Effective January 1, 2014, an adverse incident occurring in the practice of optometry must be reported to the department in accordance with this section.

REPORT OF ADVERSE INCIDENTS IN THE PRACTICE OF OPTOMETRY

The required notification must be in writing and submitted to the department by certified mail. The required notification must be postmarked within 15 days after the adverse incident if the adverse incident occurs when the patient is at the office of the licensed practitioner. If the adverse incident occurs when the patient is not at the office of the licensed practitioner, the required notification must be postmarked within 15 days after the licensed practitioner discovers, or reasonably should have discovered, the occurrence of the adverse incident.

REPORT OF ADVERSE INCIDENTS IN THE PRACTICE OF OPTOMETRY

- Any condition that requires the transfer of a patient to a hospital licensed under chapter 395.
- Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459, other than a referral or a consultation required under this chapter.
- Permanent physical injury to the patient.
- Partial or complete permanent loss of sight by the patient.
- Death of the patient.

REDUCING MEDICAL ERRORS WITHIN THE OPTOMETRIC PRACTICE

Malpractice and How it Happens – a Look at Some Cases
MALPRACTICE

- A dereliction of professional duty or a failure to exercise an ordinary degree of professional skill or learning by one (such as a physician) rendering professional services which results in injury, loss, or damage.
- An injurious, negligent, or improper practice

ROLE OF THE EXPERT WITNESS

- Handle an adversarial situation
- Be fair and objective
- Be balanced
- Educate
- Optometry vs ophthalmology

THREE MAIN OFFENDERS

- Failure to detect retinal detachment
- Failure to detect glaucoma
- Failure to detect tumor

IN OTHER WORDS...

- Failure to listen to the patient
- Failure to observe the signs
- Failure to make the diagnosis fit the findings
  - Not vice-versa
- Failure to do the appropriate tests and follow-up
- Failure to make the proper referral
- Making a diagnosis of exclusion the first diagnosis instead of the last

THE MOST IMPORTANT THING TO REMEMBER

Surviving the Legal Process

- It isn’t personal…it’s just business
AM I BEING SUED?

- Subpoena for your records
  - Most likely not being sued
    • Accidents, disability, etc.
  - Send immediately
    • 10 day window
    • Make sure records complete...and unaltered
- Notice of Intent to Litigate
  - Now you are being sued

NOTICE OF INTENT TO LITIGATE

- Notice immediately tries to beat you into submission.
- Doesn’t mention your care or your exam, but your negligence
  - “Prior to your negligence…”, “As a result of your negligence...”, “Was there anything subsequent to your negligence...”
- DO NOT respond to this yourself
  - Contact insurance company - get attorney

IT ALL LIES IN THE DEPOSITIONS

- Attorneys representing all parties involved
- Court reporter/ videographer
- No judge or jury
- Fact finding mission
- Don’t volunteer information
  - Won’t convince them they were wrong to file suit – cases aren’t won in deposition, but they are lost
- Insist on home field advantage

IT ALL LIES IN THE DEPOSITIONS

- Trial is nothing more than a performance
  - Written
  - Rehearsed
  - Hair and makeup
  - Jury is the audience
  - No smoking guns
  - Everything comes from the depositions
    • The “Script”

JUST ANSWER THE QUESTION

- You have to answer unless instructed not
  - Your attorney will object throughout - still answer
- Don’t try to educate plaintiff’s attorney
  - Could give beneficial information not otherwise asked
- Avoid temptation to give “great” testimony
  - You’ll have your chance in court
- Be prepared and be professional

BEWARE WOLVES IN SHEEP’ S CLOTHING

- Deposition is adversarial
- Some attorneys will intimidate, others will kill with kindness
  - He/she is the enemy
  - Wants information to use against you
  - Always keep up your guard
- Get comfortable with attorney – agree to something medically ridiculous
- If tired – take a break
**LOOK IN THE MIRROR**

- Appearance and demeanor as important as testimony*
  - Be neat
  - Avoid anger, hostility, condescension*
    - “ODs are just failed physician wannabes”
    - 172 medical schools; just 23 optometry colleges
- Questions phrased to make you appear dishonest*
  - Keep concentration and composure
  - Attorney may become intimidated by your resilience

*It’s not personal...it’s just business

**KNOW WHAT YOU ARE ANSWERING**

- Attorney is not medical professional
  - May ask confusing questions
  - Ask for question to be repeated or rephrased
- Don’t be intimidated into answers the attorney wants
  - Very few absolutes in life
- You must answer ‘yes’ or ‘no’
  - You can explain yourself after answering
    - Not before—becomes adversarial

**RED FLAGS**

- “Would you agree that...”; “Is it a fair statement...”
  - Typically precede proposition that is too broad to be answered by yes or no.
- These questions are fashioned to elicit material to use against you.
- Think before you speak

**ONE AT A TIME**

- Let attorney finish question before answering
  - Understand question before responding
  - Court reporter can only transcribe so fast
  - Your attorney has time to voice objections
- Be sure that entire question is accurate before saying yes
  - If any portion inaccurate or illogical—say no

**SOMETIMES YOU CANNOT REMEMBER**

- Facts occurred several years ago
  - Refer to records during questioning
- What about questions with no recollection or records?
  - If you remember—say so
  - If you don’t remember—say so
  - Don’t guess or speculate

**WATCH WHAT YOU ARE ANSWERING**

- Hypothetical questions are posed only to be used against you
- Sometimes a hypothetical question cannot be answered
- Make sure that you agree with entire hypothetical before answering
- No rule that you must have opinion on hypothetical
It is not a crime to meet with your attorney
- May try to intimidate

Nothing is off the record
- Keep your mouth shut

Tell the truth
- There are very few cases that can’t be defended on the facts
- There are very few cases that can be defended if the defendant is caught lying.

HOLD TO YOUR OPINION
- Attorney will try to imply that you are lying
  - Hold firm to your opinion
- If attorney doesn’t like your answer, he/she will repeat with prefices “Are you telling us under oath...” or “Is it really your sworn testimony that...”
  - Don’t be intimidated
  - Your answer is your answer; if asked repeatedly, repeatedly give the same answer
    - Rope-a-dope

PREPARE
- Read! Read! Read!
- Skilled attorney can get competent physicians to agree to medical impossibilities
- Once something is said in deposition, it is written in stone.
- You will always have a chance to explain yourself in a court of law.
- You can defend virtually anything

IN CONCLUSION...
- Risk of malpractice is a fact of professional life
- You will get through it
- It will not end your life, practice, career
- It’s not personal…it’s just business.

DIABETIC RETINOPATHY
- OD finds significant NPDR
- Educates patient
- Refers ophthalmology
- Doesn’t record referral
- Patient loses vision - multiple lasers
- Now it gets complicated

MALPRACTICE CLAIMS
- Improper care
  - Perception of improper care
**MALPRACTICE- HOW TO AVOID IT**
- Put patients’ needs over doctor’s needs
- Do not make findings fit diagnosis
- Do not be afraid to investigate further
- Insist that everything make sense
- Do not disregard patient complaints
- Check drug facts and print out medical prescriptions
- Document! Document! Document!
  - Can’t defend five words on a chart
- DFE! Fields!

**DEALING WITH MALPRACTICE**
- Let your attorney and expert witness do his/her job
- No “late notes” or amendments to chart
- Leave your expert witness alone!
- READ prior to deposition
- Consent to settle policy