

PREVENTION OF MEDICAL ERRORS

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DISCLOSURE:

Joseph Sowka, OD, in the past 24-months, has been a
Consultant/ Speaker Bureau/ Advisory Board member for Visus,
Zeiss, and B&L. Dr. Sowka has no direct financial interest in any
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presentation. All relevant relationships have been mitigated. He
is a co-owner of Optometric Education Consultants
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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



Epidemiology

- <u>November 1999</u>, 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 errorsorganization 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.

1999 INSTITUTE OF MEDICINE (IOM) REPORT—IS LIMITED AND OUTDATED.

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- 1999 IOM report <u>underestimated</u> 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
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- 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

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 Aff2011; 30:581-9

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Why we are really doing this? String of Errors Parl Florida Hospital on the Critical List Lord 1. May 100 CLUE TO THE TO

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).
 - Viroptic on bacterial conjunctivitis
 - Tobradex on dendrite



Types of Medical Errors

• 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.

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WHY ERRORS HAPPEN

 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.

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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
- Radiology 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

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Latent Error

Clinical Leadership & Infection Control

CHOP sued after 23 infants contract, 1 dies from eye infection in 2016 sterilization breach

Whitten by Alyssa Rege | August 31, 2018 | Print | Email

3. At least 23 infants in CHOP's NICU contracted viral infections stemming from the same sterification breach in 2016. The figure represented more than half of the 48 infants who underwent eye exams in the NICU during one of the contract of the contract of the contract of infection Control. All 25 patients suffered respiratory symptoms, and five went on to develop pneumonia. Between of the 25 infants experience infectious symptoms in their eyes. Six hospide employees and three parents also contracted viral infections, according to the case study. The case study did not mention patient deaths.

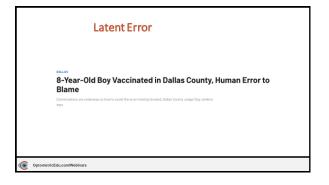
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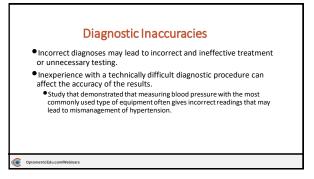
Latent Error

West Virginia National Guard: 42 residents accidentally given Regeneron antibody treatment instead of COVID-19 vaccine Medical experts believe there is no risk of harm to those individuals

rom Staff Reports Dec 31, 2020 - 1 - 1 min to read

CHARLESTON, W.Va. (WV News) — Forty-two people at a COVID-19 vaccination clinic hosted by staff at the Boone County Health Department received the Regeneron Antibody product instead of the Moderna vaccine.





Diagnostic Inaccuracies Types of Diagnostic Error Misdiagnosis leading to an incorrect choice of therapy (Steroid Combo med on a Dendrite) • 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



Failure to order the proper test or referral Thursday: 58 YOM with vision loss OD: Dx AION OD > OS; mild headache and pharyngitis Recommended: OCT (ordered), ESR, CRP, platelets (not ordered)

- · Friday: OCT performed
- Saturday: OCT interpreted- disc swelling OD > OS
 CTJ moment; fax to PCP for serology "ASAP". Office not open
- Sunday: Bupkis

- Monday: message read
 Serology and carotid testing set for Wednesday evening

 Tuesday: pt wakes up with profound vision loss OS
 Walks into ER and gets tests done- everything elevated
 Dx: temporal arteritis- legally blind

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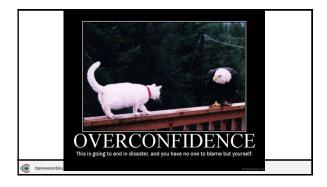
Conditions that Create Errors

- 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).

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 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

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Top 3 Medication Errors

- 1. Sound-a-like Drugs
- 2. Lack of Drug Knowledge
- 3. Dose Calculation Errors







Sound-a-Like Meds

• Vexol (rimexolone) Ophthalmic drops



Vs.



· Vosol (acetic acid) Otic drops



Sound-a-Like Meds

• Tobrex (tobramycin) Ophthalmic drops

Vs.

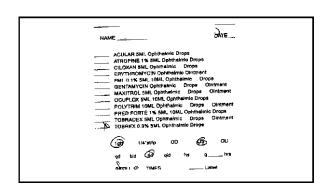
Tobradex (tobramycin and dexamethasone) Ophthalmic drops



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.





Computerized Drug Ordering

 A physician selected OCCLUSAL-HP (17% salicylic acid for wart removal) instead of OCUFLOX (ophthalmic ofloxacin) from a 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."



Sound-a-Like Meds

• Zymar (gatifloxacin) Ophthalmic drops

Vs.

• Zymase (amylase, lipase, protease) capsules for digestion



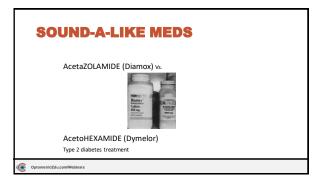
Sound-a-Like Meds

• Ocuflox (ofloxacin 0.3%) Ophthalmic drops (Allergan)

Vs.

• Ocufen (flurbiprofen 0.03%) Ophthalmic drops (Allergan)

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■ Due to a doctor's illegible handwriting, a woman was prescribed the ocular lubricant VitA-POS, was given the erectile dysfunction cream Vitaros instead. The patient 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.





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.

Sulfacetamide, Tobramycin, Neomycin Sulfacetamide, Tobramycin, Neomycin Sulfacetamide Sulfacetamide

Look-a-Like Packaging

• Sulfacetamide, Tobramycin, Neomycin, Ocufloxacin



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



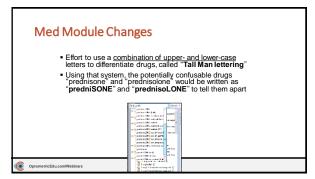












Practice Recommendations

- Special care to Sound-a-like and Look-a-Like Medications
- · Avoid pre-printed prescription pads if possible
- · Review your Erx thoroughly
- Have patient bring all medications that you've prescribed with them
- Patient Education

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

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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

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!

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Professional Communication

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

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Medical Record Keeping

- Make Obvious Chart Notations for:
 - Medical Allergies/ adverse reactions
 - Medications
 - Narrow/Occludable Angles
- Iris Fixed IOL's
- Write Legibly
 - Avoid Abbreviations
- Document! Document! Document!

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?



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)



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



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 demand.
- 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

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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

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Failure to Observe the Signs

- A 16-year-old male presents for contact lens fitting.
- His refraction is: +1.00 1.00 x 180 20/40
 - +0.75 0.50 x 005 20/20
- Fundus "WNL"; no c/d ratio
- He is diagnosed with refractive amblyopia OD and fit with contact lenses.
- At 2-week f/u, his VA is 20/100 OD "good fit" recorded.

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Failure to Observe the Signs

- One month f/u 20/200 OD "good fit"
- Discharged
- Annual exam:
- Refraction unchanged 20/400 OD, 20/20 OS
 - Fundus WNL
 - New lenses ordered
- Contact lens dispense "Right lens not clear"
- Retinal detachment OD
- Recommendation: Seek settlement

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Failure to Diagnose Retinal Detachment

- 50 YOWM
- Sees flashes and floaters
- Presents to optometrist
- Dilation and BIO performed
 - "Ø breaks, Ø detachment" recorded
- Patient warned signs and symptoms RD
- Dismissed

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Failure to Diagnose Retinal Detachment

- Patient has worsening of symptoms and vision loss one week later
- Telephones optometrist who immediately directs patient to retinal specialist
 - Does not record this in the chart
- Patient now has RD
- Poor surgical outcome
- Sues OD for malpractice
- Is it malpractice? Was standard of care breached?

Failure to Diagnose Retinal Detachment

- Could OD have missed existing break?
- Could break have been undetectable to best retinal specialist?
- Could there have been no break initially and one formed after exam?
- Bad outcome yes malpractice no



Failure to Diagnose Retinal Detachment

- Plaintiff attorney: "I have another optometrist that will swear that this is malpractice."
- Me: "Well, you better give him a call because I'm not doing it!"
- Plaintiff attorney: Even for \$\$?"
- Me: "No!"

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Failure to Diagnose Retinal Detachment

- Treating retinal specialist deposed
- Plaintiff attorney: "Could Dr. XYZ have missed the retinal break?"
- Retinal specialist : "Well, yes. It is likely he did. He is not a physician, you know".

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Legal Pot of Gold

- Treating ophthalmologist opining on OD who allegedly missed angle closure
- OD sued for infectious keratitis- is friendly with corneal specialist and recommends him as expert witness.

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Another Retina Specialist Perspective

- Q. "Do you think that you as a medical doctor, as an ophthalmologist are better trained and equipped to rule out or rule in a retinal detachment than an optometrist?""
- A. "I think optometrists are trained or supposedly are trained in their field to be able to do a dilated fundus exam to diagnose retinal tears or detachments as well as any other eye care professionals."
- Q. "You believe an optometrist has the same expertise and ability to diagnose a retinal detachment or retinal tear as you do?" $\,$
- A. "Setting my ego aside, I would say that optometrists are trained to evaluate the peripheral retina as well as an ophthalmologist and that's my answer."

Sometimes it is Black and White... or Worse

- 55 YOBM with 'weed whacker abrasion'
 - 2 ODs
 - Shallow chamber; IOP < 5 mm; hypopyon
 - End Result?

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"Standard of Care?"

•"In all medical probability, the retinal break/ corneal perforation/ whatever-it-may be was present at the time of your examination and because you failed to see and diagnose it, you fell below the standard of care. Because the standard of care dictates that you would have seen and diagnosed it. And because you didn't, you were negligent".



Standard of Care and Negligence

- Negligence refers to a person's failure to follow a duty of conductimposed by law.
- Every health care provider is under a duty to:
- use his/her best judgment in the treatment and care of his/her patient:
- to use reasonable care and diligence in the application of his/her knowledge and skill to his/her patient's care;
- to provide health care in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time the health care is rendered



Highest Degree of Skill Not Required

The law does not require of a health care provider absolute accuracy, either in his/her practice or in his judgment. It does not hold him/her to a standard of infallibility, nor does it require of him/her the utmost degree of skill and learning known only to a few in his profession. The law only requires a health care provider to have used those standards of practice exercised by members of the same health care profession with similar training and experience situated in the same or similar communities at the time the health care is rendered



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Not Guarantor of Diagnosis, Analysis, Judgment or Result

- A health care provider does not, ordinarily, guarantee the correctness of his/her diagnosis, analysis, judgment as to the nature of a patient's condition or the success of his/her health care service rendered.
- Absent such guarantee, a health care provider is not responsible for a mistake in his/her diagnosis, analysis, judgment unless he has violated the duty (one or more of the duties) previously described.



Sometimes you JUST shake your head

- Retained for defense
- Diabetic pt sees OD who diagnosis PDR OU
- Educates and warns risk permanent blindness- must see retinal specialist w/i 7 days
- Pt sees another OD 6 weeks later
- Detailed exam completely normal
- Pt now completely visually impaired from PDR



Sometimes you JUST shake your head-Part ii · Defending OD alleged to have misdiagnosed PXG • Affidavit- "There was no evidence of glaucoma at this



A Festival of Ignorance

- 37 YOF- pterygium surgery. PF post-op
- Sees OD 3 weeks p/o. Some blur • No IOP
- · Sees another OD next day
 - Dilates; swollen nerve, refers, no IOP
- · Sees retinal specialist same day
 - IOP 49.5 mm Hg • Injects steroid
- All 3 sued for missing steroid induced glaucoma
- Does any glaucoma cause a swollen nerve?

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A Festival of Ignorance

- · Plaintiff's expert witness:
- "Pallor is common in glaucoma"
- "This case had extremely fast progression of the field loss
- "Glaucoma commonly occurs with minimal cupping"
- "Extremely high intraocular pressure commonly causes a swollen nerve
- · "You never consider ischemic neuropathy in a patient under 70 years"

A Festival of Ignorance: Part II

- 55 YOF; cerebral palsy; poorly communicative; some discomfort OS
 NLP OD; 20/200 OS; -13.00 DS OU

 - Treated at ER for abrasion; OD sees no abrasion in consult
 Refers to ophthalmologist- never goes
- Caregiver perceives worsening visual function-goes back to ER: IOP 38 mm OS- Dx: angle closure
 Airlifted to another hospital (\$38,000)
- On call ophthalmologist won't go in (January 1)
 Phones in Diamox, timolol, pilocarpine

- Numerous condemnations again OD by expert witness
 Needed to dilate; uveitis not blinding; IOP of 38 immediately blinding

Surviving the Legal **Process**

The Most Important Thing to Remember

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

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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

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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"

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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

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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
 - 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

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*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 <u>after</u> answering
 - · Not before- becomes adversarial

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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
 - Complete question won't be in transcript
 Your attorney has time to voice objections
- Be sure that entire question is accurate before saying
 - 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 prefaces " 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

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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

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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.