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Preventing Medical Errors - Update

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Preventing Medical Errors

Cindy Beyer, Au.D. Suzanne Younker, Au.D.



It Happens!

- Odds are if you practice long enough
- See enough patients
- See a diversity of patients
- You will encounter an adverse and unexpected outcome





Do No Harm...

- Best interest of Patient
- Protects clinician from potential liability issues
- Follow established clinical guidelines to assist us in delivering conscientious and appropriate care.
- Scope of practice and best practices documents are available from the American Academy of Audiology <u>www.audiology.org</u> and American Speech and Hearing Association <u>www.asha.org</u>

Polling Question

 How many of you have encountered an adverse event in the course of performing audiology procedures? (Examples would be: abrasions to the ear canal during impressions or cerumen removal, an embedded impression that couldn't be removed without pain to the patient, PE tubes that were extracted through an impression)



Audiology and Liability

- Malpractice can be either a *deliberate* or a *negligent* act committed by a health care provider
- Injury may encompass a broad spectrum of incidences from actual physical injury to the unintentional mismanagement of a patient's hearing loss.
- Result is injury or other adverse outcome to the patient

What is malpractice?

- "The prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers."
- To ensure our livelihoods as licensed health care providers.....well versed in the areas of practice that may leave us subject to loss of license or disciplinary action

2005 Florida Statutes, Section 766.102

Medical Errors

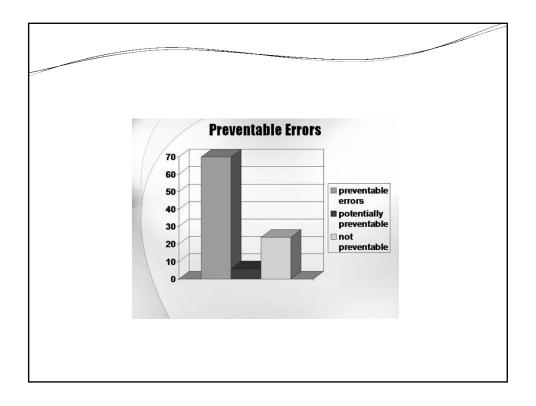
- Up to 100,000 die annually
 - More than AIDS, MVA, breast cancer
 - 2.4 million prescriptions filled incorrectly
 - 7000 people die from medication errors
- Cost the nation \$37.6B annually
- \$17M preventable injuries

Polling Question

What percentage of adverse outcomes are preventable?

- 20%
- 50%
- 70%
- 90%





Why Errors Course?

- Risks and liability associated with delivery of care increase: Audiology is not immune
- Cost of providing and receiving healthcare continues to rise
- Complex diagnoses and treatment as hearing healthcare evolves
- Hundreds of millions of dollars spent to resolve cases of medical liability
- Regulatory responsibility- licensing
- Ethical responsibility to minimize risk of error in delivering hearing care

Audiology Specific Areas

- Infection Control
- History and Documentation
- Cerumen Removal
- Evaluation and Testing
- Earmold Impressions
- Circuit Selection of Programming Errors
- Verification Errors
- Electrophysiology Errors ABR
- Electrophysiology Errors ENG/VNG

Infection Control

- Provider's responsibility to ensure patient safety and to provide an environment that controls transmission of disease from clinician to patient; patient to patient; patient to clinician
- Elderly patients present with compromised immune systems placing them at particular risk; newborns and infants
- Direct contact occurs between clinician and patient
- Between patient and equipment/tools ...that in turn come in contact with other patients.



Question:

- What's the single biggest factor in the spread of infectious disease?
 - Unclean tools
 - Unwashed hands
 - Unsanitary patients
 - Reusing tympanometry tips



Infection Control: Common Errors

- Not washing hands between patients
- Handling unclean hearing aids
- Failure to disinfect patient contact areas
- Infrequent changing of ultrasonic solution
- Failing to clean and disinfect tools
- Reusing foam earphone inserts, tympanometry tips, and real ear measurement (REM) tubing without proper disinfecting
- Not washing hands after handling used tools and equipment
- Improper storage of clean and dirty tympanometry tips

Medical Records

- Good record keeping helps us stay focused and develop logical plans for patient care; information available when reviewing the file.
- Ask questions: most appropriate direction of care hearing aids, HAT, cochlear implant, and/or med/surgical intervention.
- Patient files are legal documents and subject to subpoena, audit, and other types of regulatory review.
- Our name and license number is attached to the patient's record, and judgments and opinions are rendered according to the extent and quality of supporting documentation.

Details.....



- Keep records of exact hearing aid make, model, circuitry, features and experiences
- Appropriate recommendations for improvement should incorporate past experience as well as current and future expectations.
- If medical clearance is so indicated by the results, make reasonable effort to obtain it.
- Ultimately, patients have both the right and the responsibility to make decisions about their health care.

AMA Guidelines for Records

- Reason for the encounter;
- Relevant history;
- Physical examination findings;
- Prior diagnostic test results;
- Assessment, clinical impression, or diagnosis;
- Rationale for ordering medically necessary tests or services;
- Patient's progress, response to changes in the treatment, and revision in diagnosis as necessary;
- · Care Plan; and
- Date and legible identity of the provider (signature, initials, electronic signature), authentication.

Common Deficiencies..

- Illegible notes;
- Incomplete notes, encounter forms, flow sheets;
- Missing or illegible signature;
- Alterations or changes made to the original medical record;
- Use of non standard medical abbreviations; AS/AD and < >
- Biased or non-professional remarks;
- Disorganized or misfiled patient records;
- Repetitive, non-individualized notes especially with electronic medical records; and
- Misuse of rubber stamped or electronic signatures.



Documentation Errors:



- Failure to document all patient visits
- Failure to initial/sign and date all patient visits
- Failure to include subjective and objective data at each visit
- Failure to document actions and follow up
- Failure to evaluate and document previous hearing aid experiences
- Insufficient amplification history and documentation of needs and expectations

Documentation - Common Clinical Errors:

- Neglecting to print/save programming and real ear sheets for future reference
- Missing physician scripts and signed clearance forms as indicated
- Failure to ensure hearing aid make, model and style match billing invoice; required language
- Documentation fails to follow patient care adequately
- Failure to effectively address unresolved problems

Civil Cases

- Small claims court
- Documentation is EVERYTHING
- Patient acknowledgements are critical
- Data is important....
- HUGE inconvenience factor
- ALWAYS some concession to the patient



Licensure Actions

- Patient submits formal complaint to licensing board
- Investigation by Medical/Quality Assurance
- Alleges some violation of the state statute
- Documentation is EVERYTHING
- Patient confirmation is IMPORTANT



Reminders:

- When indicated:
- Document patient refusal to seek medical advise
- Unresolved problems
 - Collegial support



Question:

- How many use a binaural waiver? (Patient acknowledges that 2 hearing aids recommended but only 1 purchased)
 - Yes
 - No





Cerumen Removal

- Possibility of clinical error with subsequent malpractice litigation.
- Over 200,000 ears are cleaned of cerumen each week in the United States
- Cerumen management has become a prerequisite to comprehensive patient care within hearing care practices unless prohibited by a state's licensing laws.

Do you perform cerumen removal?

- Yes Curette
- Yes Curette, Suction, irrigation
- No



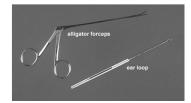
Cerumen Removal Contraindications

- Effusion in the ear canal or other active ear disease
- Hematoma in the ear canal
- Surgical modification of the canal wall
- Unidentifiable foreign objects
- Diabetic patient
- Pending legal proceedings
- Suppressed immune systems
- Bleeding disorders
- Required constraint for removal

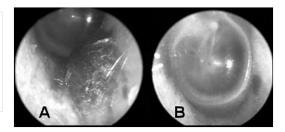


Cerumen Removal - Common Errors:

- Ignoring contraindications
- Unsigned cerumen consent form
- Neglecting to clean and disinfect cerumen tools
- Canal abrasions
- Improper storage of tools



Sizeable AD subdermal hematoma 24 hours and one month after cerumen removal



A post-cerumenectomy with a small hematoma and contusion with

bleeding (multiple exostoses)



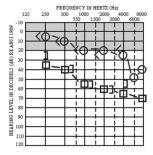
Common Errors in Audiometry

- Incomplete or poor case history
- Improper supervision of students
- Choosing the wrong test or omitting a test due to time constraints
- Over or under masking
- Misinterpretation/ under interpreting results
- Not making a referral when it is appropriate to do so
- When testing children or difficult to test patients, not keeping them on task and getting invalid results

Common Testing Errors, Cont.

- Improper placement of headphones (reversal) or bone oscillator.
- Poor or unclear test instructions to patient
- False positive air bone gaps related to insert receiver positioning
- Speech recognition testing at levels too low to reach maximum performance
- Failure to perform annual calibration on test equipment
- Failure to perform daily/weekly listening checks

Audiogram Errors



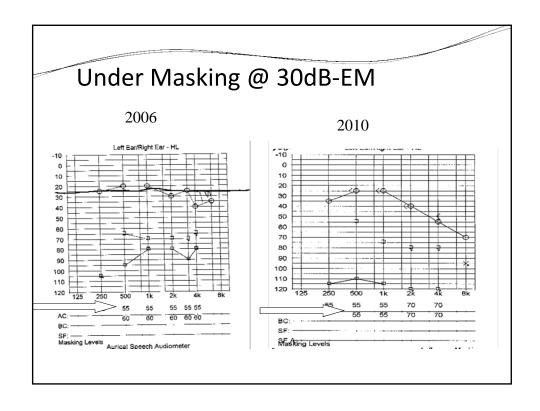
- Reversal of earphones
- Patient confusion over testing procedures = false-positive or false-negative results.
- Double check results and make sure that everything "adds up" and that obvious discrepancies are corrected.

Hearing Aid Assessment

- Hearing aid dispensing is regulated through state licensing or registration
- Testing must include as a minimum, (except where concomitant handicaps or mental or chronological age preclude) speech audiometrics -including word recognition measures, air-conduction threshold assessment, and a measure of middle ear involvement.

Masking

- Inaccurate tests due to improper masking can lead to inappropriate recommendations, improper referrals, and inadequate hearing aid fittings.
- Dispensers by law must refer patients with potential medical problems for audiologic assessment when indicated.



Medical Referral



- Coordination of care with patient's physician ensures appropriate treatment
- Refer to established practice guidelines to avoid over or under referring of medical care.
- Under referring patients may deny patients the opportunity for the most effective and appropriate resolution to the hearing condition.
- Over referral of patients for medical care is costly and inconvenient.

Earmold Impressions

- Invasive procedure that can lead to complications, and quite probably the riskiest procedure that we perform
- In our experience the vast majority of adverse events are related to the taking of ear impressions.
- Requires a conscientious approach to inspecting the ear canal and confirming otoblock placement to avoid errors



A routine procedure...

- Potential for damage to outer, middle and inner ear structures exists ... potential increases when taking deep canal impressions.
- Complications include- canal abrasions, trauma/lesions to the tympanic membrane and middle ear ossicles; accidental removal of pressure equalization tube; perilymph fistula with resultant fluctuating, progressive, or long-standing sensorineural hearing loss; or concussive inner ear trauma accompanied by temporary or permanent threshold shifts.



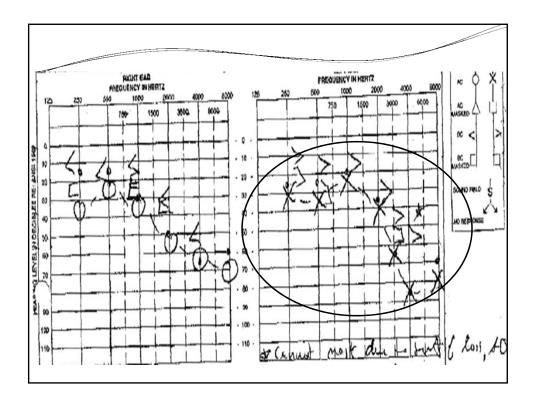
Precautions

- Appropriate bracing should be employed to avoid potential injury of the canal wall or the tympanic membrane.
- Careful examination of the ear canal pre and post otoblock placement to ensure that the material will not travel past the block.
- Especially important when working with young children, patients who may be frightened by the impression process, or patients with complicating disorders that preclude normal neuromuscular control... may lead to unexpected movement.

Earmold Impressions:

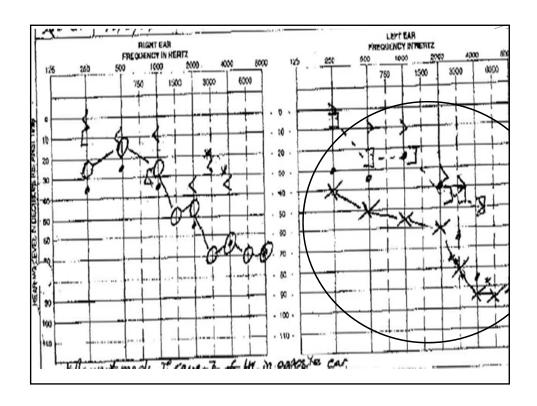
- Perforations
- Canal abrasions
- Impression embedded
- Hematoma





Case #1 Left Ear

- Impression material scraped from TM under general anesthesia
- Numbness in tongue, sense of taste distorted
- Subsequent tests and doctor visits indicate further hearing loss and additional health issues (dizziness, headaches, etc)
- \$100,000 claim settlement



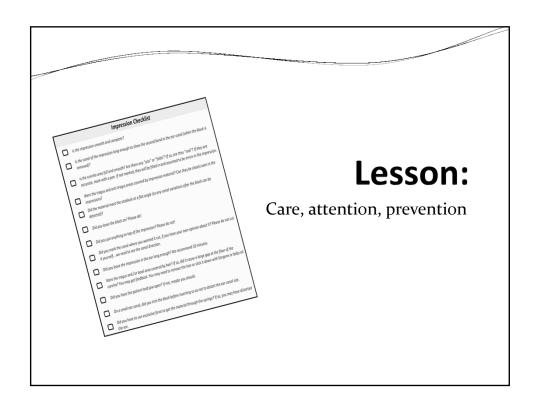
Case #2 - Blow By

- Moderate to severe SNHL in incident ear; severe SNHL in other ear. Audiologist, GP, ENT could not remove in office
- Impression removed under sedation. obliterated the TM, surrounded ossicles, entered Eustachian tube. Pt. demonstrated significant decrease in AC thresholds- now severe/profound mixed
- Subsequent dizziness and cardiac problems (for which she was hospitalized)
- Pt underwent surgery to repair TM, one ossicle removed and replaced- cleaned ET in unsuccessful attempt to restore hearing.
- Outcome- Settlement of \$560,000.
 - Audiologist: reported to HIPDB for malpractice history
 - HearUSA had to demonstrate preventive action plan



Case #3 – Dislodged PE tube

- 21 month old child
- "I did not see the gap between the cotton block/canal allowed material to blow by the block. The reason I believe the blow-by was so serious is because it was a toddler and the canal is so small that there is little margin for error. I have been doing impressions for 25 years. I should have been even more careful, but I am not sure that would have prevented the incident. I just didn't see the gap..."



Technology and Programming Errors

- With new technology features comes added complexity of multiple memories and continuously evolving options and algorithms.
- Implementation of programmable amplification will not automatically result in an improved patient outcome. It is incumbent upon us to employ the skills and techniques that will result in the patient realizing the benefits.

Common mistake...

- If at "first fit" you don't succeed, try - try again.
- First fit, then multiple visits to "tweak", "adjust" and "modify"



Circuit Selection - Programming Errors

- Handing back factory repairs not programmed appropriately
- Inappropriate compression strategy
- Not ordering appropriate options
- Not activating or programming additional memories
- Not incorporating past history into programming logic
- Over-reliance on first fit
- Not entering bone conduction scores when an air bone gap is present.

Fitting Complication

- Patient fit with CIC hearing aids
- Perforation LE longstanding
- Diabetic
- Subsequent fungus infection resulting in 24 doctor visits





Tip:

If pursuing a risky fit, take care to implement and document precautionary measures.

Verification and Validation

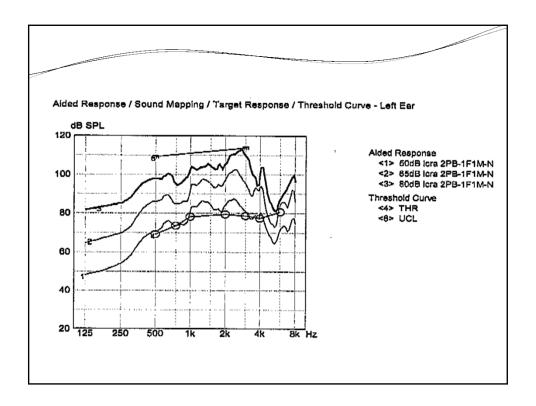
- Objective
- Subjective
- Together meet a clinical standard for delivery of care
- Minimum professional standard

Verification Failures

- Lack of objective data to verify the fitting throws into question the validity, efficacy and legitimacy of the hearing aid fitting process
- Abdicates the responsibility for guiding the patient's course of care to the patient;
 - How does that sound?
 - Let me know if you have any problems?
- Unacceptable in the practice of healthcare not to measure pre and post conditions

Verification Practices

- Multi-memories, directional microphones
- Provide adequate audibility, maximize speech intelligibility and maintain a zone of comfort within the patient's dynamic range
- Output curves give us good information about the patient's ability to hear soft, medium and loud inputs.
- Preserve dynamic range in order to preserve the elements of speech. Align the curves to preserve speech intelligibility, without compromising the louder speech sounds.



Verification: Common Clinical Errors

- Failure to verify settings
- Failure to verify multiple programs
- Failure to interpret output appropriately
- Failure to include bone conduction in real ear targets when a conductive component exists
- Not using modulated speech noise as stimulus for digital products

Validation

- Failure to employ standardized measures for patient feedback
- Failure to incorporate the feedback into management of care
 - Adjustments
 - Counseling
- Failure to aggregate the data to identify performance improvement opportunities

Oops????



Dr. Suzanne Younker, Audiology Services Manager

Pediatric Fittings ENG, VNG, ABR

Pediatric Considerations



- Test procedures modified based upon the clinician's professional judgment when working with young child/adult whose cognitive functioning precludes more standard test protocols.
- There are times that hearing instruments are fit on children before full audiometric data is available.
- Hearing instruments with flexibility are preferred for children.

Pediatric Behavioral Testing 16-Year Audiologist Perspective



<u>Incomplete test session can be viewed an error:</u>

- "Telling a parent that they need to come back to complete a test series because child has fatigued delays appropriate treatment for the child...."
- "It is easy to misdiagnose a response when in fact it was a behavioral response due to a non-hearing related issue. I find if I observe the patient in the waiting room before I take them back it helps to get a better understanding of where they are developmentally so I know where to begin."
- "My iPhone has become my greatest tool when testing OAEs. There are free apps that entertain the kids - keeping artifact and noise to a minimum."
- "Energy level and praise is important. Get silly, jump around. When I see a child with attention issues starting to fatigue I often have them come out of the booth and do jumping jacks to get them going again."

Pediatric Behavioral Testing 16-Year Audiologist Perspective

Parents can cause errors:

- "Being independent providers in an office, sometimes, we need the child's caregiver to assist in the booth with Play/VRA. Parents' natural tendency is to "coach" the child into providing a response that really accurate. Instructing the parent prior to entering the booth on the importance of not leading their child's responses is vital to obtaining reliable results.
- "With pediatric ABR testing it is important to keep the atmosphere relaxed. New mothers are often stressed due to lack of sleep and I find when I put them at ease from the beginning, I have a greater chance of not obtaining inconclusive results. Putting the parents at ease from the beginning can be instrumental in obtaining accurate test results."
- "In addition, I always troubleshoot my equipment when I see questionable results. Without alarming the parent, make sure a stimulus is being presented from the transducer, electrodes haven't slipped, insert is in ear, etc."

Pediatric Hearing Aid Fittings 16-Year Audiologist Perspective Ineffective/inadequate counseling is an error...

"It is important to inform the parents that this is a process. I explain that it's a puzzle and we will fill in pieces as we can and monitor child's progress routinely."

"On very young children, it's important the parent doesn't expect the child to respond to their name as soon as the hearing aids are fitted. I've explained my first few goals are (1) that the child keeps the hearing aids in their ears (2) that the parent keep a journal sound awareness, and (3) the child and parent are enrolled/referred to the proper agencies and programs that will maximize success."

Pediatric Hearing Aid Fittings 16-Year Audiologist Perspective

Not providing child with proper motivation is an error...

"Parents fight many battles and getting children to wear their hearing aids is one of them. I try to make their job easier. I always direct the counseling presentation to both the parent and child, if old enough."

"For children that are old enough, I encourage the parents to let them choose their color. It's hard enough as it is to get kids to wear their hearing aids due to peer pressure."

"Inform the child of what hearing aids are capable of doing these days – they can hear that their music and cell phone streamed through their hearing aids, it's very exciting!"

Pediatric Hearing Aid Fittings 16-Year Audiologist Perspective

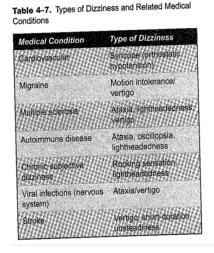
"I ask older children how much they think their hearing aids cost. Most of them have no idea. I tell them the cost, even if insurance benefit was used to pay for it.

After they understand the value of the hearing aids, they tend to take care of them better. I always feel the parent appreciates their child hearing it from a professional.

I know I can tell my son to wear his headgear every night, but, until the Orthodontist reinforces what I said their is no value in it."

Vestibular Reminders/Cautions

- General Precautionary Reminders:
 - Pre-test instructions to limit/omit food, medications, caffeine, etc.
 - Assess patient medications that may affect responses
 - Obtain a thorough medical history
 - (table from McCasling, ENG/VNG, Singular Publishing 2013)



Vestibular Reminders/Cautions

- General Error Possibilities:
 - Professional Behavioral Errors
 - Fatigue
 - "Nonchalant" routine methodology
 - Failure to task patient adequately during vision denied testing
 - Under refer for VRT
 - Under refer to ancillary health care providers

Vestibular Reminders/Cautions

- General Error Possibilities
- Patient "Behavioral" Errors
 - Anxiety
 - Neck/back injuries
 - Visual impairments
 - Unable to be tasked adequately due to cognitive issues or hearing loss
 - Physical stature
 - Osteoporosis "hump"



Vestibular Reminders/Cautions

General Error Possibilities:

- <u>Vestibular rehab</u> assure appropriate pathology prior to administering therapy techniques
- Calorics
 - Not assessing TM/EC status with tympanometry
 - Inappropriate irrigation time, pressure, or temperature
 - Not allowing vestibular system to rest in between Irrigations

Vestibular Reminders/Cautions

- A note about normal results for a symptomatic patient...

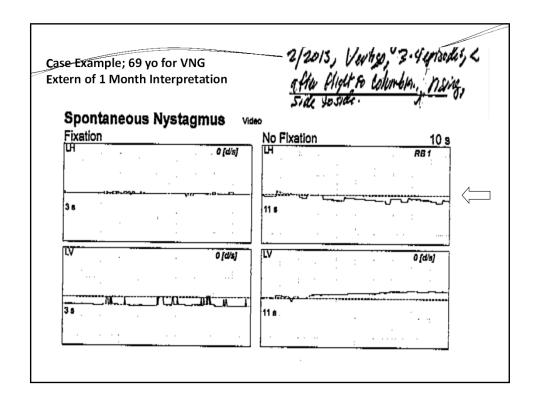
Chronic Subjective Dizziness

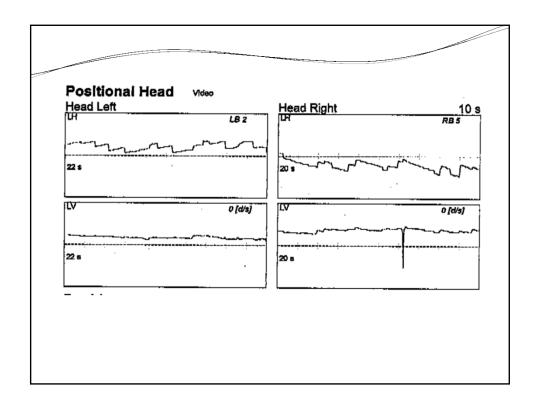
"The clinician seeing dizzy patients inevitably encounters patients who complain not of vertigo, but of a constant dizziness or "rocking"...they have normal results on quantitative assessments...could be suggestive of an anxiety disorder..." (D. McCaslin; "ENG/VNG", Plural Publishing, 2013)

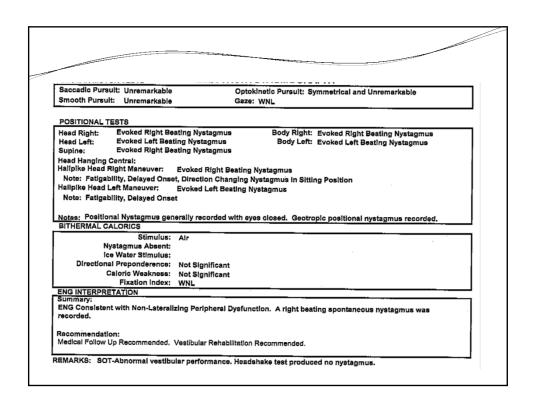
VNG

4th Year Extern Perspective

- Avoid "Over-Interpreting" results
 - Eye blinks mistaken for nystagmus
 - Recording not long enough to determine artifact versus true nystagmus
 - Not focused on overall outcome
 - Not identifying Primary versus Secondary Pathologies







VNG

4th Year Extern Perspective

• After 4-months experience at company, the question was posed to same extern:

Do you feel you have the same "sensitivity" to interpreting results as "abnormal/pathologic" now as you did when you started your externship?

VNG

4th Year Extern Perspective

Answer:

- "I don't think I am less sensitive, but, more prepared...If I see a horizontal or down beating nystagmus, I always try to make sure that it is not just an artifact or singular event."
- "A lot of my patients produce a lot of noise in their recordings with excessive eye movements and blinking that tends to obscure the results. Now, I make sure that what I am seeing is valid through the noise."
- "I think I have become a little less sensitive in the fact that I have a greater tendency to disregard "small" findings if they do not agree with the overall picture.

VNG

2nd Year Audiologist Perspective

Case History Story: "Often we go through case history and are concerned with the patient's <u>recent</u> complaints. However, certain vestibular dysfunctions can occur years prior and leave a lasting affect on the results."

"I had an elderly patient due to **brief** dizziness upon standing. Caloric testing indicated a unilateral weakness; all other findings normal."

"After the examine I decided to follow up with another question 'has there ever been a time in your life that the world started spinning for many hours?" Patient seemed surprised and said yes but over 40 years ago. ... it plays a factor on interpretation of results.

<u>"Secondary</u> to the patient's complaints, he had a compensated unilateral weakness. Without a thorough case history, the unilateral weakness finding would have had more baring on the diagnosis than it should."

Question

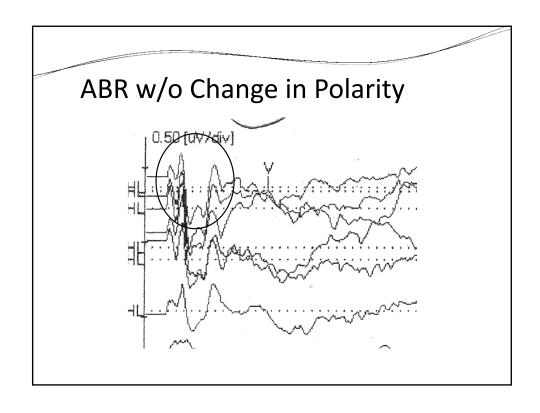
- 7
- Vestibular compensation is most effective when?
 - A. Patients are taking vestibular suppressants
 - B. Patients continue to move in the position that makes them dizzy
 - C. Patients wear glasses

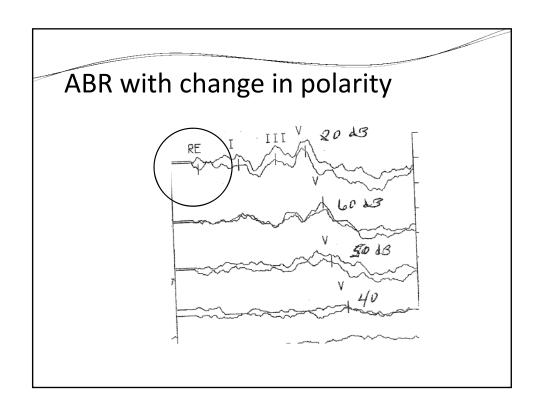
ABR Reminders/Cautions

- General Reminders
 - Electrodes
 - Prepare skin adequately for low impedance
 - Make test parameters optimal-rate, gain, stimulus, filters, sweeps, runs, etc.
 - Ambient noise is quiet and calm
 - Fluorescent lighting in test room (adjoining rooms)
 - Patient state is quiet and calm
 - Patient's cell phone off and removed from body
 - Pacemakers create ongoing EEG

ABR Reminders/Cautions

- General Error Possibilities
 - Failing to assess middle ear status prior to evaluation
 - Switch of insert earphones
 - Wave selection inconsistent marking
 - Not masking with asymmetrical loss
 - Not addressing impact of $HL \ge 4KHz$
 - Not addressing impact of conductive loss
 - Pediatrics: Failing to change polarity to assess for CM during L-I Function





ABR

10-Year Audiologist Perspective

"One issue I am picking up on is cerumen and Pediatric ABRs. Despite the fact that otoscopy yields clear canals and tymps are appropriate, I have had a few babies where, after placing the insert earphone, would have no responses at high intensity levels."

"Upon verifying, I noticed the issue was cerumen. For some reason, slight cerumen, though not noticeable to the eye or maybe considered minimal due to the fact we can view the TM, may get pushed into the earphone tip upon insertion."

"Since then, I have made a point of changing the insert tips and rechecking at the high intensity runs to confirm or negate the initial response."

ABR

10-Year Audiologist Perspective

"I have had incidents of no hearing function on one ear."

"Upon rechecking that same ear at that same intensity on another channel (aka the opposite side left for right or right for left) the patient will then pass in that ear with flying colors.)

"When a patient has no response on the ABR on one side, it behooves the clinician to check :1- the tip for cerumen; 2- the insert for leaks; 3- the channel being used."

"Verification, verification, verification....These have helped me to not misdiagnose a patient."

In Summary:

- Wrong treatment
- Wrong *site* treatment (L/R side errors)
- Poor record keeping and documentation
- Age extremes (very young, very old patients)
- Improper technique

- Misdiagnosis
- Inexperience
- Fatigue or distraction
- Inadequate or inaccurate labeling (including translation)

87

2012 Patient Care Related Incident Distribution

| Impression | Canal Abrasion | Dome Dislodge | Cerumen Removal | Procedure |
|------------|-------------------|------------------|--------------------|-----------|
| 11 | 3 | 34 | 2 | 3 |

When Clinical Errors Occur

- Potential errors and mishaps are possible during administration of a variety of hearing care services.
- Most of these are avoidable by the conscientious clinician and quickly corrected when they occur.
- Responsibility of clinicians to provide the most efficacious services to patients within a clean and safe environment.
- When error does occur:

Fully document the circumstances and details of the event.

- If indicated at time of incident or follow up, call the patient's physician- explain situation and ask if the physician would see the patient, or if there is an ENT that should be contacted.
- Consider a 3rd party to do the follow up inquiry.
- Document appointment date and time.
- Demonstrate compassion, concern, and verbalize "blameless apology".
- Do a root cause analysis and implement corrective action, as indicated.

Root Cause Analysis



• Root cause analysis (RCA) is a class of problem solving methods aimed at identifying the root causes of problems or events. The practice of RCA is predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms.

- Do not file details in the patient file. File separately under an incident file.
- Clinician or designee follows-up with patient and/or physician following the medical consultation. The clinician's supervisor should be kept apprised of all developments.
- Take care to communicate and follow the patient through the incident. By conveying a sense of care and concern, we are best able to control the outcome and minimize further adversity.

Communicate with resources:

- Risk Management
- Insurance Carrier
 - 30 days!
- In house legal department



Improving Patient Safety

- Find out why it happened
- Strategize about new methodologies
- Foster a culture where people are interested in quality of care and discuss near misses, risks, problems
- Patient education is an important part of this process
- Quality oversight is necessary
- Staff training is paramount

Closing remarks...

- Routine visits and procedures are not always routine
- Take good care, use a disciplined process to ensure minimal risk to the patient and the provider
- Handle adverse incidents with concern and professionalism
- Manage the incident to the best probable end
- Train and re-train; foster a culture of excellence

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