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Preventing Medical Errors in Your Audiology Practice

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Presenter Disclosures:
- Financial: Cindy Beyer is employed by Your Hearing Network. She received an honorarium for presenting this course. Non-financial: Cindy Beyer has no relevant non-financial relationships to disclose.
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Learning Outcomes

1. Identify the highest probable origins of adverse audiology outcomes.
2. Discuss common audiology errors and steps to minimize them in an audiology practice.
3. Explain the benefits of a root cause analysis and risk management program.

Agenda

- Error and Liability Overview
- Administrative Errors
- Clinical Errors
- Treatment Errors
- Preventive Errors
- Risk Management
- Summary and Closing
Why Errors Course?

- Hearing healthcare is not immune to risk
- Cost of providing and receiving healthcare continues to rise
- Complexity of amplification and hearing loss evolving
- Cost involved to resolve cases of medical liability
- Increased regulatory responsibility instilled by licensing authority
- Ethical responsibility to minimize risk of error in delivering hearing care

Medical Errors

- 2016 John Hopkins study reported medical errors as 3rd leading cause of death
  - 250-4000 deaths
  - More than AIDS, MVA, breast cancer
  - 2.4 million prescriptions filled incorrectly
  - 7,000 people die from medication errors
- Cost the nation $17-29B annually
- 74% are preventable

Adverse Effects of Medical Treatment

- Recent studies have revisited that research
- Much lower numbers of death and contributory numbers (<6000)
- Conclusions:
  - (1) AEMTs are not uncommon;
  - (2) the vast majority of AEMTs that occur in patients who die aren’t the primary cause of death;
  - (3) only a relatively small fraction of AEMTs are due to misadventure or medical error; and
  - (4) population-adjusted AEMT rates have been slowly decreasing.

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
How many of you have encountered an adverse event while performing hearing care procedures?

- Adverse event – caused by medical management rather than the condition of the patient
- Examples: 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, earphones reversed, insufficient masking

Standard of Care establishes uniformity across individuals in an organization & sets expectations for acceptable performance.

Do No Harm...

- Practice in the best interest of the patient
- Protects provider 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
  - American Academy of Audiology www.audiology.org
  - American Speech and Hearing Association www.asha.org
  - International Hearing Society www.ihsinfo.org

Q3
Types of Errors

- Errors of omission occur as a result of actions not taken.
  - Not performing the right test when indicated
  - Not performing all parts of the test
  - Not making hearing aid or physician referral

- Errors of commission occur as a result of the wrong action taken.
  - Incorrect masking or procedure
  - Incorrect test interpretation
  - Wrong hearing aid recommended
  - Poor programming

What is Liability?

- Adverse incident may result in an injury to the patient
- Injury may encompass a broad spectrum of incidences
  - Physical injury
  - Unintentional mismanagement of a patient's hearing loss
- Liability refers to the responsibility for the damages that occurred as a result of the incident
- Malpractice can be either a deliberate or a negligent act committed by a health care provider
- Circumstances could result in a report to the NPDB
Provider Credentialing

- Credentialing is the processing of enrolling into an insurance plan or network
- This involves a thorough and detailed investigation of a provider’s credentials (education, experience)
- Looks at provider’s interactions with various entities
- State Licensing Boards
- Office of Inspector General (Medicare, Medicaid)
- National Practitioner Databank

National Practitioner Databank

- Information clearinghouse created by Congress
  - Improve health care quality
  - Protect the public
  - Reduce healthcare fraud and abuse
- National flagging system
  - Collects information on medical malpractice payments and adverse actions
  - Discloses information to eligible entities
- Required to report
  - Malpractice payers, hospitals, professional societies, health plans, peer review organizations, accreditation organizations, state and federal agencies
- Required to query
  - Entities making employment, credentialing, licensure, clinical privileges decisions
National Practitioner Databank

Categories of Errors

- Administrative
  - Failure of communication
  - Equipment failure
  - Record keeping
  - Facility issues

- Clinical
  - Error or delay in diagnosis
  - Failure to employ indicated tests
  - Use of outmoded tests or therapy
  - Failure to act on results of monitoring or testing

- Treatment
  - Error in the performance of an operation, procedure or test
  - Error in administering the treatment
  - Avoidable delay in treatment or in responding to an abnormal test

- Preventive
  - Failure to provide prophylactic treatment
  - Inadequate monitoring or follow-up of treatment
Administrative Errors

Provider’s responsibility to ensure patient safety and to provide an environment that controls transmission of disease from provider to patient; patient to patient; patient to provider

Elderly patients present with compromised immune systems placing them at particular risk; newborns and infants

Direct/indirect contact occurs between provider and patient

Between patient and equipment/tools… in turn come in contact with other patients

Negligence is probably the biggest fail

Written infection control plan is required
  - Kemp and Bankaitis
  - Professional organizations
Pandemic Response Plan

- National pandemic disaster
- Written process and business continuity plan
- Heightened infection control processes
  - Social distancing
  - Barriers, scheduling, pathways
  - Personal protective equipment - Masks, goggles
- Resources:
  - https://www.asha.org/About/Coronavirus-Updates/
  - https://www.audiologist.org/practice/covid-19-resources
  - http://ihsinfo.org/covid-19/

Face Mask – Face Shield - Barriers

- Face masks create communication barriers
- Face shield is effective substitute
  - May allow for visual cues
- Be sensitive to additional hardship
- May need creative accommodations
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 - sterilization
- 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, testing, 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 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.
• Dates of service, rendering provider in the treatment records should line up with claims documents.

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.
AMA 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;
- 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, unresolved problems
- Insufficient amplification history and documentation of needs and expectations
- Missing physician scripts
Documentation or Billing Error

- After it self-disclosed conduct to OIG, Towson University Speech Language & Hearing Center (Towson), Maryland, agreed to pay $10,000 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that Towson submitted claims for audiology services with a National Provider Identification (NPI) number that did not correctly identify the provider that rendered those audiology services. OIG further alleged that for these services to be paid by Medicare, the audiologist must have been credentialed by Medicare as a provider and that audiologist’s NPI number must accompany the claim.

https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp

Unlicensed Testers

- United States Attorney Jaquith said: "... provided improper inducements to attract patients, allowed audiology testing by unlicensed and unsupervised employees, and then falsely billed Medicare and TRICARE as if the exams had been done by professionally licensed audiologists.

- The inducements included entering beneficiaries into a contest for a free iPad, and offering beneficiaries free Butterball turkeys, $15 Visa gift cards, $15 Dunkin Donuts gift cards, and $30 Omaha Steaks gift cards.

15 Million patient records compromised in 2018 – up 270% from previous year

Stolen health information is a valuable commodity

Identity Errors

- Take steps to ensure that patient identity is established and verified
  - Fraud
  - Record mix-ups
  - Identity theft
  - HIPAA issues

Housekeeping

- Safe environment
  - Wires
  - Chairs
  - Steps
  - Booth

- Facility issues
  - Slip and fall
  - Bumps, bruises, breaks
Clinical Errors

Cerumen Removal
Evaluation and Testing
Earmold Impressions
Hearing Aid Selection and Programming
Errors
Verification Errors
Continuous Care Errors

"An ounce of prevention is worth a pound of cure."
Benjamin Franklin
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.

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

Common Errors in Audiometry

- Incomplete or poor case history
- Improper supervision of trainees
- 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.
- 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

- 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.
Testing & Interpreting Errors

Right Ear
- Canal clear of excessive cerumen.
- Using Headphones.
- Moderate high frequency mixed loss.
- Speech reception validates pure tone response.
- Word recognition ability excellent.

Left Ear
- Canal clear of excessive cerumen.
- Using Headphones.
- Moderate high frequency sensorineural loss.
- Speech reception validates pure tone response.
- Word recognition ability good.

No BC thresholds for LE.
Recommendation Error

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.

Under Masking @ 30dB-EM

2012

2016
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.
Potential for damage to outer, middle and inner ear structures exist…potential increases when taking deep canal impressions

A Routine Procedure…

- 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.
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

- ENT could not remove in office
- Impression removed under sedation.
  - Obiterated 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
  - 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... I just didn't see the gap..."

Case #4 Impression Related

Day of Appointment
- While inserting impression material, patient moved.
- Upon removal, patient expressed significant pain
- After removal, inspection of impression revealed a slight “blow by”.
- Otoscopic inspection revealed an abrasion on the floor of the canal with no blood.
- Tympanometry was normal
- Did not appear to require medical attention
Case #4 Impression Related Continued

Picture #2: VO pulled slightly back

Picture #3: VO focused on abrasion site

Bridge and Brace

Incorrect Method

Correct Method

Permission to use photos granted by the International Hearing Society
Additional Impression Notes

- Block materials include the traditional cotton and the newer polyfoam. Because of its compressibility, the latter ear dam material is often a poor choice for use with viscous, high density silicone impression materials.
- Material mix consistency and injection force are also critical variables in the impression-taking process.
- Friable and monomerically scarred tympanic membranes and surgically altered ears are at particular risk.
- The use of a lubricant such as mineral oil will prevent material from adhering to canal wall.

Treatment Errors
Selection & Programming Errors

- With new technology features comes added complexity of multiple programs and continuously evolving options and algorithms.
- Remember the basics; the appropriateness of amplification at any given frequency depends on the ear canal length & size, and the amount of ear canal “insertion loss” or occlusion from dome, earmold, or shell.
- Selecting appropriate dome shape and size matters to overall success of hearing acuity.

Inadequate gain

- Due to Complaint of Poor Speech Clarity: Not taking a low frequency loss into account and under amplifying the low frequencies.
- Due to Complaint of Voice Occlusion: in a barrel or echoing a commonly made adjustment error is to reduce the input in the low frequencies for all the input levels (i.e. soft/average/loud).
- Changing dome style/venting, but not updating in the software.
- Not considering manufacturer recommendations on receiver strength and dome size; open fit is not always the best fit and is not always the answer to occlusion issues.
User doesn’t notice much difference

- Complaint of not being able to tell a difference between wearing and not wearing hearing instruments other than a noted increase in sharpness of sounds.
- Failure to attain the full potential of the hearing aid over time

Feedback issue

- If the feedback control system has been run but feedback persists a common adjustment error is to reduce the gain for all inputs in the high frequency region which may reduce speech intelligibility.
- Adjustment may be to decrease the gain only for the soft input curve in the high frequency region
Hearing Aid Programming Error

- Patient dissatisfied
- Severe loss bilaterally
- Initially fit with mid-level; exchanged to high-level due to lack of noticeable benefit
- Several check-ups for “Thinks they need to be turned up.”
- No contact 6-months

REM of Exchanged “upgrade” at time of delivery.
Hearing Aid Verification

- Research continues to show that hearing aids that provide real-ear verified aided speech audibility result in better outcomes than hearing aids that do not provide as much aided speech audibility.
- Study done in 2017 by Leavitt, Bentler and Flexer showed that 97.7% of subjects showed deviations from the NAL-NL2 in excess of 5 dB in both ears.
Verification and Validation

- Objective
- Subjective
- Together – meet a clinical standard for delivery of care
- Minimum professional standard
- Hold yourself accountable

Verification Failures

- Biggest mistake is not performing verification at all
- 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
- Today’s deluxe hearing aid features do not obviate the need for real ear validated speech audibility
Verification Practices

- Provide adequate audibility, maximize speech intelligibility and maintain a zone of comfort within the patient's dynamic range.
- Traditional REM procedures including input signals for soft, medium, and loud speech.
- Speech Mapping utilizes live speech to identify amplification outcomes to a real person speaking.
- Autofit programming methods include the patient's REUG information and automatically programs the hearing aids to fit soft, medium, and loud targets.

First Fit vs. REM Fit

Dashed Lines = Prescriptive Target
Solid Lines = HA Response

Don't REM
Unsatisfactory Verification Errors

Verification: Common Clinical Errors

- Failure to insert probe tube to appropriate length: 5mm from TM and 3-5mm from HA sound bore
- Failure to verify for soft, medium and loud inputs
- Failure to select the correct dome and/or receiver type in programming software (RIC products)
- Not using modulated speech noise as stimulus for digital products
Failure to employ standardized measures for patient feedback

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<td>• Failure to employ standardized measures for patient feedback</td>
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<td>• Failure to incorporate the feedback into the management of the care</td>
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<td>• Adjustments</td>
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<td>• Counseling</td>
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<td>• Opportunity to use this information in tandem with verification to guide the patient’s best direction of care</td>
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Preventive Errors
Continued Care Errors

• Failure to recommend a Remote Care option to all patients with applicable technology
• Failure to schedule 6/12-month follow up appointments
• Failure to activate acclimation schedule for new users
• Failure to offer instructional video options to reinforce care and maintenance for new users

Dome Care and Maintenance

• Professionally changed by staff every 3-6 months
• Assure receiver clear of wax debris; remnants may prevent a secure attachment
• Assure “click” sound is heard to confirm secure attachment
• Assure correct size and style
Follow Up Care

- Always schedule a follow up appointment
- 6-month HAC, 1 Year annual audiogram
- Document in the patient record
- Best practices

Risk Management
The human element

- Ignorance
- Inexperience
- Faulty judgment
- Fatigue
- Job overload
- Breaks in concentration
- Medical record keeping
- Faulty communication
- System flaws
- Unsupervised externs

Wrap Up:

- Medical errors (AEMT) are a continuing concern
- Audiologists are not immune to this concern
- Liability in the audiology practice can occur as the result of many activities that take place within the practice
- We grouped those into administrative errors
- Further grouped them into clinical errors, specifically for a hearing aid dispensing practice
- Errors of omission and commission
When Clinical Errors Occur

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

Stay cool, calm and collected

- 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.
- Demonstrate compassion, concern, and verbalize “blameless apology”.
- Stay in touch. Consider a 3rd party to do the follow up inquiry.
- 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.

Documentation is important


- Provider or designee follows-up with patient and/or physician following the medical consultation. The provider’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!
- Legal

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

References