Absolute Medical Errors to Avoid: Guidelines for Audiologists

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Medical Records:
Reasons for Demise on Actual Death Certificates

- “Went to bed feeling well … woke up dead.”
- “Don’t know … never fatally ill before.”
- “Nothing seriously wrong.”
- “Blow to head. (Contributory cause was another man’s wife.”
- “Don’t know … died without the aid of a doctor.”

*St. Louis Genealogical Society*
Absolute Medical Errors to Avoid: Guidelines for Audiologists

- Rationale for a medical errors course “of, for, and by audiologists”
- Definitions of important terms
- Standard of care
- General steps for preventing errors and minimizing liability
- Professional responsibility, professional liability, and risk management in audiology
- Patient scenarios … Errors and steps to prevent them (You make the call!!)
- Real examples of medico-legal cases in the state of Florida
- Questions and answers
Absolute Medical Errors to Avoid:
Rationale for a medical errors course “of, for, and by audiologists”

- Most common medical errors committed by physicians and medical personnel
  - Drugs
    - Giving the wrong drug
    - Giving right drug to wrong patient
    - Giving right drug to the right patient, but with the wrong dose
    - Giving the right drug to the right patient with the right dose at the wrong time
    - Giving the right drug to the right patient with the right dose at the right time via the wrong route (e.g., IV versus oral)
    - Giving two or more drugs that interact unfavorably or cause poisonous metabolic byproducts
Absolute Medical Errors to Avoid:
*Rationale for a medical errors course “of, for, and by audiologists”*

- Most common medical errors committed by physicians and medical personnel (*continued*)
  - Wrong-site surgery, e.g.,
    - Amputating the wrong limb
    - Operating on the wrong ear
  - Gossypiboma or textiloma (Wikipedia)
    - Definition: Gossypiboma or textiloma is the technical term for a surgical complications resulting from foreign materials, such as a surgical sponge, accidentally left inside a patient's body.
    - The term "gossypiboma" is derived from the Latin gossypium (cotton) and the Swahili boma (place of concealment)
    - "Textiloma" is derived from textile (surgical sponges have historically been made of cloth) and the suffix "-oma", meaning a tumor or growth.
  - Patients' implementation of drugs and treatments
Absolute Medical Errors to Avoid:
Prevention of Medical Errors for Audiologists (ProCourse)

- List topics to cover in a cerumen management course
- List reasons to obtain medical clearance before being fit with hearing aids
- List things to examine during a biologic check of an audiometer
- List tests to use when non-organic hearing loss is suspected
- List clinical applications for otoacoustic emission
- Explain the difference in information obtained in otoacoustic emissions and hearing testing
- Identify information obtained through a tinnitus assessment
Absolute Medical Errors to Avoid: Guidelines for Audiologists

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- Definitions of important terms
- Standard of care
- Factors contributing to “medical” errors in audiology
- Audiology errors just waiting to happen
- Professional responsibility, professional liability, and risk management in audiology
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Absolute Medical Errors to Avoid: 
Defining Professional Liability

“An individual who causes injury to another either intentionally or unintentionally can be held liable for the action. By virtue of advanced knowledge, training, and skill, a professional has a responsibility to conform to certain standards of conduct to protect the public from unreasonable risks.

... The responsibility of licensed and/or certified professionals to conform to those standards may be referred to collectively as professional liability.”

Absolute Medical Errors to Avoid: Definitions of Important Terms

- Civil professional liability (see ASHA, 1994)
  - Tort from Latin for twisted or distorted: Any wrongful act, damage, or injury done willfully or negligently
  - Action in tort is a private legal action in which
    ✓ A plaintiff seeks a remedy (generally monetary) for damages to health, property, peace of mind, or reputation
    ✓ The defendant is the health care provider to provided services to the plaintiff
    ✓ Plaintiff must prove defendant fault before payments are required from defendant
  - Intentional tort
    ✓ Illegal actions were intentional
    ✓ A reasonable person would conclude that the alleged result was substantially certain to follow the action, e.g.,
      - Assault (attempt to do violence)
      - Battery (unauthorized physical contact), e.g. failure to obtain consent to treat
      - Defamation of character
      - Violation of confidentiality, e.g., unauthorized release of PHI
Absolute Medical Errors to Avoid: Definitions of Important Terms (2)

- Unintentional tort
  - Most common form of negligence in civil litigation involving audiologists
  - Defendant (practitioner) failed to exercise standard degree of care, e.g.,
    - Negligence
    - Misdiagnosis
    - Incorrect or inadequate treatment
    - Injuries from equipment or premises
    - Harmful effects of human subject research
  - Four elements of unintentional tort
    - A legal duty (practitioner/patient relationship) exists between audiologist and plaintiff
    - Breach of legal duty exists (e.g., improper diagnosis, physical injury)
    - Cause and effect established (proximate cause) between breach of duty and injury
    - Injury results in actual loss or damage
Absolute Medical Errors to Avoid: Definitions of Important Terms (3)

- Ethical practice complaints (not discussed today)
- Action in contract (see ASHA, 1994)
  - A form of civil litigation
  - Failure to fulfill promises and other obligations, e.g.,
    - Audiologists must never imply a guarantee of results of treatment
- Criminal liability
  - Commission of misdemeanors or felonies during conduct of professional activities, e.g.,
    - Battery
    - Fraud
    - Grand larceny
    - HIPAA violations
  - Often criminal liability reflects ignorance of regulations, e.g.,
    - Medicare and Medicaid law
    - State insurance codes
  - Audiologist is subject to fines and incarceration
Absolute Medical Errors to Avoid: Definitions of Important Terms (4)

- Employer liability
  - Employer has “vicarious” responsibility (respondeat superior) for those who work for them
  - Unlicensed person inadequately supervised by licensed audiologist
  - Support staff under supervision of an audiologist

- Product liability
  - Audiologist drawn into third party liability litigation following dispensing of a product or device, e.g.,
    - Ingestion of hearing aid battery by a child
    - Allergic reaction to electrode paste or an ear mold
    - Tinnitus worsened by sound generator that produces high frequency squeal
    - Malfunctioning FM system contributing to academic failure
    - Defective cochlear implant
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- **Standard of care**
- General steps for preventing errors and minimizing liability
- Professional responsibility, professional liability, and risk management in audiology
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Absolute Medical Errors to Avoid: Guidelines for Audiologists

"Those who fall in love with practice without science are like a sailor who steers a ship without a rudder or compass, and who can never be certain whither he is going."

Leonardo Da Vinci (1452-1519)
Absolute Medical Errors to Avoid:
Standard of Care

- Consistent with local, regional or national clinical practice
- Follows guidelines or recommendations on clinical practice approved by national multi-disciplinary professional committees or panels, e.g., Joint Committee on Infant Hearing
- Follows guidelines or recommendations on clinical practice approved by national professional organizations, e.g., AAA or ASHA
- Is consistent with statements of
  - Scope of Practice
  - Code of Ethics
- Is in compliance with Federal guidelines for clinical practice and services, e.g., Joint Committee on Accreditation of Healthcare Organizations (JCAHO)
Absolute Medical Errors to Avoid:
Legal Definitions of Standard of Care

- In tort law, the standard of care is the degree of prudence and caution required of an individual who is under a duty of care.  
  (en.wikipedia.org/wiki/Standard_of_care)

- In tort law, the degree of caution that a reasonable person should exercise in a given situation so as to avoid causing injury  
  (en.wiktionary.org/wiki/standard_of_care)

- The degree or level of service, attention, care and protection that a person owes another person according to the law (see also Duty of care).  
  (www.ibc.ca/en/need_more_info/glossary/S.asp)

- The level of care which all persons with a particular illness should receive; the level below which care would be considered substandard. standard therapy  
  (aids.hallym.ac.kr/dict/s.html)
Absolute Medical Errors to Avoid:
Legal Definitions of Standard of Care (2)

- Treatment regimen or medical management based on commonly accepted practices.
  ([www.nortonhealthcare.com/body.cfm](www.nortonhealthcare.com/body.cfm))

- It's the level of care, which an average practitioner would practice. Or in other words how a similar qualified practitioner would manage their patient's care under similar circumstances. Medical Malpractice claims must establish the standard of care and show that the standard has been breached.
  ([www.gmlaw.com/medical-malpractice-resources-terms.cfm](www.gmlaw.com/medical-malpractice-resources-terms.cfm))

- In medicine, treatment that experts agree is appropriate, accepted, and widely used. Health care providers are obligated to provide patients with the standard of care. Also called best practice and standard therapy.
  ([National Cancer Institute](National Cancer Institute))

- This is the degree of cautionary action which must be performed at all times when treating and/or performing surgery on a patient. If a breach of contract occurs, the care provider can be held liable for negligence.
  ([www.cosmeticsurgerymalpractice.com/resources.cfm/malpractice-glossary.html](www.cosmeticsurgerymalpractice.com/resources.cfm/malpractice-glossary.html))
Best Practices in Audiology Today: Specific Sources for Practice Guidelines (Standard of Care)

- Guidelines for different clinical practices, e.g.,
  - Diagnostic audiometry in adults
  - Pediatric diagnostic audiology
  - Hearing aids and amplification
  - Auditory processing disorders (APD) assessment and management
  - Tinnitus assessment and management

- Selected sources of guidelines
  - V.A. guidelines by Joint Commission (Audiology Today)
  - Tinnitus guidelines (www.audiology.org)
  - Joint Committee on Infant Hearing (JCIH) 2007 Statement
  - Guidelines for auditory processing disorders. AAA (2010)
  - Guidelines for otoacoustic emissions (OAEs). AAA (in progress)
Categories for Strength of Evidence used in Developing Clinical Guidelines

- **Grade I**: Evidence is strong and usually obtained from randomized controlled trials or well-designed clinical studies.
- **Grade II**: Evidence is from clinical studies that were based on retrospective data analysis, clinical trials that were not randomized and/or carefully-controlled, or from panel consensus based on existing guidelines and practice patterns.
- **Grade III**: Evidence is secondary in that it is based on current or long-standing practice without substantial supporting basic or clinical data.
Year 2007 JCIH Position Statement:
Protocol for Evaluation for Hearing Loss
In Infants and Toddlers from Birth to 6 months

- Child and family history
- Evaluation of risk factors for congenital hearing loss
- Parental report of infant’s responses to sound
- Audiological assessment
  - Auditory brainstem response (ABR)
    - Click-evoked ABR with rarefaction and condensation single-polarity stimulation if there are risk factors for auditory neuropathy
    - Frequency-specific ABR with air-conduction tone bursts
    - Bone-conduction stimulation (as indicated)
    - Auditory steady state response (ASSR) is optional
  - Otoacoustic emissions (distortion product or transient OAEs)
  - Tympanometry with 1000 Hz probe tone
  - “Clinical observation of infant’s auditory behavior. Behavioral observation alone is not adequate for determining whether hearing loss is present in this age group, and is not adequate for the fitting of amplification devices.”
### Year 2007 JCIH Position Statement: Risk Indicators Associated with Permanent Congenital, Delayed-Onset, or Progressive Hearing Loss in Childhood (1)

- Caregiver concern regarding hearing, speech, language, or developmental delay.
- Family history of permanent childhood hearing loss
- NICU stay of > 5 days or
  - ECMO
  - Assisted ventilation
  - Exposure to ototoxic medicines
  - Hyperbilirubinemia requiring exchange transfusion
- In utero infections, e.g.,
  - CMV
  - Herpes
  - Rubella
  - Syphilis
  - Toxoplasmosis
- Craniofacial anomalies, including involvement of the
  - Pinna
  - Ear canals
  - Ear tags and pits
  - Temporal bone anomalies
Year 2007 JCIH Position Statement:
Risk Indicators Associated with Permanent Congenital, Delayed-Onset, or Progressive Hearing Loss in Childhood (2)

- Physical findings associated with a syndrome, e.g., white forelock
- Syndromes associated with hearing loss, e.g.,
  - Neurofibromatosis
  - Osteopetrosis
  - Usher syndrome
  - Waardenburg
  - Alport
  - Pendred
  - Jervell
  - Lange-Nielsen
- Neuro-degenerative disorders, e.g.,
  - Hunter syndrome
  - Sensory motor neuropathies
    - Friedreich ataxia
    - Charcot-Marie-Tooth syndrome
- Culture positive post-natal infections associated with sensorineural hearing loss, e.g., Confirmed bacterial and viral meningitis
- Head trauma requiring hospitalization
- Chemotherapy
Year 2007 JCIH Position Statement Recommendations for Timing and Frequency of Audiologic Follow up for Infants with Risk Indicators Associated with Permanent Congenital, Delayed-Onset, or Progressive Hearing Loss

- Prior (2000 JCIH) recommendations for follow up at 6-month intervals of all NICU graduates (approximately 400,000 babies annually) placed an excessive burden on audiologists.

- 2007 JCIH shifts responsibility for surveillance of all infants to the primary care provider who will refer to audiologists as needed, e.g.,:
  - Concerns or findings consistent with hearing loss
  - Risk factors for delayed/late onset or progressive hearing loss

- 2007 JCIH recommends at least one audiologic referral for low risk infants by age 24 to 30 months.

- Early and more frequent referral (every 6 months) to audiologists for risk factors associated with delayed onset and progressive hearing loss, e.g.,:
  - Family history
  - CMV
  - ECMO therapy
  - Potentially ototoxic chemotherapy (e.g., cisplatin)
  - Neurodegenerative disorders
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Absolute Medical Errors to Avoid: General Preventive Strategies and Steps (1)

- Awareness and education of the audiologist
  - Identify potential risks
  - Reduce risks by providing accepted standard of care
  - Practice within the scope of audiology
  - Remain up to date with professional developments (formal and informal continuing education)
  - Know
    - State licensing laws
    - Code of ethics
    - Patient Bill of Rights
    - Policies and procedures of hospital or other organization you would within or with
  - Refer when you do not have knowledge, expertise, or credentials to provide a service the patient needs … “When in doubt, always refer out!”
  - Verify licensure, certification, and other qualifications of professionals you refer patients to
Absolute Medical Errors to Avoid:
General Preventive Strategies and Steps (2)

- Maintain professional credentials in audiology, e.g.
  - State license with required continuing education
  - Board certification with required continuation education
  - Specialty certification
- Effective communication with patient and family, e.g.,
  - Establish positive relationship with patient and family
  - Explain all test findings, treatment options, and treatment goals
  - Fully disclose fees, billing schedules, etc
  - Provide written warranties and warnings
  - Secure patient signature on informed consent, release of information, and other documents
    - Adequate verbal and written communication with patient and family
- Documentation, record keeping, and reporting
  - Written documentation in official medical or clinic records
  - Documentation is legible and thorough
  - Make corrections appropriately
  - Document all contacts with patient and family (face to face, telephone, email)
  - Document all contacts with professionals regarding the patient
  - Retain all correspondence between audiologist with or about the patient
Absolute Medical Errors to Avoid:
General Preventive Strategies and Steps (3)

- Compliance with state and federal privacy and security regulations, e.g.,
  - Health Insurance Portability and Accountability Act (HIPAA) of 1996
- Follow accepted policies for infection control, e.g.,
  - Compliance with Joint Commission
  - Institutional policies
- Equipment calibration
  - Periodic physical calibration with documentation
  - Daily biological checks
- Meet or exceed national standards of care for audiology
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“To err is human, to forgive is divine.”

“A little knowledge is a dangerous thing.”

Alexander Pope (1688-1744)
An Essay on Criticism
Absolute Medical Errors to Avoid: Risk Exposure
(Adapted from ASHA, 1994)

- Audiologists are vulnerable to liability claims
- Important factors in reducing exposure to liability are
  - Awareness
  - Education
- “Risk exposure may be increased if services are provided for:
  - Invasive procedures
  - Specific disorders
  - In certain physical settings
  - For special populations
  - *Can you name some examples of the above?*
Absolute Medical Errors to Avoid:
Claims Summary from Liability Insurance Broker (1)
(128 audiology and SLP claims between 1985-1993, ASHA, 1994)

- Improper procedure treatment (25 claims)
  - Most frequent category of “malpractice” claim
  - Details not available
- Hearing aids (23 claims)
  - 11 claims related to ear mold material left in ear canal
  - 5 claims for dispensing “wrong” hearing aid
  - 1 claim for child swallowing a hearing aid battery
- Employment conflict (15 claims)
  - Breach of confidence (remember … time period is pre-HIPAA!)
  - Slander
  - Workmen’s compensation
  - Discrimination
- Physical injury to the ear/hearing
- Physical injury to other parts of the body
### Absolute Medical Errors to Avoid:
#### Claims Summary from Liability Insurance Broker (2)
*(128 claims between 1985-1993, ASHA, 1994)*

- **Physical injury to the ear/hearing (11 claims)**
  - Damage to ear canal
  - Hearing loss caused by assessment or treatment
  - Tinnitus worsened by assessment or treatment
- **Physical injury to other parts of the body (11 claims)**
  - Burns to face from solvents or electrodes most common in category
  - Eye damage
  - 1 claim for shortness of breath during an examination (maybe SLP)
- **Improper diagnosis (10 claims)**
  - Improper or misdiagnosis (e.g., failure to diagnose hearing loss in young child)
- **Injuries due to falls (9 claims)**
  - Patients who fell from examining tables or wheelchairs
  - Falls are a major problem in health care facilities
  - In 2000, the total direct cost of all fall injuries for people 65 and older exceeded $19 billion
  - Fall prevention policies and regular education now mandatory in hospitals
Absolute Medical Errors to Avoid:
Claims Summary from Liability Insurance Broker (3)
(128 audiology and SLP claims between 1985-1993, ASHA, 1994)

- Patient death (8 claims)
  - Patient with heart attack in preparation for examination
  - Fatal accident associated with travel to repair of defective hearing aid
  - Distraught individual who killed her father after having a speech, language, and hearing evaluation
- Sexual harassment (3 claims)
- Property damage (3 claims)
- Failure to provide sufficient information (2 claims)
  - Warning of medical risks was not provided
  - Ex-employer who tested positive for HIV
Absolute Medical Errors to Avoid:
Claims Summary from Liability Insurance Broker (4)
(128 audiology and SLP claims between 1985-1993, ASHA, 1994)*

- Intra-operative monitoring (1 claim but largest ... > $1,000,000)
  - Examiner “failure to advise the surgeon” during somatosensory monitoring
- False guarantee of results (1 claim)
  - A stutterer was told he’d be cured in 2 days
- Other (4 claims)
  - Mistaken identity
  - Announcing death of wrong person
  - Unspecified criminal/fraudulent act
  - Fatality and subpoena of the insured to serve as expert witness

* Note: Majority (58%) of claims related to audiology. Data are not necessarily representative of audiology: 1) include data for SLPs, 2) only derived from one insurance company, 3) Only 1/3 of ASHA audiologists were covered by the carrier, 4) in medical settings audiologists are often covered by institutional professional liability, not the ASHA carrier
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Absolute Medical Errors to Avoid:
Guidelines for Audiologists

“I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrongdoing.”

Hippocratic Oath (c. 460-400 B.C.)

“...I will keep pure and holy both my life and art...”
Absolute Medical Errors to Avoid:
A Short List of Potential Professional Liability Cases

- Inadvertent over-stimulation of patient due to audiometer settings
- Middle ear complications following ear mold impressions
- Acoustic reflex measurement in hyperacusis
- Inadvertent over-stimulation of patient due to audiometer settings
- Patient with severe tinnitus commits suicide
- Patient with APD and TBI loses job
- Failure to diagnose infant with hearing loss
- Failure to diagnose a child with APD and resultant academic failure, reading disorder, psycho-social problems
- Failure to diagnose BPPV
- Recommendation for cochlear implant in post-synaptic ANSD
- Over-amplification of patient with mild hearing loss
- Loss of hearing and facial nerve function during intra-operative monitoring
- Inadequate management with hearing aids
- Noise induced hearing loss following audiologic assessment (e.g., failure to provide adequate education (or to document) about hearing protection leading to noise induced hearing loss
Patient Scenarios … Errors and steps to prevent them

- Ear mold impressions are made for a 70 year old woman prior to hearing aid fitting. The woman’s primary care physician calls the next day. The patient is in the PCPs office complaining of ear pain. The physician’s otoscopic examination shows a foreign body on the woman’s right ear drum.
- Preventive Measures
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Patient Scenarios … Errors and steps to prevent them

- A 50 year old woman complaining of intolerance to loud sounds is scheduled for an audiologic assessment. During testing, the patient is inadvertently exposed to sound intensity levels exceeding 90 dB HL. The patient abruptly leaves the clinic very upset and angry. The following day you receive a call from the patient’s attorney.

- Preventive Measures
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Patient Scenarios … Errors and steps to prevent them

- Otoscopic inspection of a 30 year old man prior to tympanometry shows excessive cerumen bilaterally in the lateral portion of the external ear canal. As you attempt to manage the cerumen, it is pushed medially around the first bend. Unfortunately, in a further attempt to remove the cerumen patient’s ear canal is lacerated and begins to bleed profusely.

- Preventive Measures
  - 
Patient Scenarios … Errors and steps to prevent them

- In 2008, a 15-month old boy was referred to you for diagnostic assessment of auditory function due to concerns about speech and language delay. Records from the test date show that tympanograms were “type A” bilaterally, and behavioral audiometry findings are consistent with normal hearing sensitivity. You just received a letter from an attorney indicating that you are a defendant in a legal case for the boy (now almost 4 years old) who has a severe hearing loss and severe speech/language delay.

- Preventive Measures
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In 2008, a 7 year old boy was referred for hearing assessment due to concerns by his parents and teacher about his listening ability, and poor academic performance. The boy’s audiogram was normal. The child, almost 10 years old, is now failing in school. He is clinically depressed. The parents are initiating legal action against the school system. You must testify in a due process hearing before an arbitrator, and attorneys representing the parents and the school system.

Preventive Measures

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Failure to diagnosis an acoustic tumor

- Each of two plaintiffs (two separate cases) were adults with vestibular schwannoma
  - Tumors were removed surgically
  - Plaintiffs claimed hearing would have been spared with earlier diagnosis and/or tinnitus would have been avoided
- Defendants were general otolaryngologists
  - Conducted complete history and physical examination
  - Only performed (automated) screening audiometry
  - Outcome: Defendants followed standard of care for physicians
  - What are the guidelines for physicians for referral of patients for MRI to rule out vestibular schwannoma?
Absolute Medical Errors to Avoid:
AAO-HSN Criteria for Identifying Candidates for MRI to Rule Out Vestibular Schwannomas*

- Asymmetric pure-tone air-conduction sensorineural thresholds
  - Asymmetric SNHL of 25 dB or more at any two consecutive test frequencies
  - Unilateral or asymmetric hearing impairment by AAO-HNS criteria
    - Average difference in air-conduction thresholds between ears of 15 dB or greater at 500, 1000, 2000, and 3000 Hz

- Asymmetric word recognition scores
  - Statistically significant difference in word recognition scores (WRS) between ears using Thornton & Raffin (1978) data and NU6 word lists

- Persistent unilateral or asymmetric tinnitus

*Same guidelines should be used by audiologists for referral of patients to otolaryngologists to rule out vestibular schwannomas
Absolute Medical Errors to Avoid:
Selected Requests for Services as Expert Witness
(JWH3 during past 10 years)

- Standard of care for making ear mold impressions
  - Case 1: Defendant was hearing instrument specialist (non-audiologist)
    - Plaintiff was 77 year old woman who presented to otolaryngologist \textit{(after ear mold impressions were made by dispenser prior to planned hearing aid fitting)} with hardened impression material within ear canal and middle ear space
    - History included mastoidectomy on the side of the problem with ear mold impressions
    - Previous audiogram showed mixed hearing loss on the problem ear
    - Outcome:
      - There was no documentation in clinic records that physician referral for medical clearance was first obtained
      - Records failed to document that appropriate oto-block was used
Absolute Medical Errors to Avoid:
Selected Requests for Services as Expert Witness
(JWH3 during past 10 years)

- Standard of care for making ear mold impressions
  - Case 1: Defendant was 75 year old veteran who referred to an audiologist by the VA Healthcare System on for hearing aids (contractual arrangement)
    - Patient sought consultation by otolaryngologist for ear discomfort the day after ear mold impressions were made by the audiologist
    - Small amount of residual impression material within medial ear canal near tympanic membrane
    - Patient filed > $1 million claim alleging that audiologist caused:
      - Middle ear infection
      - Permanent severe hearing loss
      - Marital discord secondary to inability to have regular daily sexual inter-course with wife due to severe hearing loss
  - Outcome
    - Careful documentation in clinic charts confirmed that audiologist followed standard of care in making ear mold impressions
    - Patient had long history of chronic middle ear disease
    - Hearing status was unchanged before versus after ear mold incident
    - Patient was successfully fit with hearing aids
## Absolute Medical Errors to Avoid:
### AAO-HSN Criteria for Audiologist Referral to a Physician*

- History of active drainage from the ear within the previous 6 months
- History of sudden or rapidly progressing hearing loss within the previous 6 months
- FDA rules for unilateral or asymmetrical hearing loss
  - Air-conduction PTA (500, 1000, 2000, 3000 Hz) difference of $\geq 15$ dB
- Sudden or recent onset within the previous 6 months
- Bilateral hearing loss greater than 90 dB
- Complain of hearing impairment with positive history of:
  - Tuberculosis  
  - HIV  
  - Auto-immune disease  
  - Von Recklinghausen’s NF  
  - Syphilis  
  - Meniere’s disease  
  - Otosclerosis  
  - Paget’s disease of the bone
Absolute Medical Errors to Avoid:
FDA (1977) Criteria for Audiologist Referral to a Physician for Hearing Aid Use

- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressing hearing loss within the previous 90 days
- Acute or chronic dizziness
- Unilateral hearing loss of sudden or recent onset within the previous 90 days
- Audiometric air-bone gap equal to or greater than 15 dB at 500, 1000, and 2000 Hz
- Pain or discomfort in the ear
- Child under 18 years of age
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal

*NOTE: Cerumen, including cerumen impaction, is not a criterion as cerumen management is within the scope of practice of audiology in the state of Florida*
### Absolute Medical Errors to Avoid:
Selected Requests for Services as Expert Witness
(JWH3 during past 10 years)

- Cerebral spinal fluid leak after surgery for removal of right vestibular schwannoma
  - **Plaintiff:** Woman who had complications due to post-operative CSF leak
  - **Defendant:** Audiologist who conducted intra-operative neurophysiologic monitoring. Surgeons implicated audiologist by implying that she perforated the tympanic membrane during the monitoring procedure
  - **Facts based on my review of medical records and the literature:**
    - Surface (disc) electrodes were used for monitoring with ABR. There was no documentation that electrodes were near the tympanic membrane
    - A normal and bilaterally symmetrical ABR was recorded at baseline (after electrode placement)
    - ABR on the operated side was lost during tumor resection
    - Otorrhea occurred at day after the surgery, along with an associated "linear perforation in the right posterior-superior part of the eardrum"
    - Peer reviewed literature (e.g., Friedman et al, 2007) includes reports of CSF leak following acoustic tumor removal
Thank You!

*Questions?*

“It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood, who strives valiantly; who errs and comes short again and again; because there is not effort without error and shortcomings.

… his place shall never be with those cold and timid souls who know neither victory nor defeat.”

Theodore Roosevelt (1858-1919)